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Health Law
Proposed Safe Harbor for Electronic Prescribing Arrangements: More Questions Than Answers

Offering a shield for doctors, hospitals, pharmacies, and certain payors, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) proposed a new safe harbor to the Federal Anti-Kickback Act. The OIG hopes to encourage the adoption of electronic prescribing (“e-prescribing”) technology. The bad news is that the proposed safe harbor raises a lot of questions, thereby providing no assurances about protected activity. The good news is that the OIG acknowledges the gray areas and seeks public comment. The health care community would therefore be well advised to provide input on the proposed safe harbor by the comment due date, December 10, 2005.

THE FEDERAL ANTI-KICKBACK ACT
The Anti-Kickback Act makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration intended to induce the referral of business that is reimbursable under a Federal health care program. Prohibited conduct also includes the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item reimbursable by a Federal health care program. The broad reach of prohibited conduct caused Congress and the OIG to establish safe harbors to protect certain otherwise innocuous commercial business practices that may potentially be capable of inducing prohibited referrals from prosecution.

THE E-PRESCRIBING TECHNOLOGY PUSH
E-prescribing combines hardware and software technology, as well as certain connectivity and training services, into an electronic package. The package can take a variety of forms, from a stand-alone computer to small handheld devices no bigger than some of today’s cellular telephones. Regardless of the form, the prescriber “writes” a prescription by entering the information into the system at the point or place at which the medication is prescribed, such as a doctor’s office or a patient’s hospital room, instead of writing it on a paper prescription pad. The system then transmits the electronic prescription to the desired pharmacy.

Some e-prescribing systems can also provide clinical support by analyzing prescriptions for potential errors such as excessive dosage or by identifying potential interactions with other medications, duplicate therapies and
other conditions – all of which prevent the patient from incurring further medical costs. These benefits depend upon the degree to which the e-prescribing system has access to other automated patient information. Even the most basic systems, however, have the capability to streamline filling prescriptions and to reduce costs.

Congress jumped on the e-prescribing technology bandwagon in 2003 when it passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA) that established the Medicare Part D prescription drug benefit. Congress wanted to encourage the use of e-prescribing technology as a part of the Part D benefit but recognized that many health care providers have little resources, and incentive, to adopt this technology. Congress therefore directed the OIG to develop safe harbors under the Anti-Kickback Act that would allow certain health care professionals to receive donated e-prescribing technology without risking prosecution under the Act. Donors of e-prescribing technology would also be protected. In both cases, the donation must not be intended to induce or receive illegal referrals.

THE PROPOSED SAFE HARBOR
Pharmacies, group physician practices, and hospitals will be the beneficiaries of the e-prescribing safe harbors. As proposed, hospitals will be able to donate e-prescribing technology to staff physicians; group practices to their members; and Medicare Advantage (MA) and Prescription Drug Plan (PDP) sponsors to pharmacies, pharmacists, and prescribing health professionals who participate in the MA and/or PDP program. To qualify, the e-prescribing technology must be “necessary and used solely to receive and transmit electronic prescription information.” The OIG candidly admits that this provision houses a lot of uncertainty. For example,

- What items and services would be considered “necessary”? The OIG believes that necessary items and services are ones that are not “technically or functionally equivalent” to items or services the recipient already has.
- How would the donor know whether the donated items are technically or functionally equivalent to items the recipient already has? The OIG proposes that the recipient certify this fact in writing to the donor. Of course, the donor may not have any actual knowledge that is contrary to the certification.
- How would donors or recipients of the e-prescribing technology know whether it would be used “solely” for e-prescribing? The OIG recognizes that e-prescribing technology will probably have other uses. The OIG is therefore also invoking its authority under Section 1128B(b)(3)(E) of the Social Security Act to protect some limited hardware and connectivity services as long as “a substantial use” of them is for e-prescribing purposes. Software will receive similar protection if it is integral to the operation of the hardware and distinct from other software applications that are unnecessary for the hardware to operate.
- How much is “substantial use”? The safe harbor will require the donated e-prescribing technology to be compatible
with standards that are yet to be determined by the Secretary. Donors and recipients may not take any action to limit the compatibility with other electronic prescription information items or services or electronic health information systems. Such compatibility minimizes the opportunities for closed affiliations that guarantee streams of illegal referral business.

E-prescribing technology must be interoperable so that the prescribing provider can transmit a prescription to any pharmacy – as opposed to only pharmacies that accept a particular format. Such interoperability will promote freedom of choice for patients and, again, minimize the opportunity for illegal arrangements and referrals. Moreover, any patient’s information should be able to be transmitted – not just patients who have Part D coverage.

Finally, no aspect of the donation of the e-prescribing technology may take into account the volume or value of referrals between the parties, and the entire arrangement must be in writing.

COMMENTS ENCOURAGED
The requirements of the proposed safe harbor are indefinite in many respects, and there is plenty of room and opportunity for making comments and raising questions. For example, in addition to the questions identified above, the OIG has asked for commentary on such issues as:

- Should recipients of donations be required to certify in writing that the technology is necessary (i.e., not duplicative of other technology)? If so, should the certification be required initially or also prior to any donated upgrades, or both?
- What standards should be included in a corresponding safe harbor to address issues related to multifunctional hardware (including necessary operating system software) or connectivity services?
- How should the OIG quantify whether the donated hardware is substantially used for the receipt or transmission of electronic prescription information?
- Should there be a cap placed on the value of donated technology and, if so, how should that cap be assessed? A fixed value? A percentage of the value of the donated technology?
- Should items other than prescription drugs be included within the safe harbor, such as prescriptions for tests and supplies?
- Should other entities be included within the scope of the safe harbor?

It will be important to determine how the safe harbor may interact with state laws and regulations pertaining to professional licensure. For example, what effect would electronic prescriptions have on record-keeping requirements of both providers and pharmacies? Donors and recipients therefore must identify and analyze potentially conflicting laws and regulations before entering into an e-prescribing technology donation arrangement.

NEXT STEPS
Comments on the proposed safe harbor are due by December 10, 2005. They may be mailed or hand delivered to HHS at the following address:

Office of the Inspector General
Department of Health and Human Services
Attention: OIG-405-P
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Alternatively, comments may be submitted electronically to http://www.regulations.gov. Comments should state that they are for the Department of Health and Human Services, Office of Inspector General, and include identifier RIN 0991-AB36.

Even if you do not want to comment individually, you should contact your professional association to make sure that it is following this issue and providing commentary.

The full text of the proposed regulation can be located at http://oig.hhs.gov/authorities/regulatory.html.

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