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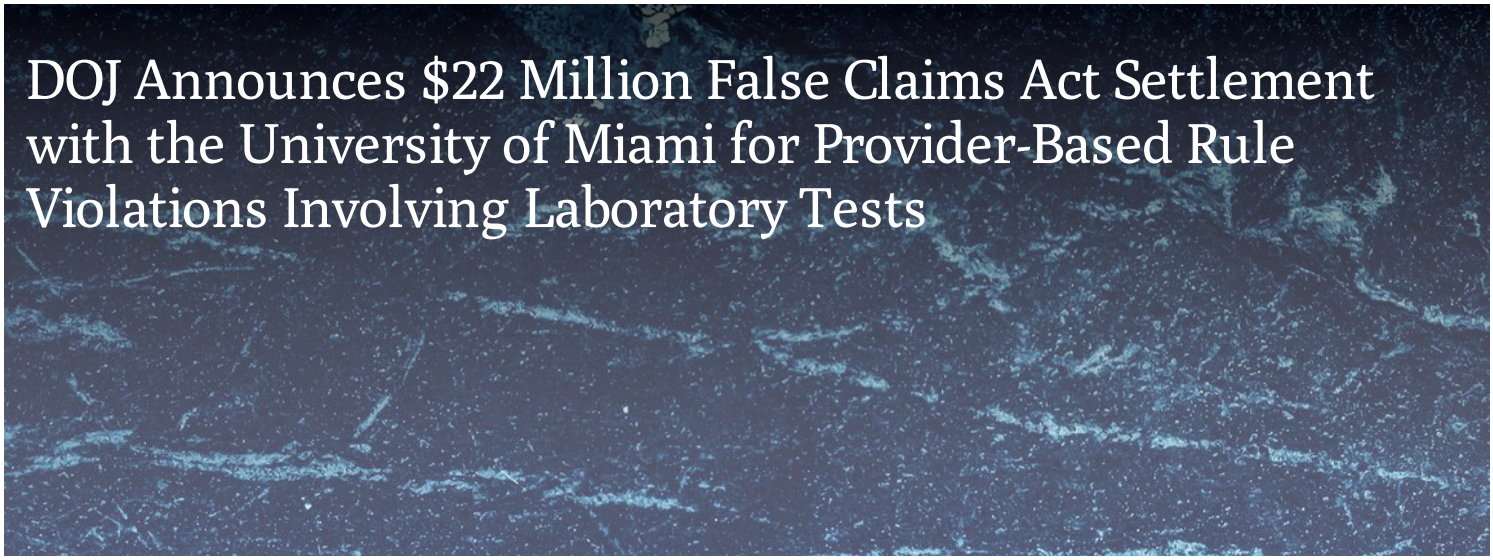

DOJ Announces $22 Million False Claims Act Settlement with the University of Miami for Provider-Based Rule Violations Involving Laboratory Tests

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Key Takeaways:

- The settlement emphasizes the importance of strictly complying with the notice requirements for off-campus billing of Medicare patients.
- Violations of the provider-based rule can trigger false claims liability for services rendered and billed from the non-compliant provider-based location.

On May 10, 2021, the U.S. Department of Justice (DOJ) announced that the University of Miami (UM) agreed to pay a $22 million settlement concerning alleged violations of the False Claims Act (FCA).[1] The settlement resolves claims from three separate lawsuits alleging that UM violated the FCA by ordering medically unnecessary laboratory tests and submitting false claims for pre-transplant lab testing through its laboratory and off-campus hospital based facilities (Hospital Facilities).[2] Relatedly, DOJ entered into a separate $1.1 million settlement with Jackson Memorial Hospital concerning the same pre-transplant lab testing allegations, which Jackson Memorial Hospital purchased from UM.

The allegations were first raised in a 2013 *qui tam* complaint, and two additional whistleblower lawsuits of the same ilk were filed in late 2013 and in 2014. All of the lawsuits alleged that UM participated in the following fraudulent conduct.

First, the complaints allege that UM knowingly engaged in improper billing related to its off-campus Hospital Facilities. Medicare regulations allow medical systems to convert physician offices into Hospital Facilities provided that they satisfy certain requirements. One of those requirements is that off-campus Hospital Facilities give notice to Medicare beneficiaries explaining that they will face higher costs when receiving services at an off-campus Hospital Facility as opposed to physician offices.[3] However, UM allegedly converted multiple physician offices to off-campus Hospital Facilities, seeking payment at higher rates, but without providing beneficiaries the required notice—even after it was advised to do so by a Medicare Administrative Contractor.

