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OIG Special Fraud Alert Is a Warning to Laboratories and Referring Physicians

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In late June, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released a Special Fraud Alert (Alert) regarding laboratory payments to referring physicians. Although the Alert focuses on two specific payment arrangements, which are described further below, its message should be viewed as a general warning and reminder that payment arrangements involving laboratories and referring physicians may result in a violation of the federal Anti-Kickback Statute (AKS), which is emblematic of the position that the OIG has consistently taken in the past.

Specimen Processing and Registry Arrangements

As mentioned above, the Alert focuses on two specific types of arrangements – Specimen Processing Arrangements and Registry Arrangements.

According to the Alert, a "Specimen Processing Arrangement" is an arrangement where a physician is paid by a clinical laboratory to collect, process, and package patients' blood specimens. The Alert explains that these arrangements typically involve a laboratory paying a physician for certain specified duties, such as collecting and centrifuging blood specimens, maintaining the specimens at a particular temperature, and specimen packaging to prevent damage in transport.

The Alert describes a "Registry Arrangement" as an arrangement under which a clinical laboratory creates, coordinates, or maintains databases purportedly to collect information on patients who have undergone or may undergo certain tests performed by the laboratory, and goes on to say that such arrangements typically involve laboratories paying physicians for certain specified duties, such as submitting data for incorporation into the registry, reviewing registry reports, and answering patient questions related to the registry.

Risk of Violating AKS

AKS is implicated anytime a clinical laboratory pays a physician, but it is also an intent-based statute, so a particular payment arrangement will only violate AKS if one purpose of the arrangement is to award or induce referrals of federal healthcare program business. The Alert lists certain characteristics of Specimen Processing Arrangements and Registry Arrangements that may provide evidence of improper intent under AKS, including: (i) payments for services for which a physician is separately compensated from another source, such as Medicare; (ii) payments on a per-specimen, per-test, per-patient, or other basis that takes into account the volume or value of referrals; (iii) payments for services/tests that may be duplicative or that are otherwise not reasonable and necessary; (iv)

payments made to an ordering physician rather than the physician's group practice, which may have incurred the cost of processing and collection; and (v) payments made to an ordering physician or his or her group practice when the specimen processing is actually performed by an in-office phlebotomist placed there by the laboratory or a third party.

Notwithstanding the foregoing, even if some of the suspect characteristics are present, an arrangement still would not violate AKS if there was no intent to award or induce referrals. Likewise, even if an arrangement only involves fair market value payments and does not include the suspect characteristics identified in the Alert, it would still be an AKS violation if the intent of the arrangement is to award or induce referrals.

Consistent with messages delivered in the past by the OIG, the Alert also points out that even if an arrangement applies only to non-federal healthcare program patients, that fact alone would not be sufficient to prevent an AKS violation, as an otherwise questionable arrangement may still violate AKS despite carving out federal healthcare program beneficiaries from the arrangement by, for example, disguising remuneration for such patients' business through payments purportedly related to non-federal healthcare program beneficiaries.

Implications and Take Away

The Alert is yet another warning to anyone involved in arrangements with referral sources of federal healthcare program business that if any purpose of an arrangement is to award or induce such referrals, it will violate AKS. As highlighted in the Alert, this is true even if the arrangement involves payments that are consistent with fair market value, as the government's aggressive position has shown that although it may be helpful evidence that no AKS violation occurred, fair market value compensation, in and of itself, is not a shield against AKS liability. Likewise, even if an arrangement carves out federal healthcare program beneficiaries and only applies to non-federal healthcare program patients, it would still be a violation of AKS if the requisite intent is present.

An AKS violation can result in penalties to parties on both sides of the arrangement, so both laboratories and physicians should be mindful of the analysis provided in the Alert, particularly if they are involved in either Specimen Processing Arrangements or Registry Arrangements. Based on the Alert's guidance, to help protect against a possible AKS violation, laboratories and physicians should avoid structuring payments on a per-patient encounter, per-test or per-specimen basis, and should instead consider a per-type of specimen payment, which is less likely to be driven by the volume or value of referrals.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:

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