Recent false claims settlements and case developments

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Two recent False Claims Act settlements highlight the importance of having a robust, effective compliance program. In the first, a medical device company that lacked an effective compliance program agreed to pay a record-breaking $646 million settlement. In the second, a hospital system that promptly self-disclosed its noncompliance to the government settled for $2.48 million.

Medical device company agrees to record-breaking $646 million settlement

Olympus Corporation of the Americas, the largest distributor of endoscopes and related equipment in the United States, has agreed to pay $623.2 million to resolve criminal charges and civil claims related to a scheme to pay kickbacks to doctors and hospitals. An Olympus subsidiary has also agreed to a $22.8 million settlement under the Foreign Corrupt Practices Act, resulting in a total settlement of $646 million — the most ever for violations of the Anti-Kickback Statute and the largest settlement ever paid by a medical device company.

The criminal complaint, which was filed in federal court on March 1, alleges that Olympus paid substantial kickbacks to physicians and hospitals over a number of years. The kickbacks included consulting payments, foreign travel, lavish meals, and millions of dollars in grants and free endoscopes. The Department of Justice (DOJ) press release stressed that Olympus lacked training and compliance programs and did not even create a compliance officer position until 2009.

U.S. Attorney Paul J. Fishman stated that, "For years, Olympus Corporation of the Americas and Olympus Latin America dropped the compliance ball and failed to have in place policies and practices that would have prevented the substantial kickbacks and bribes they paid. It is appropriate that they be punished for that[.]" Olympus entered into a three-year deferred prosecution agreement that will allow the company to avoid conviction if it complies with the compliance requirements outlined in the agreement.

The DOJ press release announcing the Olympus settlement stressed that the DOJ has "longstanding concerns" regarding the financial relationships between medical device manufacturers and providers who prescribe or use their products. Principal Deputy Assistant Attorney General Mizer stated that, "Such relationships can improperly influence a provider's judgment about a patient's health care needs, result in the use of inferior or overpriced equipment, and drive up health care costs for everybody." The press release makes clear that the DOJ intends this settlement to "send a clear message" to all health care entities that such relationships will not be tolerated.

This unprecedented settlement highlights the critical role that an effective compliance program must play in every health care organization's business. Olympus belatedly created the position of the compliance officer in 2009. Once created, however, it appears that the position was not effective at preventing or reversing the culture at Olympus. Indeed, the original civil action was brought by the former compliance officer of Olympus — an insider who knew that Olympus did not have appropriate policies and procedures in place and did not effectively train its sales representatives as to appropriate interactions with providers. Organizations must both have vigorous compliance programs in place and heed the findings and recommendations of those compliance programs. Failure in either respect exposes organizations to the type of penalties levied against Olympus, which must now operate under the microscope of a corporate integrity agreement and pay a record-breaking penalty.

Southern Tennessee Medical Center to pay $2.48 million to settle False Claims Act allegations

Southern Tennessee Medical Center LLC (STMC) recently entered into a settlement with the Department of Justice to pay $2.48 million to resolve allegations that it violated the False Claims Act. The overpayment at issue in the case was initially brought to the attention of the DOJ via a self-disclosure submitted by STMC in 2015.

The government alleged that, between 2009 and 2014, STMC submitted claims and received payment for medically unnecessary days of inpatient geriatric psychiatric services and inpatient geriatric services for which a physician certification or recertification was not obtained. The DOJ press release stressed that STMC avoided a harsher penalty by voluntarily reporting the potential violations. "When medical providers self-disclose potential violations directly to the U.S. Attorney's Office they avoid the costs associated with protracted investigations and minimize the risks of costly fines and exclusion under the False Claims Act," said Acting U.S. Attorney Jack Smith.

This settlement stands in contrast to the Olympus case and underscores the importance of a robust compliance program that includes a mechanism for identifying and self-disclosing violations to the government. Had STMC not had an effective compliance program in place, and had these overpayments been discovered by the government or reported by a whistleblower in the absence of disclosure by STMC, the penalty would likely have been much more severe.

Any compliance officer who is struggling to convey the importance of an effective compliance program to senior leadership should present the examples of the Olympus and STMC cases. Organizations that attempt to short-change the compliance function place themselves at great risk over compliance issues.

Authors