Changes to Stark Exceptions and Anti-Kickback Safe Harbors For Electronic Prescribing and Electronic Health Records

On August 1, 2006, the Department of Health and Human Services ("HHS") released final regulations concerning the use of electronic prescriptions and electronic health records. These regulations differ in a few key respects from the original proposed regulations. As discussed further below, important changes include: (1) a requirement that recipients pay 15% of the cost of donated electronic health records software and equipment; (2) a significant broadening of the criteria on which donors may select recipients; (3) elimination of pre- and post-interoperability standards in favor of a single, currently effective interoperability certification process; and (4) clarification that the e-prescribing regulations apply to technology used to prescribe any item or service traditionally provided by prescription, rather than just pharmaceuticals.

We also note that last Thursday, the House passed a version of a bill to adopt the Health Information and Technology Promotion Act of 2006 (a different version has passed the Senate). Both versions of the bill would create a more generous safe harbor for donations of technology and would, most importantly, supersede contrary state laws. It remains to be seen whether adoption of the final regulations will have any effect on the pending legislation.

Background:

In October, 2005, HHS issued proposed regulations under which certain donations of technology related to electronic prescribing and/or electronic health records would be exempted from the Stark and anti-kickback laws. In order to reduce the perceived potential for abuse, the proposed regulations set restrictions on: (i) permissible categories of donors and recipients; (ii) the types of technology to be protected under the regulations; and (iii) the criteria by which recipients were chosen, and also allowed for the possibility that the permissible value of donated technology might be limited. The proposed regulations were published with significant gaps, which HHS committed to resolve in the final regulations. For a more detailed description of the originally proposed regulations, please see this prior Client Alert.

Links to Relevant Documents:

HHS has now released the final regulations, along with its responses to the comments it received. Although the regulations will not be officially published in the Federal Register until August 8, 2006, advance copies of the regulations are available from the Centers for Medicare and Medicaid Services ("CMS") and Office of Inspector General ("OIG") websites (click here for the full text of the Stark regulations and commentary or here for the full text of the Anti-kickback regulations and commentary). This alert focuses on those elements of the regulations that have been amended.

E- Prescribing:

The regulations that protect certain arrangements involving electronic prescribing technology were mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. HHS states in the final rule that it felt constrained in its ability to expand or otherwise modify the proposed regulations based on the language of the Act. The final regulations materially modify the proposed regulations only in the following ways:

Protected Technology:
Under the proposed rule, HHS protected items and services "necessary and used solely for" e-prescribing, without specifying whether e-prescribing included prescriptions only for drugs or also for other items and services. The final rule retains the "necessary and used solely for" standard, but expands the definition of e-prescribing to include prescriptions for any item or service normally accomplished through a written prescription (including, for example, laboratory tests and durable medical equipment orders).

Certification Requirement:
HHS also stated in the proposed rule that items and services would not be "necessary" if the physician already possessed equivalent items or services. To prevent the donation of duplicative items and services, the proposed rule required that physicians provide a written certification that the donated technology was not technically or functionally equivalent to technology that the physician already possessed. Although the final regulations continue to exclude duplicative items or services, the certification requirement has been abandoned.

Value Caps:
In the proposed rule, HHS sought comments on whether there should be a cap on the value of information technology that a doctor can receive from a single donor. HHS has decided that the value of donations under the e-prescribing regulations should not be capped.

Electronic Health Records:

The final electronic health records regulations contain a larger number of modifications. The key changes are as follows:

Interoperability:
In the proposed rule, HHS stated that it planned to adopt a set of product certification criteria, with special attention paid to interoperability. Based on this plan, HHS presented two separate exceptions related to electronic health records: one for use before the adoption of certification standards, and one for use after their adoption. In the final rule, HHS adopted certification standards, eliminating the need for two separate exceptions.

Under the final rule, all donated technology must be interoperable, which is defined in the regulations as the ability "to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." HHS recognized that standards for interoperability are evolving as the technology develops. Donors and recipients must therefore ensure that donated technology is "as interoperable as feasible given the prevailing state of technology at the time the items or services are provided."

Parties can also avoid uncertainty as to whether specific technology meets the interoperability definition by using technology that has been deemed interoperable by a "certifying body." Under the final regulations, the Secretary of HHS may contract with third parties to develop certification criteria and a certification process. HHS has already contracted with at least one such body, the Certification Commission for Healthcare Information Technology (CCHIT), and CCHIT announced last month the certification of 20 electronic health records products. To access the CCHIT website for a list of approved electronic health records products, click here.

Permitted Donors and Recipients:
The proposed regulations protected donations of electronic health records technology only when provided by: hospitals to active members of their medical staff, group practices to their members, or prescription drug plan sponsors or Medicare Advantage organizations to their participating pharmacists, pharmacies, and prescribing health care professionals. The final regulations greatly expand the scope of the exception by allowing for donations from any donor to any recipient.

The proposed rule would have prohibited the selection of recipients in a manner that took into account the volume or value of referrals or other business generated between the parties. The final rule retains this requirement, but provides further guidance regarding permissible ways to choose recipients. Specifically, the selection of recipients will be deemed not to take into account the volume or value of referrals or other business generated between the parties if any one of seven criteria is met. These criteria include size of the recipient's practice and whether the recipient is a member of the donor's medical staff.

Value Caps:
In the proposed rule, HHS sought comments on whether there should be a cap on the value of information technology that a doctor can receive from a single donor. HHS has not implemented a cap, but instead the final rule protects only those arrangements where the recipient pays for at least 15% of the cost of the donated technology. This 15% cost sharing must be paid at the time of, or prior to, receipt of the technology and may not be financed by the donor.

Certification Requirement:
As with the e-prescribing regulations, HHS has eliminated any requirement that physicians provide a written certification that the donated technology is not technically or functionally equivalent to technology that the physician already possesses.

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