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### Exagen Settles FCA Case for Restitution, Paid Physicians Specimen Fees Despite OIG Alert

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By Nina Youngstrom

In the second recent False Claims Act (FCA) case that ended with restitution, Exagen Inc.—a life sciences company that makes diagnostic tests for autoimmune conditions—agreed to pay \$653,143 to settle allegations it gave kickbacks to referring physicians in the form of specimen processing fees, the U.S. Attorney’s Office for the District of Massachusetts said Oct. 17.<sup>[1]</sup>

“It’s unusual in my experience that there is a dollar-for-dollar payback in addition” to a release from the relator’s FCA claims and the government’s common-law theories of payment by mistake, unjust enrichment and fraud, said former federal prosecutor Robert Trusiak. With restitution as opposed to double or triple damages, the company gets a tax benefit, said Trusiak, with Trusiak Law in Buffalo, New York.

According to the settlement, many physicians and medical groups ordered Exagen lab tests to help diagnose autoimmune conditions. Exagen paid some referring physicians to do blood draws for patients under specimen processing agreements (SPAs) between June 25, 2014, and June 21, 2021.<sup>[2]</sup> Exagen billed Medicare for tests it performed after receiving orders from the referring physicians who were paid specimen processing fees under the SPAs.

The HHS Office of Inspector General (OIG) on June 25, 2014, released the Special Fraud Alert on Laboratory Payments to Referring Physicians, which “indicated that these arrangements could present a substantial risk of fraud and abuse under the Anti-Kickback Statute [AKS].”<sup>[3]</sup> Exagen ended its physician referral arrangements by June 21, 2021, and doesn’t have these types of agreements with referring physicians anymore, according to the settlement.

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