Electronic Prescribing and Electronic Health Records: Proposed Regulations for Stark Exception and Anti-Kickback Safe Harbor

There is industry-wide agreement that the use of electronic prescriptions and electronic medical records will result in increased safety, quality, and efficiency in the provision of health care services. Two of the obstacles to widespread adoption of this technology are the Federal Stark law and the Federal anti-kickback law. Prodded by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other pending legislation, the Department of Health and Human Services ("HHS") responded by not only proposing regulations regarding electronic prescribing ("e-prescribing") but also proposing regulations regarding electronic records technology. These proposals except certain donations of technology from the Stark and anti-kickback laws. The proposed regulations have significant gaps, and HHS is seeking comments on many elements of its proposals.

Many of HHS's proposals are designed to guard against two risks. First, closed health care information technology systems could result in a physician being tied to the donor entity, necessarily providing that donor with all his referrals and other business. HHS seeks to mitigate this risk by requiring system compatibility, which it calls "interoperability." The second risk is that free technology might influence a physician's health care decision-making, especially when the

technology includes valuable extraneous functions. The proposed regulations therefore limit the value of donated technology to a physician by limiting the core functions of donated technology to e-prescribing and electronic records.

HHS is seeking comments mainly in the four following areas:

1. Donors and Recipients

HHS is proposing to protect donations from: hospitals to active members of their medical staff, group practices to their members, and prescription drug plan sponsors or Medicare Advantage organizations to their participating pharmacists, pharmacies, and prescribing health care professionals. It is seeking comments on whether to protect other potential donors.

To avoid abuse, the proposed rules prohibit the recipient from conditioning its business with the donor on receiving technology. Similarly, the donor is forbidden from using technology to induce a physician to change hospital affiliation. Donors are also prohibited from imposing restrictions on interoperability or unnecessarily restricting the right to use the technology to a given set of patients, such as Medicare patients.

2. Protected Technology

E-prescribing
The e-prescribing rules will protect transfers of technology that are "necessary and used solely" for the purpose of e-prescribing. Donations under this exception may include hardware, software, internet connectivity, and training services.

Donated technology under this exception may not include software with electronic records, general office management, or billing functions.

HHS, in the comment process, will refine the meaning of "necessary" and "used solely." Necessary items are ones that are not "technically or functionally equivalent" to those which the physician already has. HHS would not protect a physician who divests current technology to receive new technology. The physician must certify in writing that the "necessary" requirement is met. In addition, the donor would violate the rule if it knew (or acted in reckless disregard or acted with deliberate ignorance) of the falsity of the certification. HHS is particularly concerned with this process becoming a mere formality and is seeking comments on further ways to prevent this perceived abuse.

The "used solely" standard may be weakened in the final rule. HHS is seeking comments on whether to allow donations of information technology used for more than one function, so long as a substantial use is e-prescribing. It is also seeking comments on how to quantify substantial use and whether the ability to prescribe items other than drugs, such as lab tests, should be an acceptable use.

Electronic Health Records

Two exceptions from Stark and two anti-kickback safe harbors are proposed to permit the donation of electronic health records technology. HHS plans to adopt a set of product certification criteria with special attention given to interoperability. With this in mind, HHS has proposed two separate exceptions for electronic records technology: one exception will apply before the adoption of certification criteria (the pre-interoperability exception) and a broader exception will apply thereafter (the post-interoperability exception). HHS is also considering requiring compliance with other standards, such as the Public Health Information Network preparedness standards.

Under the pre-interoperability standard, HHS is proposing to protect electronic health records technology only in the form of software and directly related training. Under the post-interoperability standard, integrated software packages that *could positively affect patient care* would meet the exception. Such packages could include billing and scheduling software for instance, but the core functions must remain e-prescribing and electronic health records. The e-prescribing function is a required component under each exception. Comments are also being sought as to whether hardware and connectivity services should be protected under this exception, especially for rural area providers. Finally, HHS is seeking comments on how to define "electronic health records."

3. Selection Criteria

When determining which physicians will receive technology and what they will receive, the proposed rules prohibit the donor from taking into account the volume or value of referrals that the recipient makes to the donor or any other business that might be generated between them. Under the post-interoperability exception, selection criteria that *indirectly* take into account the volume or value of referrals may be used by the donor in determining which physicians will receive the technology. Direct correlations with Medicare referrals would remain prohibited.

HHS has proposed the following non-exclusive list of acceptable criteria that may be used under the post-interoperability exception:

- The total number of prescriptions written by the recipient;
- The size of the recipient's medical practice;
- Total number of hours that the recipient practices medicine; and
- The recipient's overall use of automated technology in the physician's medical practice.

4. Value Caps

In each of the proposed exceptions, HHS is considering, and seeking comments on, setting a cap on the value of the particular elements of information technology a physician can receive from a single donor. It is seeking comments on a cap for each exception and how a total cap for all exceptions might apply. The cap might be based on a fixed dollar amount or a percentage of the value of the donated technology, but other methodologies can be suggested. Moreover, HHS is seeking comments on how to value the technology transferred. HHS does not expect the final regulations to protect all possible costs. In addition, the cap could be lowered as the technology becomes more available and prices decline.

Conclusion

While the proposed rules are a step in the right direction, the process needs to be completed without further delay if the Administration's e-health initiative is to succeed. Congressional action may still be needed to dismantle barriers to wide-spread proliferation of health care information technology.