MINTZ

OIG Updates Its COVID-19-Related FAQ Guidance to Okay Certain Specimen Processing Payments by Laboratories

May 12, 2020 | Blog | By **Samantha P. Kingsbury**

VIEWPOINT TOPICS

- Health Care Enforcement & Investigations
- Health Care Compliance, Fraud & Abuse, and Regulatory Counseling
- Health Care
- COVID-19

RELATED PRACTICES

- Health Care Enforcement & Investigations
- Health Care Compliance, Fraud & Abuse, and Regulatory Counseling

RELATED INDUSTRIES

- Health Care

A few weeks ago, we **posted about** a publication by the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) of responses to certain **frequently asked questions (FAQs)** received from the health care community regarding regulatory flexibility for providers that needed it to adequately respond to COVID-19 concerns. This flexibility specifically relates to the OIG's administrative enforcement authorities, including the federal Anti-Kickback Statute (AKS) and Civil Monetary Penalties Law prohibiting beneficiary inducement (Beneficiary Inducement CMPL).

While the OIG periodically updates these FAQs (and so we encourage readers to check **this site** frequently), the OIG posted an update this past week that we found to be notable in light of the OIG's previous guidance to the contrary. This FAQ relates to an arrangement where a retail pharmacy operating a COVID-19 testing collection site incurs costs related to running these sites, including costs for "processing and sending the specimens" to the laboratory for testing (among others). The testing laboratory would pay the pharmacy a fair market value (FMV) fee for these costs. Laboratories often refer to payments for such services as "processing and handling fees."

The OIG observed that this arrangement would implicate the AKS because the laboratory would be paying remuneration to a referral source. However, the agency ultimately concluded that the arrangement, in the context of the COVID-19 public health emergency, would be sufficiently low-risk under the following conditions: (i) the pharmacy incurs costs in operating the testing collection sites; (ii) the payment is FMV for the items and services furnished by the pharmacy in running the sites; and (iii) the retail pharmacy is not submitting claims to federal health care programs or receiving other federal or state funding that would reimburse it in any way for the items and services for which it is "reimbursed by the laboratory."

What is remarkable about this response is that it is a significant departure from the OIG's **previous guidance**, which the OIG actually cites in its response and distinguishes based on the facts. Particularly notable is the OIG's characterization of the laboratory's payments to retail pharmacies – in the context of COVID-19 testing - for "processing and sending the specimens" as "reimburse[ment] by the laboratory" of the pharmacy for those costs, suggesting that these are costs that the *laboratory* properly bears. In contrast, in the OIG's non-COVID-19 guidance, the agency has argued that processing and handling costs are properly born *by test-ordering physicians* and thus are reimbursed through a bundled payment made to the physician under a specific Current Procedural Terminology code, making any such payments by the laboratories a duplicative payment that implicates the AKS.

As many of our readers know, a number of laboratories have been investigated and/or prosecuted by federal prosecutors for their historic (and, as a result of these investigations and prosecutions, now largely non-existent) payment of processing and handling fees to test-ordering providers. In defending those cases, many laboratories argued that their payment of these fees did not run afoul of the AKS at least in part because (i) the test-ordering providers incurred real costs in collecting, preparing, and sending specimens to the laboratory for testing; (ii) the payments were consistent with FMV; and (iii) the test-ordering providers agreed not to submit claims to federal health care programs for these specific services (i.e., there would be no double payments to the physicians). Whereas many laboratories found that these arguments were often not successful in defending these cases, the OIG now cites them as providing comfort that the arrangement is sufficiently low-risk from a fraud and abuse perspective.

Of course, we are mindful that the OIG's goal in this time of such uncertainty is to allow providers on the front lines of the COVID-19 pandemic sufficient flexibility (from an enforcement perspective) that they can focus on caring for patients – and that it is in this context that the OIG has issued this response (with all of the attendant caveats for these FAQs). Nevertheless, for laboratories who have defended cases involving allegations related to processing and handling fees (and their lawyers), this position by the OIG

will certainly come as a surprise.

Authors

Samantha P. Kingsbury, Of Counsel

Samantha advises clients on regulatory and enforcement matters. She has deep experience handling violations of the federal ant-kickback statute and FCA investigations for clinical laboratories and hospitals.

More Viewpoints

OIG Publishes FAQs Addressing Application of Its Administrative Enforcement Authorities During the COVID-19 Public Health Emergency

April 28, 2020 | Blog | By Samantha Kingsbury, Karen Lovitch

Read more