

## To Adopt or Not to Adopt? Electronic Health Information Technology and the Fraud and Abuse Laws

Peter M. Hoffman, Esquire  
Nora Colangelo  
*Garfunkel Wild & Travis PC*  
*Great Neck, New York*

We live in an increasingly fast-paced, wireless, interconnected age, one in which reams of electronic information instantaneously pass between us. In the healthcare world, electronic health information technology (HIT) promises a wide range of benefits to both clinicians and patients, including the portability of, and easy access to, patient information, a reduction in clinical errors, enhanced business efficiency, and, most importantly, an overall increase in the quality of patient care. Yet, healthcare providers have been slow to embrace the potential benefit of HIT.

The federal government would like that to change. To that end, the U.S. Department of Health and Human Services (DHHS) has made the implementation of HIT a “compelling national priority . . .”<sup>1</sup> From the government’s perspective, however, the goal of promoting an open and interoperable HIT system must be balanced against many competing “fraud and abuse” concerns, including the possibility that the wide-spread adoption of HIT could lead to tainted clinical decision making, overutilization, unfair competition and an increase in costs borne by federal healthcare programs, such as Medicare and Medicaid. These competing interests leave the healthcare world in a quandary: the government is promoting

the adoption of HIT, yet the federal “fraud and abuse” rules currently in place caution providers to proceed at their own risk. This raises an important question: Will the development and adoption of HIT outpace the development of the “fraud and abuse” laws as they relate to such technology? At the present time, the answer appears to be “yes.”

### I. The Federal Anti-Kickback and Stark Laws

From a legal perspective, the federal government’s concern about “fraud and abuse” that may accompany the wide-spread adoption of HIT is understandable. After all, given the cost associated with implementing HIT, many physicians and other healthcare providers likely will not be able to afford the necessary hardware, software, or training. To fill the vacuum, we are likely to increasingly see providers receive offers of free or discounted products and services in the HIT arena—including offers that run counter to the DHHS Office of Inspector General’s (OIG’s) “longstanding concern about the provision of free or reduced price goods or services to an existing or potential referral source.”<sup>2</sup> Such offers potentially implicate both the federal Anti-Kickback Statute (AKS) and the federal Stark Law (Stark).

In general, the AKS prohibits anyone from knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickbacks, bribes, or rebates)—directly or indirectly, overtly or covertly, in cash or in kind—in order to induce or reward the referral of business that is paid for, in whole or in part, by any federal healthcare pro-

gram.<sup>3</sup> Violation of the AKS may lead to, among other things, jail, substantial fines and penalties, as well as exclusion from federal healthcare programs.<sup>4</sup>

Stark is a strict liability law that prohibits a physician from making referrals to an entity for the furnishing of certain “designated health services” reimbursable by Medicare if the physician (or an immediate family member) has a direct or indirect financial relationship (including an ownership or investment interest, or a compensation relationship) with that entity, unless an exception to the law is met. If the referral is prohibited, so too is the submission of a claim for payment by the entity receiving it. The possible penalties for violating Stark include: (1) the denial or the required refund of any payments for services that resulted from an unlawful referral; (2) civil monetary penalties; and (3) exclusion from federal healthcare programs.<sup>5</sup>

The giving of free or discounted HIT items or services can create both a remunerative relationship under the AKS and a “financial relationship” under Stark, thus squarely bringing these laws into play in many potential HIT transactions.

### II. Balancing Competing Concerns

In an initial attempt to balance “fraud and abuse” concerns against the government’s desire to see rapid adoption of HIT, DHHS released two sets of proposed regulations in October of 2005. The Centers for Medicare and Medicaid Services (CMS), charged with enforcement of Stark, released a proposed rule that would except from Stark’s

reach certain arrangements involving hospitals, group practices, prescription drug plan sponsors (PDPs), and Medicare Advantage (MA) organizations that wish to donate certain electronic prescribing (E-prescribing) hardware, software or information technology and training services to specified recipients. At the same time, CMS also proposed a set of rules that would except from Stark the provision of certain electronic health records (EHR) software and directly related training services to certain recipients. On the same day that CMS acted, the OIG, charged with AKS enforcement, released its own proposed E-prescribing “safe harbor”<sup>6</sup> to the AKS, which is substantially similar to the E-prescribing Stark exception proposed by CMS. Unfortunately, while it discussed adopting a set of EHR AKS safe harbors similar to CMS’, and indicated its intention to do so, no such proposed rules have been promulgated by OIG to date.

While CMS’ and OIG’s proposed rules are a good first step toward encouraging the wide-spread adoption of HIT, they are just that—a first step. The rules remain in proposed form and, as explained below, are very narrowly drawn, thus leaving providers and others involved in HIT transactions to worry whether their particular deals may violate the AKS and/or Stark.

