On October 11, 2005, the U.S. Department of Health and Human Services (HHS) published two proposed regulations that are designed to protect certain donations of electronic prescribing (e-prescribing) and electronic health records (EHR) technologies from scrutiny under the federal Stark law and the federal anti-kickback statute. These two proposed rules are needed to advance the development of computerized patient records.

The benefits of an interoperable computerized patient record have long been recognized. Such a system could reduce medical errors, improve the coordination of services and improve the efficiency of our nation’s health system. Home health care providers and physicians caring for patients in their homes would have ready access to relevant patient data on a real time basis if we are able to establish a coordinated electronic patient record system.

One of the barriers to moving forward has been the federal fraud and abuse statutes. The Stark law and the anti-kickback statute have limited the ability of health systems to provide the necessary hardware and software to physicians and other providers who are responsible for coordinating care and prescribing medications. As part of the Medicare Modernization Act of 2003, Congress required HHS to...
promulgate additional exceptions to the Stark law and a safe harbor under the anti-kickback statute to protect the development and deployment of e-prescribing technologies.

The Stark Law prohibits physicians from making referrals for certain designated health services (including home care services) payable by Medicare and Medicaid to entities in which the physicians have a financial interest unless an exception applies. The anti-kickback statute prohibits individuals and entities from knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or reward the referral of business reimbursable under Medicare or Medicaid. These two laws have limited the ability of hospitals and healthcare systems to contribute technology systems to doctors or other potential referral sources.

However, HHS’ proposed regulations would make it easier for hospitals to provide e-prescribing and EHR technology to those doctors and physician groups. Specifically, the regulations proposed by the Centers for Medicare and Medicaid Services (CMS) on October 11, 2005, created a new exceptions to the Stark law for donations of non-monetary remuneration that is used solely to receive and transmit electronic prescription drug information. The proposed exception would protect only necessary donations of e-prescribing technology, and each doctor receiving such donations would be required to certify that the items provided by the hospitals are not technically or functionally equivalent to technology the physician already possesses. To qualify under this first exception, the donated technologies and services must be used solely for the transmission or receipt of electronic prescription information. However, CMS also proposed a second exception that is slightly broader covering electronic patient records and training. Under this exception, the software must be used solely for the transmission, receipt or maintenance of electronic health records or directly related training services, and the software must include an electronic prescribing component.

A separate proposed rule was proposed on October 11th by HHS’ Office of Inspector General (OIG) proposing a safe harbor under the anti-kickback statute to protect arrangements involving hospitals, physician groups, prescription drug plan sponsors and Medicaid Advantage organizations that provide information technology and training services necessary, and used solely for the receipt and transmission of e-prescribing drug information. However, unlike the Stark law exceptions proposed by CMS, OIG’s proposed anti-kickback regulations do not include an additional exception to protect donations of technology relating to electronic health records. The OIG has requested the public to provide additional information to assist in its determination of whether to also prepare a safe harbor for EHRs.

The proposed exceptions to the Stark law and anti-kickback violations could have a profound effect on the delivery of patient care including home health care. Many experts believe that if a large number of physicians were to adopt compatible and interoperable information technology systems, the quality and efficiency of health care, including home based care, would dramatically improve. However, physicians have generally been slow to adopt e-prescribing and electronic health records capabilities due to the costs associated with establishing these systems.

While hospitals and large health systems provide an obvious source of funding for new technology, the Stark law and anti-kickback statutes preclude hospitals from providing technology to referring physicians except on a fair market value fee basis. Under the current provisions, a doctor is not allowed to receive donations of any technology that facilitate the transmission or receipt of information regarding the patient’s prescriptions or health records from an unrelated hospital, health system or other designated entities to which the physician makes referrals.

The regulations proposed by CMS and OIG would help ease these technology burdens. Under the October 11 regulations, hospitals would be permitted to provide referring doctors and physician groups with in-office software and personal digital assistants (PDAs) that are interoperable with other health networks. These tools could help ensure that the information provided to home health agencies includes the most up-to-date and accurate information from the physician, and that patient information related to homecare can more easily be integrated into a larger and more comprehensive patient record.

These two new proposed regulations are an important step to ensure that advanced communications technologies can be deployed for the benefit of patients. Additional work is needed to ensure that all providers of health services have the appropriate flexibility to coordinate their information technology needs and the artificial barriers that exist based on site of care and legal structure of the provider system, do not unfairly advantage certain providers or impede improving quality of care.

About the Author: Robert J. Waters, JD, is a partner with the firm of Gardner Carton & Douglas LLP, where he serves as General Counsel to the Center for Telemedicine Law and Executive Director of the Home Care Technology Association of America. Bob can be reached at rwaters@gcd.com.