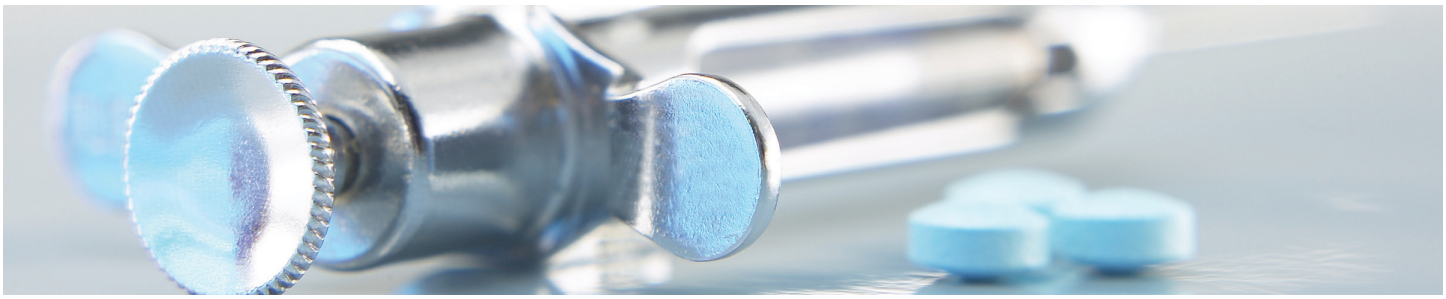
VORYS *On the Horizon in* HEALTH LAW

A publication of Vorys, Sater, Seymour and Pease LLP May/June 2009



In This Issue:

MEDICARE AND MEDICAID

MSP Mandatory Reporting Requirements Take Effect July 1, 2009

On July 1, 2009, health care providers that self-insure their workers' compensation plans and/or professional liability risks became subject to a new federal mandatory reporting law. This law, codified at 42 U.S.C. §1395y(b)(8), requires all liability insurance (including self-insurance) carriers, no-fault insurance carriers, and workers' compensation plans to report settlements, judgments, awards or other payments with/to a Medicare beneficiary to the federal Centers for Medicare and Medicaid Services ("CMS"). Penalties for non-compliance with these new reporting requirements are staggering - $1,000 per day, per file for as long as the claim is not reported.

Under the new law, designed to maximize Medicare Secondary Payer ("MSP") recoveries, insurers must, "determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the [Medicare] program." See 42 U.S.C. § 1395y(b)(8)(A). If the insurer determines that the claimant is a Medicare beneficiary, then certain information must be reported to CMS, including but not limited to the claimant's name, date of birth and address, social security number or health identification number, insurance information including type of insurance and policy and claim numbers, policy holder information, date of injury, and claim resolution information. The required information must be submitted "after the claim is resolved through settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability)." 42 U.S.C. § 1395y(b)(8)(R) (emphasis added).

Before the new Mandatory Insurer Reporting law takes effect, all entities required to comply with the new reporting requirements must register with the CMS Coordination of Benefits Contractor ("COBC"). This electronic registration must be completed by the insurer itself (not a designated

agent) between the dates of May 1, 2009 and June 30, 2009. The secure registration website is still being developed by CMS, but will be posted at www.cms.hhs.gov/MandatoryInsRep, sometime before May 1, 2009. CMS has also indicated that it intends to provide online training courses on the registration process. Interested parties may enroll in this training in advance by calling (646) 458-6740.

Once the registration process is completed, there will be a testing period, insurers will then be expected to submit their first reports to CMS between January 1, 2010 and March 31, 2010. These initial file submissions must generally report on all claims, where the injured party is/was a Medicare beneficiary, that are resolved (or partially resolved) through a settlement or other payment after June 30, 2009. Insurers must also report on claims where there is responsibility for ongoing payments for medical services as of July 1, 2009, even in cases where the initial resolution occurred prior to July 1, 2009. CMS is permitting insurers to delay reporting on claims settled prior to July 1, 2009 until July, 2010 to allow the necessary information to be gathered.

FRAUD AND ABUSE

OIG Pulls Back On Scope Of Provider Self Disclosure Protocol, Sets Minimum Value On Disclosures

In an Open Letter to Health Care Providers, dated March 24, 2009, the Office of Inspector General, Department of Health and Human Services, has notified providers that it will no longer entertain disclosures of violations of the physician self referral law within the scope of the Provider Self Disclosure Protocol ("SDP"), unless they are accompanied by the disclosure of liability under the federal anti-kickback statute. The letter goes on to state that there will now be a $50,000 minimum settlement amount on those disclosures that the OIG will continue to accept for treatment within the SDP. This position pulls back on the 2006 self-disclosure initiative articulated by the OIG in an Open Letter to Health Care Providers, dated April 24, 2006, that was aimed at specifically including within the scope of the SDP physician self referral law violations between physicians and hospitals.