### III. The E-Prescribing Exception and Safe Harbor<sup>7</sup>

Both CMS and OIG proposed substantially similar rules relating to E-Prescribing. Some of the

more important requirements/conditions of these rules are:

- *The Participants In The Arrangement.* As presently drafted, the proposed rules provide that hospitals would only be permitted to donate non-monetary items or services (specifically, hardware, software, or information technology items or services) to physicians on their medical staffs. Group practices would be permitted to donate to their group members (owners and employees), and PDPs and MAs could donate to prescribing physicians (under Stark) and to network pharmacists and pharmacies, as well as prescribing professionals (under the AKS).
- *Eligibility.* Donors would be prohibited from taking into account the volume or value of the recipients' referrals to the donor, or other business that is generated between the parties, in determining either the eligibility of a recipient or the amount or nature of items or services to be provided.
- *The Scope Of The Technology.* The items or services to be donated would need to be "necessary" and "used solely" to receive and transmit electronic prescription information. They would also have to meet applicable standards under Medicare Part D.
- *Certification.* Recipients would have to certify in a written agreement that the items or services received are not "technically or functionally equivalent" to items or services they already possess or have obtained. The proposed rules would also require that

the donor not have actual knowledge of, or act in reckless disregard or in deliberate ignorance of, the fact that the recipient already possesses items or services "technically or functionally equivalent" to those donated.

- *Compatibility and Interoperability.* Donors—and those acting on their behalf—would be prohibited from taking any action to unnecessarily limit or restrict the use or compatibility of their items or services with other E-prescribing items, services, or electronic health information systems. Moreover, if the items or services could be used for any patient (regardless of payor status), the donor would not be allowed to limit the recipient's right or ability to use the technology for any patient.
- *Other Conditions.* Both sets of rules would also prohibit recipients from making the donation of E-prescribing technology as a condition of doing business with the donor, and require written, signed agreements covering all the items/services to be provided by the donor to the recipient, specifying what is being provided and its value.<sup>8</sup>

#### IV. CMS' Proposed Exceptions for EHR<sup>9</sup>

CMS' proposed Stark exceptions for the provision of EHR technology contain many of the same requirements as the E-prescribing regulations discussed above. Both DHHS agencies are taking an incremental approach in this area, with CMS proposing (and OIG agreeing to propose) "pre" and "post-interoperability" EHR regulations based

on when DHHS adopts product certification criteria for the interoperability, functionality, privacy and security of EHR.

Among the differences between CMS' EHR proposed rules and the proposed E-prescribing rules are CMS' EHR proposals would apply only to software and directly related training services; and, in the "pre-interoperability" phase, the items or services covered by the proposed exception would not include any billing, scheduling or other similar general office management or administration software or services—nor could the donor offer to staff a physician's office. In the "post-interoperability" phase, certain specified criteria for selecting physicians to receive the covered items or services would be "deemed" under the rules to not be directly related to the volume or value of referrals or other business generated between the parties. Moreover, in the "post-interoperability" phase, there would be a loosening of what items or services could be provided within the exception's scope (though staffing and items used solely to conduct personal business or business unrelated to the doctor's medical practice would still be prohibited).

#### V. A Start—But a Long Way to Go

It is not difficult to foresee that the roll-out of HIT in the healthcare arena will be fraught with "fraud and abuse" questions. While CMS' and (to a lesser extent) OIG's proposed rules are salutary in their intent to encourage the healthcare community to adopt HIT—particularly E-prescribing technology—they leave plenty of room for both doubt and improvement from a Stark and AKS perspective.

Put simply, HIT is an area where the rapid development of technology and the national push to adopt it is far outpacing the development of the federal fraud and abuse laws. This will continue to be the case for quite some time. As a result, providers must proceed cautiously, paying special attention to ensuring that their HIT transactions do not run afoul of the fraud and abuse laws as currently drafted.

#### Endnotes

- <sup>1</sup> 70 Fed. Reg. 59182, 59187 (Oct. 11, 2005).
- <sup>2</sup> 70 Fed. Reg. 59015, 59016 (Oct. 11, 2005).
- <sup>3</sup> See 42 U.S.C. § 1320a-7b(b).
- <sup>4</sup> See 42 U.S.C. § 1320a-7b(b); 42 U.S.C. § 1320a-7a(a)(7); 42 U.S.C. § 1320a-7(b)(7).
- <sup>5</sup> See generally 42 U.S.C. § 1395nn; 42 C.F.R. Part 411, Subpart J.
- <sup>6</sup> The "safe harbors" to the AKS are payment practices that are deemed to not violate the AKS. See 42 C.F.R. § 1001.952. To fit within a safe harbor, each of the safe harbor's requirements must be squarely met.
- <sup>7</sup> CMS' proposed E-prescribing exception is found at 70 Fed. Reg. 59182 (Oct. 11, 2005). OIG's proposed E-prescribing safe harbor is found at 70 Fed. Reg. 59015 (Oct. 11, 2005).
- <sup>8</sup> Both OIG and CMS have stated that they believe a limit or "cap" on the value of protected technology is appropriate, and each is considering the appropriate amount and methodology for implementing such a cap.
- <sup>9</sup> CMS' proposed Stark exceptions for EHR are found at 70 Fed. Reg. 59182 (Oct. 11, 2005).