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Q&A: Regarding EHR Rules

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Q: Our laboratory is considering offering physicians the opportunity to request tests and receive test results electronically. What are some of the important regulatory issues we should consider?

A: Any such arrangement must comply with the federal self-referral statute (Stark Law), the Federal Anti-Kickback Statute (FAS), and any state law that governs financial arrangements between providers of laboratory services and referring physicians. Additionally, the arrangement may not prevent a laboratory from complying with regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), and from satisfying other legal and regulatory requirements.

There are several different types of arrangements for electronic transmission of information related to laboratory services. Since 1995, the Stark Law has permitted a clinical laboratory to provide items, devices, or supplies that are used solely to order or communicate the results of tests or procedures for the particular laboratory. This statutory provision permits a hospital or independent laboratory to provide a custom software interface to physicians that may be used solely to order tests or communicate test results with the hospital or laboratory. These types of arrangements can be integrated with the laboratory's own system.

Recently, however, there has been increased use of electronic health record (EHR) software which can perform these same functions plus numerous other tasks. EHR adoption has been encouraged by at least two regulatory changes. First, coordinated changes to Stark Law and the FAS safe harbor regulations (EHR Rule)

permit hospitals, independent laboratories, and certain other specified "donors" to subsidize up to 85% of the cost of a medical practice's EHR. Second, under Medicare's EHR Incentive Program, starting in May 2011, hospitals and qualifying physicians who demonstrate "meaningful use" of certified EHR technology may receive additional Medicare payments. A hospital's or physician's incorporation of more than 40% of clinical-laboratory test results in certified EHR technology as so-called "structured data" can support a claim for such payments.

Given the EHR Rule's substantial limitations, it is not always clear whether it makes sense for a laboratory to donate EHR to medical practices. The EHR software must be interoperable. This means that it can be used with different types of technology systems, software, and networks in various settings. The donor may not limit or restrict its use, compatibility, or interoperability with other EHR systems. This means the EHR can be used to order tests from other laboratories. While the lab may use selective criteria for choosing physicians who may receive EHR donations, it cannot base this determination directlyon the physician's past, present, or future (anticipated) volume or value of referrals or other business generated for the laboratory. Selection criteria that are intended to induce a physician to discontinue or limit referrals to another laboratory in favor of the donor laboratory are impermissible. Similarly, an EHR donation that is made to a medical practice which has made the donation a condition of doing business with the practice would not be protected.

Moreover, a laboratory must make sure its EHR donation does not violate the laws of a particular state in which it does business. The state may have adopted a self-referral or anti-kickback statute similar to the Stark Law or FAS but then failed to later adopt laws or regulations to accommodate the provision of EHR, similar to the EHR Rule. For example, the New York Department of Health has advised laboratories that "provision of EHR, software and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in [New York State]." Similarly, New Jersey does not permit a laboratory to donate electronic medical record systems for a physician office in which it operates a specimen collection station.

Additionally, regardless of the type of arrangement, a laboratory must remain CLIA-compliant, particularly with requirements related to test requests and test reports. Use of certified EHR does not guarantee CLIA compliance. CMS has indicated that each laboratory's systems and processes are unique; therefore, a laboratory must evaluate the results of its use of a particular EHR.

Finally, HHS Office of Inspector General (OIG) compliance guidance emphasizes that claims for payment must reflect the tests ordered by the physician and performed by the laboratory. Similarly, laboratories should take steps to ensure their claims are for services that are "covered, reasonable, and necessary." According to the OIG, the laboratory's requisition should "promote the conscious ordering of tests by physicians," and physicians should be provided with annual written notices that address Medicare payments for laboratory services and with special notices related to their use of custom profiles. These same principles apply when tests are ordered electronically. Additionally, an EHR system may not reflect the particular name or codes used by a laboratory for tests or test panels. Special care may be necessary, therefore, to ensure that the tests that the laboratory performs and bills are those that the physician intended to select.