Legal Corner

Electronic Health Records: How the New Stark Law and Anti-Kickback Rules May Help Speed Adoption

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Many physicians are excited by the potential benefits of electronic health records (EHRs) and electronic prescribing (e-prescribing) technology. These technologies provide an opportunity not only to reduce paperwork, but also to improve quality of care and provide metrics for use in pay-for-performance contracting. At the

same time, physicians have been put off by the high costs often associated with the implementation of these new technologies.

Hospitals and other large providers also are interested in the benefits of widespread adoption of e-health technology. Until recently, however, these providers have been largely unable to assist physicians with the purchase of e-health technology because of legal concerns. In particular, the Stark Law and Anti-Kickback Statute have been significant barriers to the donation of e-health technology to their associated physicians. The Stark Law prohibits the referral of Medicare or Medicaid patients for “designated health services” to an entity with which the referring physician has a financial relationship, while the Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration in exchange for referrals or business that is reimbursable by a federal health care program.

On August 8, 2006, the US Department of Health and Human Services (HHS) published final regulations under the Stark Law and Anti-Kickback Statute that may help speed adoption of e-health technology by allowing entities to provide e-prescribing and EHR technology to physicians and other persons under specified circumstances. This article provides an overview of the rules, focusing on the requirements and issues that may be of particular concern to physicians.

EHR Rules

The EHR Rules allow hospitals and other entities involved in the delivery of health care to transfer EHR technology to physicians for much less than the market price of the technology, so long as the selection of recipients is not related

to referrals or other business generated between the parties. Thus, a hospital could provide EHR software to all physicians in a single department, or to all physician groups of at least a certain size.

The EHR Rules require that recipients pay for at least 15% of the donor’s cost. This 15% cost sharing must be paid at the time of, or before, receipt of the technology and may not be financed by the donor.

Not all technology is covered by the EHR Rules, though. The rules allow gifts of software and Internet connectivity, as well as related training and maintenance, necessary and used predominantly to create, maintain, transmit, or receive EHR. While donated technology must be used predominantly for EHR, HHS recognized it is common for EHR software to be integrated with other features. HHS has therefore clarified that, so long as software’s core functionality is EHR, it also may include other functions directly related to the care and treatment of patients, such as scheduling, billing, or clinical support.

In addition to being necessary and used predominantly for EHR, technology provided under the EHR Rules must be interoperable. The rules define interoperability as the ability to transfer data accurately, effectively, and securely across different systems or software applications without destroying or altering the purpose or meaning of the data. The requirement for interoperability is consistent with the government’s goal of fostering the use of open, interconnected EHR systems that will help improve patient care and efficiency by allowing patients and providers to more easily access a patient’s full medical record as the patient moves from one provider to another.

Although interoperability will allow the transfer of information within one health system, many community oncologists work at sites that interact with several hospital systems. The ultimate goal of an EHR system is to allow one physician to interact with a variety of health care entities for each patient they care for.

E-Prescribing Rules

The E-Prescribing Rules are, in many ways, more restrictive than the EHR Rules. The E-Prescribing Rules cover only items and services that are necessary and used solely to transmit and receive e-prescribing information. Technology

that has uses outside of e-prescribing, such as software that includes a billing function, is not permitted under the E-Prescribing Rules. Permitted donors and recipients also are more restrictive. In particular, physicians may only receive e-prescribing technology from their group practice or from a hospital where the physician serves on the medical staff.

Despite these limitations, the E-Prescribing Rules do have some benefits. First, the rules permit the transfer of hardware, in addition to software and connectivity services. Second, there is no interoperability requirement. Finally, physicians are not under any obligation to cover a portion of the cost of the donated technology.

Conclusion

Used properly, the EHR and E-Prescribing Rules can help physicians gain access to exciting, and expensive, new

technologies. The rules do have a number of complicated requirements, though, and any proposed donation or subsidy of e-health technology will need to be structured carefully. In addition, while the EHR and E-Prescribing Rules may help physicians by lowering the cost of adopting e-health technologies, physicians will need to consider other legal and business issues not addressed by the EHR and E-Prescribing Rules, including patient privacy concerns.

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DOI: 10.1200/JOP.0722501

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