The SDP, first promulgated by the OIG in October 1998, was designed to provide a formal avenue for providers to voluntarily disclose health care compliance issues that may amount to violations of federal civil, criminal and administrative laws.[1] It provides the prospect of more favorable dispositions for such matters with respect to on-going compliance demands and the civil monetary penalties and program exclusion risks that attend such misconduct. The SDP is not intended to address billing errors and overbilling situations. Compliance with the SDP generally results in settlements with providers "at the lower end of the damages continuum."

Since its promulgation, the SDP has undergone a number of informal refinements by the OIG in the form of Open Letters. This latest refinement is aimed at refocusing the OIG's resources on illegal kickback arrangements, which have long been a high priority for the OIG, and is characterized as a measure to better utilize those resources.

The federal anti-kickback statute, 42 USC § 1320 a-7(b), is a criminal statute which, in addition to severe criminal penalties, carries the risks of severe civil monetary penalties ($50,000 for each kickback and 3 times the total remuneration) and program exclusion. It proscribes the offering, receiving, soliciting or accepting any remuneration (including any kickback, bribe or rebate) directly or indirectly in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made by a federal health care program, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made by a federal health care program. Conduct subject to this statute has received consistent and intensive attention by the OIG and the Department of Justice.

The federal physician self-referral statute, 42 USC § 1395nn, commonly known as the Stark law, prohibits physicians making referrals for Medicare designated health services to entities with which they or immediate family member have a financial relationship unless the relationship fits within a statutory or regulatory exception. This statute is a civil statute which imposes strict liability and carries with it risks of severe civil monetary penalties ($15,000 per service billed in violation and 3 times the amount of the subject claims) and program exclusion.

The March 24, 2009, Open Letter claims to signal no change in the government's approach to the Stark law. The OIG will continue to focus its energies on dealing with voluntary disclosures of violations of the federal anti-kickback statute under the SDP, provided the disclosing parties are prepared to enter into a settlement of as least $50,000.

Physicians Target Of OIG Scrutiny

In a speech in late May, Lewis Morris, Chief Counsel of the Department of Health and Human Services Office of Inspector General, noted that physicians have become a prime target of the OIG's effort to combat health care fraud. Current practices under scrutiny include medically unnecessary procedures and "upcoding", or improperly

[1] See 63 Fed. Reg. 58,399 (October 30, 1998); http://oig.hhs.gov/fraud/selfdisclosure.asp.

coding a claim for the purpose of obtaining a higher level of reimbursement. Morris further indicated that for the first time in many years, the OIG is focusing on home health care fraud involving physicians.

According to Morris, there are two trends that are emerging relative to health care anti-fraud efforts. The first is a greater demand for transparency throughout the entire health care system, but especially in physician relationships with vendors, suppliers and laboratories. The OIG has expressed concern about the significant risk that industry payments to physicians are "kickbacks" designed to influence medical decision-making rather than legitimate payment for services. The second trend that was expressed is a desire on the part of regulators to improve the coordination and collaboration of health care delivery.

In his speech, Morris also summarized recent enforcement activity and noted that the options for federal enforcement actions against physicians include the False Claims Act, the Anti-kickback Statute; and the Civil Monetary Penalties Law. Morris called the federal False Claims Act "by far" the civil division's most effective tool in going after fraud. Since 1986, more than $22 billion has been recovered, 65 percent of which—$14.3 billion—resulted from health care fraud.

Ultimately, these recent comments on physician scrutiny call attention to the fact that physician financial relationships and billing practices are a high-enforcement priority for the OIG. Accordingly, physicians must take steps to ensure compliance and minimize risk in these areas.

EMTALA

Proposed Rule Change To Amend EMTALA Sanction Waiver Provisions

The Centers for Medicare and Medicaid Services ("CMS") recently issued a proposed rule to limit the provisions for waiver of sanctions under the Emergency Medical Treatment and Labor Act ("EMTALA"). Congress originally enacted EMTALA under the Social Security Act ("Act") in order to ensure that individuals with emergency medical conditions are not denied vital lifesaving services. Though the Act sets forth numerous requirements for screening and stabilizing patients with emergency medical conditions, section 1135 of the Act allows for waiver or modification of some such provisions in emergency situations. It is these waiver provisions that are subject to CMS's most recent amendment.

Under the existing rules, the Secretary of Health and Human Services ("Secretary") is authorized under section 1135 of the Act to temporarily waive or modify certain treatment requirements for hospitals in an emergency area during an emergency period. Under the current rule, EMTALA sanctions against hospitals may be waived under two circumstances: 1) inappropriate transfers of patients who have not been properly stabilized during a national emergency, and 2) relocation of individuals requiring medical screening pursuant to an applicable state emergency or pandemic preparedness plan. Generally, the waiver is in effect for no more than a 72-hour period beginning with the implementation of hospital disaster protocols, but in cases involving pandemic infectious diseases, the waiver will continue for the duration of the public health emergency.

