

New Stark Law Exceptions and Anti Kickback Statute Safe Harbors Encourage the Adoption and Implementation of Health Information Technology Systems

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On August 1, 2006, Michael Leavitt, Secretary of the Department of Health and Human Services, announced the promulgation of final rules providing new exceptions to the Stark Law and new safe harbors to the Anti-Kickback Statute designed to encourage physicians to implement electronic prescribing and interoperable health records systems. The final rules take effect on October 10, 2006.

Electronic prescribing technology allows physicians to transmit a prescription electronically to a patient's pharmacy, while interoperable electronic health records systems allow for the sharing of health records among multiple providers and/or facilities that may be treating a patient. Proponents of these new technologies have asserted that both will contribute to the reduction in the total number of errors and will improve efficiency and overall patient care. Introducing the new rules, Leavitt said, "Electronic health records help doctors provide higher quality patient care, improved efficiency and with less hassle. . . . By removing barriers, these regulation changes will help physicians get these systems in place and working for patients faster."

Ordinarily, providing such technology to referral sources without charge or at a below market rate would run afoul of the Stark Law and the Anti-Kickback Statute, potentially triggering investigations, fines and criminal liability. The Stark Law prohibits physician self-referrals unless an exception applies, while the Anti-Kickback Statute prohibits receipt of monetary and non-monetary remuneration in exchange for referrals. Both the Centers for Medicare and Medicaid Services ("CMS") and the Office of the Inspector General ("OIG") announced new regulations that essentially mirror each other, as CMS has jurisdiction over Stark Law matters and the OIG has jurisdiction over matters brought pursuant to the Anti-Kickback Statute.

Under the new electronic prescribing technology rules, certain entities, including, for example, hospitals and group practices, may donate items and services such as hardware, software, internet connectivity and training and support services to qualifying physicians. These transactions will now fall outside the prohibitions of the Stark Law and the Anti-Kickback Statute if the donor of the items and services does not limit the compatibility of the technology with other systems, make receipt of the technology conditioned on doing business with the recipient or take into consideration the volume or value of the referrals the donor receives from the recipient. The parties must also enter into a written agreement setting forth several terms, including the items being provided along with their costs.

While the interoperable health records systems rules are similar to the electronic prescribing technology rules and include each of the above stated requirements, there are a few meaningful differences. First, noticeably absent from these rules is a provision allowing for the donation of hardware. Instead, these rules allow for the donation only of software and information technology and training services. Moreover, physicians must pay 15% of the donor's costs, the amount of which must be specified in the written agreement of the parties, and a donor may not make a loan to a recipient to enable the recipient to make this payment. Finally, these rules are set to expire on December 31, 2013, as President Bush has expressed a desire to have interoperable health records systems in place across the country by 2014.

Benesch's Health Care Practice Group regularly counsels clients on health information technology issues. To find out more about recent developments in this area, please contact [Harry M. Brown](#) or [Alan E. Schabes](#) in Cleveland or [Janet K. Feldkamp](#) or [Frank Carsonie](#) in Columbus.