Second, DOJ alleged that UM billed federal health care programs for medically unnecessary laboratory tests for patients who received kidney transplants at the Miami Transplant Institute (MTI) (a transplant program jointly operated by UM and Jackson Memorial Hospital). Each time a patient sought treatment at MTI, UM's electronic ordering

system automatically prompted the ordering of a number of tests for the patient at UM's laboratory. DOJ alleged that several of these laboratory tests were medically unnecessary and "dictated by financial considerations rather than patient care."

Finally, the government alleged that UM caused Jackson Memorial Hospital to submit inflated claims for reimbursement for pre-transplant laboratory testing conducted at MTI in violation of related party regulations, which limit the reimbursement a provider can obtain for tests performed by a related entity compared to that entity's actual costs. While UM could have billed Medicare directly for the tests, DOJ alleged that UM effectively controlled Jackson Memorial Hospital's decision to purchase the tests at inflated rates in exchange for UM's surgeons continuing to perform surgeries at Jackson Memorial Hospital. In turn, Jackson Memorial Hospital then passed those inflated costs on to Medicare and used those Medicare dollars to remit payment back to UM.

Along with the settlement secured by DOJ, UM also agreed to enter into a five-year Corporate Integrity Agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services (OIG-HHS).[4] The CIA applies to the University of Miami Health System (UHealth) and all of its facilities, clinics, and clinical locations. While UHealth represented to the government that it has an established compliance program—including a compliance officer, written policies and procedures, education and training programs, and a disclosure program, the publicly available CIA obligates UHealth to:

- Hire and maintain a **Compliance Officer** for the duration of the CIA;
- Create a **Compliance Committee** that includes the Compliance Officer and members of senior management;
- Establish compliance **obligations of the UHealth board of directors**, including quarterly meetings to oversee the compliance program, reporting obligations to OIG-HHS, and the requirement to retain a "compliance expert" to perform a few of the compliance program's effectiveness efforts;
- **Certify obligations** of certain UHealth senior management;
- **Maintain written standards**, including incorporation of compliance with policies and procedures as an element of employee performance; and
- **Provide training and education**, including board training, provision of training records to OIG-HHS, and computer-based training.

Both the settlement and the associated CIA emphasize the significant exposure that health systems face for non-compliance with the notice requirements for off-campus billing of Medicare patients. Providers should remain cautious to avoid violations of the provider-based rule that could trigger FCA liability for services rendered and billed from non-compliant provider-based locations.

If you have additional questions or need further assistance, please reach out to **Amandeep Sidhu** (Partner, White Collar, Regulatory Defense & Investigations), **T. Reed Stephens** (Partner, White Collar, Regulatory Defense & Investigations), **Chris Parker** (Associate, White Collar, Regulatory Defense & Investigations) or your Winston & Strawn relationship attorney.

View all of our Government Program Fraud, FCA, & *Qui Tam* Litigation Playbook perspectives **here**.

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[1] *See* DOJ Press Release, "University of Miami to Pay $22 Million to Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices" (May 10, 2021), *available at* https://www.justice.gov/opa/pr/university-miami-pay-22-million-settle-claims-involving-medically-unnecessary-laboratory (last visited June 6, 2021).

[2] *United States ex rel. Jonathan Lord, M.D. v. University of Miami*, Civ. No. 13-22500 (S.D. Fla.); *United States ex rel. Philip Chen, M.D. and Joshua Yelen v. University of Miami and Miami-Dade Public Health Trust*, Civ. No. 13-24320 (S.D. Fla.); and *United States ex rel. Mitchell Wallace v. University of Miami and Miami-Dade Public Health Trust*, Civ. No. 14-21206 (S.D. Fla.).

[3] *See* 42 C.F.R. § 413.65(g)(7)(i) (Requirements for a determination that a facility or an organization has provider-based status).

[4] *See* University of Miami's Corporate Integrity Agreement (April 9, 2021), *available at* https://oig.hhs.gov/fraud/cia/agreements/University_of_Miami_05072021.pdf (last visited June 6, 2021).

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