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## Health Information Technology: A Regulatory and Legislative Update

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The health care industry is buzzing in response to recent regulatory and legislative developments relating to the adoption and use of health information technology (“HIT”). On Tuesday, August 8, 2006, the Centers for Medicare and Medicaid Services (“CMS”) and the Office of the Inspector General (“OIG”) published final rules, effective October 10, 2006, intended to accelerate the use of electronic health record (“EHR”) and electronic prescribing (“e-prescribing”) technology. These rules provide that donations of such technology will not violate the physician self-referral (“Stark”) law or the anti-kickback statute (“AKS”) if certain conditions are met. Meanwhile, Congress has made significant progress with respect to HIT legislation, and such progress is expected to continue after the August recess.

### Regulatory “Relaxation”

#### *EHR*

CMS and OIG have attempted to make the EHR Stark exception and AKS safe harbor consistent while allowing for the differences in the underlying statutes. For example, because the AKS is broadly applicable, the safe harbor provisions allow health plans and individuals and entities that provide covered services and submit claims or requests for payment, either directly or through reassignment, to any federal health care program to donate technology to any individual or entity engaged in the delivery of health care. On the other hand, because the Stark law applies only to physicians, the exception protects the donations of technology to physicians from any entity furnishing designated health services as defined in the Stark law. Aside from these differences driven by the underlying statutes, the new EHR rules have much in common:

1. Donors may not select recipients in a manner that directly takes into account the volume or value of the recipient’s referrals or other business generated between the parties. However, donors may select recipients in a wide variety of other ways, including the size of the recipient’s practice, the level of uncompensated care provided by the recipient, or the total number of prescriptions written by the recipient (but may not select recipients based on the number or value of prescriptions written that are dispensed or paid by the donor).
2. Only software “necessary” and “used predominantly” to create, maintain, transmit, or receive EHRs is protected as long as all the other conditions are met. Such software must include an e-prescribing component that meets the Medicare drug benefit standards and may also include billing, scheduling, and other administrative functions as long as the core function remains EHR. The new rules also protect donations of information technology and training services, including connectivity services, help desk functions, and maintenance functions that are “necessary” and “used predominantly” to create, maintain, transmit, or receive EHRs. However, hardware, including modems, wireless routers, and storage devices may not be donated pursuant to these rules.

3. Software must be interoperable as defined in the rules: “at the time of donation, the software is able to: (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.” Software that has been certified by an agency recognized by HHS is deemed interoperable as long as the software was certified within the previous 12 months and remains certified at the time of donation. Donors may not take any actions to limit or restrict the ability of the donated items or services to be interoperable with other electronic health information systems.
4. Arrangements involving donations of EHR technology must be set forth in writing and signed by the parties, and the parties must accurately document the donor’s cost of the technology. Although the proposed EHR rules would have required that recipients of donated technology certify that items and services received were not technically or functionally equivalent to items or services the recipient already possessed, CMS and OIG have agreed that such a requirement may be overly burdensome. Moreover, the requirement that donated items or services be “necessary” for EHR purposes means that equivalent items or services will not be protected. Therefore, although there is no written certification requirement in the final rules, the donor and recipient should still ensure that donated items and services are not duplicative.
5. The recipient must pay 15% of the donor’s cost of the donated items and services. Donors cannot finance the recipient’s payment of this 15% of the cost or loan funds to the recipient to pay the recipient’s share. While CMS and OIG, in the proposed rules, solicited comments on a cap on the value of donations, the final rules do not impose such a cap.
6. Consistent with President Bush’s goal of widespread adoption of EHR technology by 2014, this exception and safe harbor will sunset on December 31, 2013.

While these EHR final rules are still limited in some respects, notably the failure to protect donations of hardware, they are significantly broader than the proposed rules and are likely to be utilized by parties wishing to increase the level of HIT adoption.

### ***E-prescribing***

The Medicare Modernization Act of 2003 (the “MMA”) established a prescription drug benefit in the Medicare program; in conjunction with this benefit, Congress mandated a Stark exception and an AKS safe harbor for arrangements involving the donation of e-prescribing technology. Generally, the e-prescribing exception and safe harbor protect donations of hardware, software, and information technology and training services that are “necessary” and “used solely” for e-prescribing. Such items and services must be provided as part of, or used to access, an e-prescribing program that meets the requirements of the Medicare prescription drug benefit. CMS and OIG state that licenses, upgrades, and help desk and maintenance services can potentially fit within this exception and safe harbor. While many criticized the proposed rules as too narrow due to the “necessary” and “used solely” requirements, CMS and OIG note that these requirements are statutorily mandated and must therefore remain in the final rules.

The following donors and recipients may take advantage of the e-prescribing exception and safe harbor: hospitals to members of their medical staffs; group practices to physician members; and prescription drug plan sponsors and Medicare Advantage organizations to prescribing physicians and, under the safe harbor, to network pharmacists and pharmacies. Other conditions of the e-prescribing rules are similar to those of the EHR rules. However, because this exception and safe harbor only apply to donations of e-prescribing technology, both CMS and OIG

note that most parties seeking to make or receive donations of HIT may find the EHR exception and safe harbor more useful.

## Legislative Activity

While CMS and OIG were finalizing these Stark exceptions and AKS safe harbors, the House of Representatives, on July 27, 2006, passed House Resolution 4157, the Health Information Technology Promotion Act of 2006 ("H.R. 4157"). Among other things, H.R. 4157 would: (1) codify the Office of the National Coordinator of Health Information Technology ("ONCHIT"); (2) set a October 1, 2010 deadline for conversion to ICD-10 codes; (3) enable HHS to provide grants to spur HIT adoption; (4) require HHS to study the impact of varying state and federal laws governing the privacy and security of electronic health information; and (5) reform the Stark law and AKS to allow for technology donations. After the August congressional recess, H.R. 4157 will move to the conference phase with the Senate HIT legislation, the Wired for Health Care Quality Act of 2005 ("S. 1418"). Like H.R. 4157, S. 1418 would codify ONCHIT and provide grants to facilitate HIT adoption; however, S. 1418 does not address the Stark law or the AKS.

## Conclusion

Increased use of HIT could significantly reduce health care costs while simultaneously improving the quality of care. Despite these potential benefits, many in the health care industry still believe that high costs, privacy and security concerns, and the lack of true interoperability will prohibit the widespread adoption of HIT. While uncertainty still exists, this summer's flurry of activity demonstrates that the days of paper prescriptions and charts are numbered.

**If you have any questions about these regulations or any HIT legislation, please contact your regular Womble Carlyle attorney or Dick Vincent at (404) 879-2422, Jill Girardeau at (404) 879-2426 or Leighton Roper at (919) 755-2138 or (336) 433-5625. To learn more about Womble Carlyle's Health Care Practice Group and the attorneys on our team, we invite you to visit our web page at [www.wcsr.com/healthcare](http://www.wcsr.com/healthcare).**

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