The New Face of Physician Compliance Programs: Physicians Must Manage New Stark Law Risks under the Health Care Reform Act

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There are a number of provisions contained in President Obama's healthcare reform legislation (hereby referred to as the Act) that strongly urge physicians and other healthcare providers/suppliers to take a proactive approach to compliance with the Federal Stark Law. Failure to do so could potentially trigger an unacceptably high risk of false claims acts liability for physicians and other healthcare providers. Given this background, all healthcare providers should begin implementing steps to revisit their existing compliance programs to ensure that areas of potential risks under Stark are evaluated, incorporated, and factored into such programs.

Stark and the Medicare Billing and Payment Prohibitions
Under Stark, unless an exception applies, a physician is prohibited from referring Medicare covered services to an entity for designated health services (DHS) (eg, inpatient and outpatient hospital services, physical therapy, DME, diagnostic imaging services, clinical lab services) if the physician (or his/her immediate family member) has a financial relationship with that entity. If Stark is triggered and an exception is not met, the entity may not present a Medicare claim for the DHS furnished via prohibited referral. Sanctions for violating this Stark billing prohibition include civil monetary penalties of up to $15,000 for each such claim, damages of up to three times the amount claimed, and exclusion from federal healthcare programs. Notably, the Centers for Medicare and Medicaid Services (CMS) considers physicians who make prohibited referrals under Stark to have caused such prohibited claims submissions, regardless of the fact that the DHS entity (ie, the recipient of their referrals), rather than the referring physicians, actually submitted the claims at issue to Medicare. In addition to the Stark Medicare billing prohibition, CMS also takes the position that an entity receiving payment for a DHS that was performed as a result of a prohibited referral must refund all collected amounts on a timely basis. A failure to timely refund (ie, 60 days from the day the prohibited amounts are collected) could result in civil monetary penalties assessed of up to $15,000 per service or item.

Technical Stark Violations and the Refund Dilemma
For years, it was commonplace for physicians and other industry stakeholders to creatively "fix" certain technical violations of Stark in order to avoid the draconian penalties that would otherwise apply to seemingly compliant physician financial relationships. For example, many typical Stark exceptions (eg, lease of space, lease of equipment, personal services agreements) require a "signed writing" between the referring physician and the entity performing the DHS. Thus, even if all of the other elements of an applicable Stark exception (eg, fair market value compensation not related to referrals) were met, if, due to administrative oversight, the parties failed to obtain a signature at the commencement of the arrangement the parties, they potentially could be subject to civil monetary penalties of $15,000 per claim, unless they found some means to correct that technical error. In 2008, however, CMS confirmed that it interprets the "signed writing" requirement to mean that the signatures must be concurrent with the commencement date of the arrangement. Thus, parties were no longer able to "correct" Stark "signed writing" omissions simply by observing effective dates after the fact. In light of CMS's position, an increasingly greater number of people in the industry have taken notice of these so-called technical Stark violations, partially in order to identify potential refund obligations. During this same time, however, although the Office of Inspector General (OIG) Self-Disclosure Protocol had been a reasonably viable mechanism for resolving technical Stark violations, the OIG suddenly discontinued accepting Stark violations under its protocol, leaving physicians and other healthcare providers without this channel to redress the substantial dollar figures often attached to technical Stark violations.

In 2009, President Obama signed the Fraud Enforcement and Recovery Act of 2009 (FERA), which amended the False Claims Act to further extend liability for knowingly and improperly avoiding or decreasing an obligation to pay the federal government, which had been interpreted by many to include retention of overpayments related to technical Stark violations.

Finally, in March 2010, as a result of the Act, material amendments were enacted to Stark, which now specifically requires repayment of Medicare overpayments within 60 days of identifying overpayments (including Medicare payments for DHS rendered pursuant to a prohibited Stark referral). The Act also mandates a Self-Referral Disclosure Protocol by late September

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2010 that permits (but does not require) the government to compromise Stark refunds (the Stark SDP).

Given this history, it is imperative for physicians and other healthcare providers to establish and maintain an effective Stark compliance plan.

Revisiting Stark Compliance

In light of the recent provisions of FERA and the Act, physicians and healthcare providers would be remiss if they fail to take a proactive approach to, and a heightened focus on, compliance. This is particularly true given the fact that it is likely that the new Stark SDP will reward physicians and healthcare providers that affirmatively adopt a proactive approach to Stark compliance. An important initial step for a Stark compliance plan should be determining who in the organization will be responsible for Stark compliance (eg, compliance officer, physician shareholders, office of general counsel [for hospitals], etc). Next, the universe of financial relationships should be identified and categorized in order to properly evaluate Stark risk areas and implement policies and procedures for tracking and monitoring financial and referral relationships that fall within the domain of Stark. Some Stark areas to evaluate under a Stark compliance plan may include contract management systems and contract review, accounts receivable and accounts payable records, tracking of nonmonetary compensation, and fair market value analysis.

A critical part of an effective Stark compliance program is indentifying potential implementation challenges, such as obtaining missing signatures before services are rendered and prior to submitting claims to Medicare, and assessing when it is advisable to obtain fair market valuations from an independent source prior to entering into certain transactions.

Another key issue for an effective Stark compliance plan is to obtain experienced healthcare counsel in order to analyze whether, in those circumstances where an arrangement potentially has Stark implications, a Stark violation in fact exists. For example, if there is no formal written document observing the arrangement, the provider should consider whether there are other forms of email correspondence, memoranda, or communications that support the argument there is written instrument for purposes of Stark compliance. Under an effective Stark compliance plan, however, after careful analysis and review, if it is determined that a Stark violation has occurred, a physician or other healthcare provider must actively determine the consequences of failing to act, potential repayment calculations, who should be approached with the Stark issue (eg, CMS, OIG, the carrier, etc), and timing concerns.

Physicians and other healthcare providers should remain attentive to the Stark SDP, which is expected to be published later this year (possibly in September) which will hopefully provide more guidance to physicians and healthcare providers in making determinations related to Stark compliance. Finally, physicians and other healthcare providers and suppliers that do not have existing compliance programs should also be aware that the Act establishes mandatory compliance programs as a requirement for healthcare providers and suppliers that elect to maintain and establish Medicare billing privileges. Note that this is in addition to mandatory compliance programs that certain states (eg, New York) have instituted for certain classes of providers.