# PUBLICATION

## Two Laboratories Settle Claims Regarding Specimen Processing Fees [Ober|Kaler]

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**Continuing the scrutiny of laboratory arrangements with referring physician practices, the United States Department of Justice (DOJ) recently announced the settlement of False Claims Act allegations against two cardiovascular testing laboratories, Health Diagnostics Laboratory, Inc. (HDL) and Singulex, Inc. (Singulex).**

The settlement agreements resolve qui tam actions filed against the respective laboratories alleging that the laboratories violated the federal antikickback statute by improperly paying the physician referral sources $10 to $20 "processing and handling fees" associated with the submission of each specimen. The government alleged that these payments, along with the routine waiver of certain copayments and deductibles, provided illegal remuneration to the physicians in exchange for patient referrals covered by the federal health care programs, and led to the ordering of medically unnecessary tests. The relators, who worked as a billing agent and nurse for a referring physician, alleged that, despite documentation provided by the laboratories suggesting that the physicians would be required to perform multiple "specimen processing tasks," the physicians would perform little or no services in exchange for the payments.

Pursuant to the settlement agreements, in which both companies deny any wrongdoing, HDL will pay $47 million, which could increase based on contingencies to more than $100 million, and Singulex will pay $1.5 million. Each laboratory entered into a Corporate Integrity Agreement with the OIG.

Prior to the settlements, and while these qui tam actions were being investigated by the Government, the Department of Health and Human Services Office of Inspector General (OIG) released a Special Fraud Alert on Laboratory Payments to Physicians highlighting the OIG's concern that such specimen processing arrangements would implicate the antikickback statute if one purpose of the payment is to induce or reward referrals. The OIG noted that specimen-processing payments are typically made on a per-service basis and are often associated with expensive or specialized tests. The OIG stated that evidence of unlawful intent may exist where, for example, the payments exceed fair market value, or are for a service that is already reimbursed to the physician by a third-party payor, resulting in double payment.

In its press release, the DOJ noted that it has also intervened in lawsuits with similar, related allegations against another laboratory, as well as BlueWave Healthcare Consultants, Inc. (BlueWave), and its owners and former CEO. BlueWave purportedly was the exclusive marketing agent for HDL and Singulex, which promoted the laboratory services and processing fees to referring physicians.