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Providing Referral Sources with Limited-Use EHR Interfaces

As many healthcare providers migrate to electronic health records (EHRs), clinical laboratories and diagnostic imaging centers have sought to provide their referring physicians with a limited-use EHR interface that allows the physician offices to submit orders and review test results electronically. Over the past several years, the Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services Office of the Inspector General (OIG) have separately approved such arrangements through regulatory guidance and advisory opinions.

In general, limited-use EHR interfaces allow referring physician practices to electronically submit orders for diagnostic services directly to clinical laboratories and diagnostic imaging centers via the physician's EHR. In addition, the clinical laboratories and diagnostic imaging centers can send reports electronically to the referring physician's EHR. This EHR interface eliminates the need to fax orders and reports back and forth and also allows immediate entry into the EHR of such records. The limited-use EHRs generally have the following characteristics:

1. They have no independent value to the physician.
2. Their use is limited to sending and receiving information between a referring physician and a clinical laboratory or diagnostic imaging center.
3. It is integrally related to the provision of the clinical laboratory's or diagnostic imaging center's services.

Clinical laboratories and diagnostic imaging centers have sought to pay for the cost of installing the interface with a referring physician's office. The arrangement typically works as follows:

1. The clinical laboratory or diagnostic imaging center purchases an interface license and pays the annual software maintenance fee. They also pay a one-time installation and set-up fee. The interface vendor invoices the clinical laboratory or diagnostic imaging center directly for these charges.
2. The clinical laboratory or diagnostic imaging center pays for the costs associated with developing software to connect their IT system to the interface software purchased in step 1.
3. The clinical laboratory or diagnostic imaging center pays for any costs associated with establishing network connectivity with the referring physician practices.

Based on a review of guidance from the OIG and CMS, it is clear that providing a limited-use interface to referring physicians is allowed, and does not violate the Anti-Kickback Statute (AKS) or Stark Law. Nonetheless, clinical laboratories and diagnostic imaging centers should develop a compliant process in which to select those physicians who will receive the interface.

Anti-Kickback Statute Analysis

The Anti-Kickback Statute, 42 USC 1320(a-7b(b), is a broad prohibition against the knowing and willful solicitation or receipt of remuneration in return for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program (including Medicare and Medicaid). Because of the wide scope of the law, the OIG has developed safe harbors for certain financial relationships. The OIG has also published guidance in the form of Special Fraud Alerts (SFA) and Advisory Opinions that identify suspect financial arrangements and address the applicability of the AKS to a proposed or existing financial arrangement.

In the preamble to the 1991 AKS safe harbor regulations, the OIG described a limited-use computer provided to a physician by a clinical laboratory – an analogous situation to clinical laboratories or diagnostic imaging centers because the referring physician generally selects the clinical laboratory or diagnostic imaging center. In the example in the 1991 preamble, the computer equipment had no independent value to the physician – it was used merely to print lab results. The OIG stated that such a limited-use arrangement was outside the scope of the AKS prohibition against illegal remuneration – and thus would not result in enforcement action by the OIG.

Again in 1994, the OIG touched upon the status of providing limited-use technologies in physician offices by clinical laboratories. In a SFA that highlighted potentially abusive relationships between clinical laboratories and physician offices, the OIG made clear that a laboratory could provide services to a referring physician without implicating the AKS. For example, the OIG stated that a lab could provide a physician's office with a phlebotomist if the phlebotomist only collected specimens from patients for testing at the lab - -and did not perform additional duties that were normally the responsibility of the physician. Likewise, the OIG stated its approval of free pick-ups and disposals of bio-hazardous waste products from a physician's office related to the collection of specimens for the lab. Moreover, a lab could provide a computer or fax machine to a physician, if it was integral to, and used exclusively for, the performance of the lab's work.

In short, the 1994 SFA established that laboratories (and other health care providers) could provide limited-use technologies to referring physicians that were integrally related to the provision of their health care services, and that had no independent value to the physician.

The OIG has maintained this position in the intervening years. Most recently, the OIG in December 2013 stated that it has long distinguished between those free items and services that are integrally related to the offering provider's services and those that are not. 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013). For example, the OIG sees no problem if a lab company provides a free computer to a referring physician if the computer could be used solely to print out test results produced by the lab company, because the computer has no independent value to the physician outside of the lab services. Additionally, the OIG sees no problem with lab companies providing phlebotomists in physician offices solely to draw blood samples for the lab – or offering free courier services to pick up samples to be tested in the lab. Again, these services are integrally related to the offering of lab services, and provide no independent value to the physician.

