

Report on Medicare Compliance Volume 32, Number 36. October 09, 2023 Gift Cards Are at Heart of FCA Settlement for \$13.75M; OIG Approved Similar Arrangement

By Nina Youngstrom

Exact Sciences Corp. (ESC) and its subsidiary, Exact Sciences Laboratories LLC (ESL), which administers Cologuard, a colon cancer screening test, agreed to pay \$13.75 million to settle false claims allegations that certain patient gift cards were kickbacks.^[1] The settlement came down seven months after the HHS Office of Inspector General (OIG) posted a favorable advisory opinion about the same kind of arrangement.^[2]

The False Claims Act (FCA) lawsuit was filed by a patient turned whistleblower. According to the settlement with the U.S. Department of Justice (DOJ), the whistleblower alleged that Exact Sciences offered some patients who had been prescribed Cologuard prepaid Visa gift cards or Super Certificates to return a stool sample and complete the test in violation of the Anti-Kickback Statute (AKS) from April 1, 2015, to Oct. 31, 2020. The gift cards and Super Certificates were worth between \$10 and \$75, and Exact Sciences billed Medicare and TRICARE for the Cologuard tests.

“It sends a strong message that you can’t use cash or cash equivalents to buy government business,” said attorney Marlan Wilbanks, who represents the whistleblower.

But OIG’s advisory opinion makes it hard to draw conclusions about the case, said attorney Ramy Fayed, with Dentons US LLP in Washington, D.C. “It’s a very interesting and perplexing situation,” he said. “It’s hard to tell exactly what happened that would lead to the confluence of a favorable advisory opinion and a multimillion-dollar settlement for arguably what appears to be the same conduct.” Fayed noted that it’s conceivable the safeguards described in the advisory opinion weren’t in place at the time the whistleblower alleged the company was paying kickbacks. (It came out during litigation that Exact Sciences requested the advisory opinion, Wilbanks said.)

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