

Report on Medicare Compliance Volume 32, Number 36. October 09, 2023 GHI Pays \$32.5M to Settle FCA Case; Gaming of 14-Day Rule Alleged

By Nina Youngstrom

In a case about Medicare's rule on billing for certain lab tests within 14 days of a patient's discharge from the hospital, Genomic Health Inc. (GHI) has agreed to pay \$32.5 million to settle false claims allegations, the U.S. Department of Justice (DOJ) said Oct. 2.^[1] The test in question here—Oncotype DX—is a proprietary genetic test used to diagnose and treat breast, prostate and colon cancer patients.

The case, which was set in motion by two separate whistleblower lawsuits, centers on CMS's rule on billing for tests performed by third-party laboratories when patients are in the hospital. The so-called 14-day rule stipulates that third-party labs must bill the hospital if the physician orders the test during the patient's stay or within 14 days of discharge. After that, Medicare will pay separately for tests. "When a hospital must reimburse a third-party laboratory for a test ordered less than 14 days from discharge, that reimbursement has the effect of diminishing the value of the fixed DRG payment the hospital received for that patient," according to the 2016 whistleblower complaint filed by Samuel Caughron, M.D., who was laboratory medical director of Shawnee Mission Medical Center in Kansas and director of the Molecular Lab at MAWD Pathology Group in Missouri at the time the complaint was filed.^[2]

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