

# HEALTH LAW

## *Update*

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

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## Final E-Prescribing and Electronic Health Regulations Protect Certain Health Information Technologies

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The use of electronic prescribing (E-prescribing) and electronic health records (EHRs) has gradually increased in recent years as hospitals and other health care institutions donate E-prescribing handheld devices and EHR technology to practitioners. In recognition of this trend, the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) recently issued final regulations to overcome certain fraud and abuse concerns relating to the use and transfer of E-prescribing and EHR technology. These regulations are effective on October 10, 2006.

### **Advantages of E-Prescribing and EHRs**

E-prescribing allows health care providers to transmit prescriptions electronically to a patient's pharmacy of choice. It can decrease prescription errors caused by illegible handwriting and miscommunications. E-prescribing also automates the process of checking for drug interactions and patient allergies.

EHRs purport to increase safety, quality and efficiency in the delivery of healthcare services. Patient information is easily portable from one health care provider to another using EHRs. This health technology also provides a confidential and seamless exchange of patient health information for treatment decisions.

The federal government recognized these advantages and required HHS and CMS to implement regulatory protections to promote widespread adoption of E-prescribing. HHS and CMS have also taken the extra step of also adopting regulations to safeguard certain arrangements for donating EHR technology and training.

## **Free Health Technology May Implicate AKS and Stark: Overview of AKS and Stark Prohibitions**

Since non-monetary remuneration, such as free computer software, hardware and training, could trigger application of the federal Anti-Kickback Statute (AKS) and the federal Stark law, full implementation of E-prescribing and EHRs has been slow to date. The AKS and Stark Law are summarized below.

The AKS requires intent and prohibits anyone from knowingly and willfully offering, paying, soliciting or receiving anything of value in return for patient referrals for which payment may be made by a federal health care program, including Medicare and Medicaid. Compliance with an available regulatory safe harbor should prevent enforcement by the Office of Inspector General (OIG), but note that failure to meet precisely each safe harbor requirement is not a per se violation of the law. Violation of the AKS constitutes a felony, punishable by imprisonment, a fine up to \$25,000 and/or exclusion from the federal healthcare programs.

Stark strictly prohibits physicians from referring Medicare patients for certain “designated health services” to entities with which the physician or an immediate family member of the physician has a financial relationship, unless an exception applies. Violations are punishable by civil money penalties and/or exclusion from Medicare.

### **AKS and Stark Regulations Protect E-Prescribing and EHR Technology Donations**

HHS and CMS both issued final regulations protecting certain arrangements involving the non-monetary donation of (1) qualified health technology hardware, software and training that is “necessary and used solely” to conduct electronic prescription transactions and (2) certain donations of EHR software and directly related training services. These new regulations do not protect arrangements that confer some other unrelated business or personal benefit on the provider, such as billing, scheduling or other administrative office software.

### **AKS and Stark E-Prescribing Safeguard Requirements**

The AKS safe harbor and the Stark exception relating to E-prescribing and EHR contain parallel requirements. Both protect E-prescribing donations from: (1) hospitals to physicians on their medical staff; (2) group practices to physician members of the group; and (3) prescription drug plans and Medicare Advantage organizations to physicians (and network pharmacists and other prescribing health care professionals under the AKS safe harbor).

While donors may select recipients based on their total number of prescriptions, they may not condition the eligibility, amount or form of E-prescribing technology on the volume or value of referrals or other business generated by the recipient for the donor. Similarly, recipients may not condition doing business with a donor upon the receipt of such E-prescribing technology.

The E-prescribing items and services must be provided in conjunction with an electronic prescription drug program that meets applicable standards under Medicare Part D. Donors may not restrict the use or compatibility of the donated items or services with other E-prescribing or EHR

technology or the practitioner's ability to use such items or services for any patient regardless of the payer.

Additional compliance requirements include a signed written agreement between the donor and recipient that specifies and covers all of the items and/or services being provided and identifies the donor's cost. Arrangements are not protected if the donor knows that the recipient already possesses any technically or functionally equivalent items or services. HHS and CMS advise prudent donors to make a reasonable inquiry to potential recipients and to document their findings.

### **AKS and Stark EHR Safeguard Requirements**

For the most part, the EHR regulations mirror the E-prescribing standards. However, there are five key differences between the E-prescribing and EHR regulations:

1. The AKS and Stark EHR regulations protect a broader range of donors. The AKS EHR safe harbor protects donations of health technology by health plans and individuals and entities that provide services covered by a federal health care program and submit claims for payment. Permissible recipients of such EHR technology under the AKS include physicians, group practices, physician assistants, nurses, therapists, pharmacists, pharmacies, community health centers and nursing facilities. The Stark EHR exception protects donations to physicians by individuals and entities that provide "designated health services."
2. Unlike the E-prescribing regulations described above, donations of EHR technology must be made before January 1, 2014, which is when the EHR safe harbor and exception expire.
3. The EHR regulations do not protect donations of computer or other hardware.
4. The EHR regulations require the practitioner to pay at least 15 percent of the donor's cost related to the donated technology. The donor cannot finance this payment, and the AKS safe harbor prohibits the practitioner from shifting this cost to any federal health care program.
5. EHR donations must be interoperable, include directly related training services and contain an electronic prescribing capability. In order to ensure interoperability, the software must have been certified within 12 months prior to the date the software was donated.

### **Conclusion**

E-prescribing and EHR technology will continue to change the practice of medicine in the near future. HHS and CMS expect that these new regulatory protections will accelerate that change. However, before hospitals, group practices and other protected donors give E-prescribing and EHR technology to physicians or other practitioners, they should carefully consider the new AKS and Stark regulations to ensure legal compliance.

If you have any questions about these new regulations, please contact any of the attorneys in our Health Law Practice Area listed on the following page.

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