

LESSON FROM RML'S \$1.1 MILLION SETTLEMENT: BEWARE OF CARVE-OUTS AND PULL-THROUGH ARRANGEMENTS

Despite the federal government's long-standing position that pull-through business could violate the anti-kickback law, some labs apparently haven't gotten the message.

Case in point: Oklahoma-based Regional Medical Lab (RML) recently paid \$1.095 million to settle self-reported violations of the self-referral and anti-kickback laws for services performed between March 19, 2007, and March 19, 2013. RML provides onsite inpatient laboratory services for St. John Medical Center in Tulsa, as well as outpatient lab services for other hospitals, clinics and physician offices in the Tulsa metro area, northeastern, south and western Oklahoma and southeast Kansas.

The Health and Human Service Office of Inspector General alleged that RML paid remuneration to a medical group in the form of a profit-splitting arrangement related to on-site clinical reference laboratory services for non-governmental business that induced the referral of business. The OIG claimed that this arrangement induced the referral of business for which the government was the payer.

RML disclosed the conduct to the OIG on March 27, 2015, but did not admit liability. The settlement was announced May 19, 2016.



Karen Lovitch

Karen Lovitch, an attorney with Mintz Levin (Washington, DC) notes that for many years, the OIG has closely scrutinized what it refers to as “carve-outs,” or business arrangements involving non-federal health care program business that are intended to “pull through” federal health care program business.

For example, in a June 2014 Special Fraud Alert, the OIG cautioned laboratories and physicians against entering into specimen processing arrangements involving only non-federal health care program business because, in the OIG's view, such arrangements may be intended to influence physicians' referrals of federal health care business to the laboratory.

Not Illegal Per Se

“However, it is important to note that carve-outs are not per se illegal,” Lovitch tells *Laboratory Economics*. “A laboratory or other health care provider thus may decide to proceed with a carve-out arrangement in an effort to limit risk under the federal anti-kickback statute and other state and federal fraud and abuse laws, but should do so knowing that enforcement authorities may consider the arrangement to be suspect.”

“Any laboratory or other provider who chooses to implement a carve-out arrangement should take steps to ensure that it is not offered to induce the referral of federal health care program business and that the carve-out arrangement is otherwise compliant. If even one purpose of a business arrangement is to induce the referral of federal health care program business, the federal anti-kickback statute could be violated,” Lovitch continues. “Before entering into a carve-out arrangement, knowledgeable health care regulatory counsel should be consulted on potential legal risks and strategies for reducing those risks.” The OIG's advisory opinions are available at www.oig.hhs.gov.