CORPORATE COMPLIANCE ALERT

11/27/13

Be Wary of Improper Inducements from Laboratories: False Claims Act Settlement Agreement with Bostwick Laboratories, Inc.

Bostwick Laboratories, Inc. (Bostwick) agreed to pay the United States $503,668 to resolve allegations that the company violated the False Claims Act by making illegal payments ($100 per patient) to physicians to induce them to enroll their patients in a clinical trial study sponsored by Bostwick called, "Determination of the Accuracy of PCA3Plus Urine Assay for the Detection of Prostate Cancer."[1] To enroll a patient in the study, a physician was required to send Bostwick a urine sample *and* a prostate biopsy sample – which otherwise could have been sent to any other laboratory. Bostwick then billed both samples to Medicare and Tricare.

As emphasized by Loretta E. Lynch, United States Attorney for the Eastern District of New York, the settlement agreement demonstrates that decisions involving medical treatment "cannot and should not be based on illegal payments from laboratories."[2] Likewise, the settlement agreement is a strong reminder that physicians cannot accept any inducements from laboratories or third parties with contractual relationships with laboratories, *i.e.* sales representatives or members of a marketing force, that are designed to maximize the volume of patients referred to laboratories for unnecessary testing. Further, inducements are not limited to simple cash payments per patient. Laboratories may offer a vast array of incentives to physicians to increase the amount of patient referrals, including: a phlebotomist free of charge ("draw fee"), a fixed fee for collecting, handling, and sending a specimen to the laboratory for testing that is inconsistent with fair market value, or a flexible billing policy designed to minimize the burden of co-pays or deductibles to the patient.

Given these practices, it is incumbent upon physicians to implement policies and procedures to verify that a proposed laboratory test is medically necessary. Similarly, physicians must evaluate whether a seemingly innocuous arrangement or relationship with a laboratory, or any of its third-party vendors or contractors, violates federal or state self-referral and Anti-Kickback laws. Lastly, all members of a physician group practice must implement policies requiring employees and contractors to report any suspected violation of the law internally to avoid situations similar to Bostwick. Indeed, in Bostwick, the urologist whistleblower reported directly to the government and, very likely, provided information to the government about the acceptance of cash payments by other urologists.

In sum, the settlement agreement in Bostwick is simply further evidence that the government will aggressively enforce and monitor laboratory and physician practices that encourage or contribute to overutilization. Therefore, a failure to establish any of the above-described policies and procedures may result in civil penalties and fines and may further result in the imposition of administrative sanctions, *i.e.* exclusion from federal healthcare programs, or criminal penalties.

[1] http://www.justice.gov/usao/nye/pr/2013/2013aug20a.html

[2] http://www.justice.gov/usao/nye/pr/2013/2013aug20a.html

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