The proposed rule slightly limits the scope of both provisions, allowing waiver of sanctions only "if the hospital does not discriminate on the basis of an individual's source of payment or ability to pay." The changes also limit sanction waivers for inappropriate transfers of unstable patients during emergency periods to only those transfers "aris[ing] out of the circumstances of the emergency." CMS asserts that these changes are "necessary to make the language [of the implementing regulations] conform more closely to the language of section 1135 of the Act and better reflect how section 1135 authority has been used in practice."

In addition, the proposed rule also affirms the Secretary's authority to selectively waive sanctions within an emergency area. CMS notes that "existing regulations may inadvertently imply, contrary to the flexibility clearly contemplated in the statute, that all hospitals in all portions of an emergency area during an entire emergency period automatically receive a waiver of EMTALA sanctions. We are proposing revisions to the regulation text to clarify this issue." Thus, the proposed rule makes clear that the Secretary may choose to apply the waiver to a single provider, a class of providers, or to the geographic subset of providers within the emergency area, depending on what is necessary given the nature of the emergency.

According to CMS, these proposed rule changes will not affect Medicare expenditures or have a significant impact on hospitals with emergency departments.

---

[3] "Emergency Medical Condition" is defined as "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in . . . placing the health of the individual in serious jeopardy." *Id.* § 1395dd(e)(1)(A)(i). "Stabilize" means "to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer [or discharge] of the individual from a facility." *Id.* § 1395dd(e)(3)(A).

[1] This provision allows "any individual who suffers personal harm as a direct result of a participating hospital's violation" to bring suit. 42 U.S.C. § 1395dd(d)(2)(A).

For the text of the proposed rule, see Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment Systems, 74 Fed. Reg. 24,081, 24,193-95 (proposed May 22, 2009).

Sixth Circuit Recognizes Third-party Standing And Reinstates EMTALA Claims

A recent decision by the U.S. Court of Appeals for the Sixth Circuit may have a significant impact on hospitals with emergency departments. *Moses v. Providence Hosp. & Med. Ctrs. Inc.*, 561 F.3d 573 (6th Cir. 2009). In Moses, a woman's estate brought suit under EMTALA after she was murdered by her husband shortly after his discharge from the hospital following an acute psychotic episode. Prior to the murder, the woman had taken her husband to the emergency room for treatment of numerous symptoms, including headaches, disorientation, hallucinations, delusions, and overtly threatening behavior. The ER physicians admitted him for testing, and though the treating physician noted his mental instability and recommended transfer to the hospital's psychiatric unit, the man was discharged before any transfer occurred.

The case was one of first impression regarding third-party standing under EMTALA's civil enforcement provision.[2] Though a report by the House Judiciary Committee did state that only an individual patient has standing to sue under the statute, the Sixth Circuit deemed the legislative history contrary to the statutory language, and opted for a broader interpretation. The court thus held that the provision's broad language does not bar a third-party suit and asserted that the plain language seems to clearly include a suit by the estate of a woman whose death was "the direct result of the hospital's decision to release her husband before his psychiatric emergency medical condition had stabilized." The court reasoned that if Congress had intended to limit the provision to patients, it would have done so explicitly as it had in other parts of the statute. Despite its finding of third-party standing to sue a hospital, the court followed other circuit courts in declining to recognize any private right of action against individual physicians.

Significantly, the court also dismissed the hospital's argument that the patient's six-day admission for testing satisfied the institution's obligation to stabilize the patient, an argument supported by a CMS regulation stating that admission of an individual with an emergency medical condition[3] in a good faith effort to stabilize that condition is sufficient to satisfy the hospital's responsibilities under EMTALA. The court rejected CMS's construction as "contrary to clear congressional intent," instead holding that EMTALA requires a hospital to "treat a patient with an emergency condition in such a way that, upon the patient's release, no further deterioration of the condition is likely," and declaring that screening and admitting the patient in this case was not sufficient to discharge the hospital's statutory obligation. Thus, under the court's ruling, even when a patient with an emergency medical condition is properly admitted, a hospital will run afoul of the statute if it releases that patient without sufficient treatment and a determination that he or she has been stabilized.

Finally, the court held that a mental health emergency could qualify as an "emergency medical condition" under the statute's plain language. Citing various notes in the medical record regarding the patient's initial diagnosis of "atypical psychosis," the possible existence of "an acute psychotic episode," and the doctors' fear of a suicide risk, the court reversed the district court's grant of summary judgment for the hospital, finding issues of material fact regarding whether the mental episode should be properly classified as an emergency medical condition, and if so, whether the staff was aware that the patient was unstable prior to his release.