The OIG stated:

> The donation of free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services would be integrally related to the donor's services. As such, the free access would have no independent value to the recipient apart from the services the donor providers, and therefore, would not implicate the anti-kickback statute.
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> We believe that a limited-use interface … is the contemporary analog to the limited-use computer described in the example from the 1991 preamble to the safe harbor regulations. A similarly limited-use facsimile machine would not materially differ from the limited-use computer and, thus, would be analogous to the access to the limited-use interface. It is the lack of independent value to the recipient that takes the donation outside the scope of the anti-kickback statute's prohibition, not the mode of technology ... the free access to a limited-use interface would not require safe harbor protection…

Furthermore, in Advisory Opinion 12-20 (2012), the OIG approved a hospital's provision of an electronic interface to community physicians. In that arrangement, the hospital would offer free access to the interface for all physicians who requested it. The interface would be used to transmit to the hospital orders for lab and diagnostic services to be performed by the hospital. In addition, the hospital would provide, through a contractor, support services necessary to maintain the interface, including software updates. The interface would serve no other purpose.

The OIG concluded that the provision of the limited-use interface would not constitute remuneration because it was integrally related to its services. Free access to the interface, the OIG stated, would have no independent value to the physician apart from the lab and diagnostic services the hospital provided.

Stark Law Analysis

The Stark Law, 42 USC 1395nn, prohibits physicians and their immediate family members from referring a Medicare or Medicaid patient for certain designated health services (including clinical laboratory and diagnostic imaging services) to a health care entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. Financial relationships include "compensation arrangements and "ownership arrangements." The Stark Law regulations exclude from the "compensation arrangement" definition any remuneration resulting from the provision of items or services by a healthcare entity that are used solely to order or communicate the results of tests or procedures for such entity. 42 CFR 411.351.

CMS provides advisory opinions regarding the applicability of the Stark Law to proposed or existing financial relationships between physicians and entities that provide healthcare services. In 2008, CMS ruled that the Stark Law would not prohibit a hospital system from installing a software interface in physician offices that would allow the physicians to order lab tests and view lab reports from the hospital. CMS Advisory Opinion 2008-01. Following the statutory language and regulatory guidance cited above, CMS determined that the interface would not meet the definition of a "compensation arrangement" under the Stark Law because the interface had limited use, could not be modified by the physician and could not be sold, transferred or

assigned by the physician. Thus, because there was no compensation arrangement between the physician and the hospital, the Stark Law was not implicated by the arrangement.

Other Considerations

While it is well-settled that clinical laboratories and diagnostic imaging centers may provide a limited-use interface for referring physicians to order and view clinical laboratory and diagnostic imaging results, it is important to select those physicians who will receive the interface in a manner that will not implicate either the AKS or the Stark Law. It is recommended that clinical laboratories and diagnostic imaging centers use a process similar to that contained in the regulatory guidance regarding the provision of EHR support to physicians. Under the Stark and AKS regulations that allow entities to provide EHR support to physicians, there is a mechanism that those entities should use to determine whether a physician is eligible to receive such support. *See* 42 CFR 411.357(w)(6). The OIG and CMS have developed the following factors regarding the selection process, and it is recommended that clinical laboratories and diagnostic imaging centers follow this process as closely as possible. The determining factors are:

1. The number of orders written by the physician (but not the volume or value of the orders processed by the clinical laboratory or diagnostic imaging center, or billed to the government);
2. The size of the physician's medical practice (total patients, patient encounters, RVUs, etc.);
3. The total number of hours that the physician practices medicine;
4. The physician's overall use of technology in his or her practice (without specific reference to the use of technology in connection with referrals made to the clinical laboratory or diagnostic imaging center);
5. The level of uncompensated care provided by the physician; and
6. Any manner that does not take into account the volume or value of referrals or other business generated between the parties.

Using these factors to determine which physicians will receive the interface will greatly reduce the risk that clinical laboratory's or diagnostic imaging center's provision of a limited-use interface is questioned by the government.