Physicians beware: Collection and handling payments under scrutiny

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On June 25, 2014, the Office of Inspector General (OIG) issued a special fraud alert entitled “Laboratory Payments to Referring Physicians.” The alert deals specifically with laboratories paying compensation to physicians and group practices for blood specimen collection, processing, and packaging activities, as well as the submission of patient data to a database or registry.

The Medicare and Medicaid anti-kickback statute is implicated when remuneration is paid in order to induce or reward referrals for any items or services reimbursed by a federal healthcare program. The alert cautions against arrangements that improperly take into account the volume or value of referrals that may induce a physician or physician group to use a particular laboratory or cause overutilization of testing services. The OIG highlights in this special fraud alert that certain arrangements are particularly suspect under the anti-kickback statute, including specimen collection, processing and packaging arrangements, and registry payments.

RISKS

The OIG explains the risks associated with arrangements where a physician or physician group is paid by a laboratory for the collection, processing, and/or packaging of specimens. Specimen collection is reimbursed by Medicare only in certain circumstances, including where it is customary practice in the region and for that particular physician to charge for specimen collection separately. There are also separate CPT codes for processing and packaging specimens for transport to a laboratory. Since the laboratory payments to a physician or physician group for these services are often per-specimen or per-patient, the anti-kickback statute is implicated and the OIG cautions laboratories entering into these arrangements to consider, for purposes of determining fair market value, whether or not the physician is already compensated for the activity either through a bundled payment or through payments for overhead expenses. Certain characteristics that the OIG finds to be evidence that the arrangement may be unlawful include:

- The payments exceed fair market value, is calculated on a per-specimen or per patient method, or is offered on the condition of a certain number of orders.
- The physician is already paid for the services by a third party, such as Medicare.
- The payments go directly to a physician rather than the group practice that actually bears the cost of the services or where the services are performed by someone placed in the office by the laboratory.

This latest fraud alert highlights the OIG’s suspicion of financial relationships between laboratories and physicians that involve either the provision of free, or discounted goods, services, or payments of more than fair market value for services. It is noted particularly that the relationship between a laboratory and a physician or physician group is of concern particularly because there is typically no input from patients in the selection of laboratories for tests. It is important when considering relationships between laboratories and physicians or physician groups to take into account the guidance from the OIG regarding areas of concern and to structure the arrangement in a way that complies with federal and state fraud and abuse laws.

It is critical to understand that a violation of the Medicare and Medicaid anti-kickback law involves both parties: both the laboratory making the payment and the physician receiving the payment. The penalties that can be imposed against both the laboratory and the physician include civil monetary penalties, exclusion from the Medicare and Medicaid programs, and criminal sentences.

INVESTIGATION

In September 2014, The Wall Street Journal reported that the OIG and the United States Justice Department were conducting an investigation into similar payments paid by Health Diagnostic Laboratory, Inc. (HDL). As reported in The Wall Street Journal, HDL paid $20 per specimen to most physicians who ordered its cardiac biomarker test, with some physicians receiving payments totaling several thousand dollars per week. In the article, HDL was quoted as explaining that the $20 per sample fee represented the fair market value of collection, processing, and handling fees performed by the physicians. Nevertheless the government agencies are conducting an investigation into the payments received by the ordering physicians.

The exposure of physicians to the imposition of penalties under the anti-kickback law has been highlighted in the criminal prosecutions involving Biodiagnostic Laboratories, Inc. (Biodiagnostics) and its referring physicians. Biodiagnostics, a clinical laboratory in New Jersey, was accused of paying disguised kickbacks to physicians, some of which were in the form of collection payments. Biodiagnostics, and a certain amount of its referring physicians, entered into written collection agreements pursuant to which Biodiagnostics paid fixed monthly amounts to the physicians for their services involved with respect to the collection and handling of laboratory specimens sent to Biodiagnostics for testing. As of February 2015, the owners and sales representatives involved in the scheme have plead guilty or were convicted of violation of the Medicare and Medicaid anti-kickback law, and are serving criminal sentences. In addition, 23 physicians have either plead guilty or been convicted of similar criminal charges. Most of these physicians have had their medical licenses revoked and have lost their medical practices. It is important to note that certain physicians were led to believe by Biodiagnostics that the payments were legitimate because they were pursuant to formal written agreements reciting fixed compensation for the collection services. Nevertheless, the government took the position that the payments were made to induce the referral of testing by the physicians to Biodiagnostics.

OUTLOOK

In light of the developments in this area, most laboratories that were previously paying collection and handling payments to physicians have either ceased making such payments altogether, or have dramatically curtailed the amount that they pay for such services. Many laboratories limit payments now to the Medicare allowable for collection services, relying...
upon a 2008 advisory opinion issued by the OIG, in which the OIG indicated that payments that did not exceed the Medicare allowable for collection services would be unlikely to raise significant compliance issues under the Medicare and Medicaid anti-kickback law. The Medicare allowable for such collection services is approximately $3 to $4.

The author of this article also had a conversation with the OIG following the publication of the June 2014 fraud alert, exploring the parameters of collection payments that might be deemed acceptable by the OIG. Importantly, the OIG official who was principally responsible for the drafting of the fraud alert explained that the office had, at that time, not yet seen a collection payment that it would deem permissible. It is clear that the OIG would look with a high level of skepticism and scrutiny upon any collection and handling payments.

The foregoing does not mean that it is illegal for a laboratory to pay, or for a physician to accept, fair market value payments for collection of other handling services that are legitimately required by the laboratory and actually provided by the physician. However, it is clear that such payments are under intense scrutiny from the federal government as disguised payments to induce or reward referrals by physicians to the laboratories. Given the significant consequences for violation of the Medicare and Medicaid anti-kickback law, physicians should be wary of requesting or accepting any such payments, and should consult with their legal advisors with respect to any proposal for the payment of collection and handling fees.

For more information, please contact the attorney listed below.