Published on *The National Law Review* https://natlawreview.com

COVID-19: Free Lodging, Free Testing, Free of OIG Enforcement?

Article By:

Kara Sweet

Rachel B. Goodman

Not necessarily. In the past two weeks, the Office of Inspector General (OIG), the Department of Health and Human Services (HHS) watchdog, released two new FAQs regarding the Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 ("COVID-19") Public Health Emergency. While these FAQs provide helpful guideposts to the community regarding enforcement risks, it is important to remember that these responses are "informal feedback" and are not binding on any federal agency. Notwithstanding, these and the other FAQs the OIG has issued since the outset of the COVID-19 related public health emergency (PHE) serve as an indicator for how the OIG is viewing arrangements during the PHE that may not otherwise pass muster and also serve, in some capacity, as an invitation for others to seek similar guidance when dealing with challenging arrangements that are in the best interest of patients, but not clearly permitted under current laws.

COVID-19 Inquiry Process Generally

To ensure health care providers' regulatory flexibility to respond to COVID-19 concerns, the OIG is accepting inquiries from the health care community regarding the application of OIG's administrative enforcement authorities, including the federal anti-kickback statute (AKS) and civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (Beneficiary Inducement CMP).

This approach is not entirely new for the agency—as the OIG has a specific advisory opinion process that providers traditionally have used when desiring specific OIG guidance related to the legality of a particular arrangement. Similar to the advisory opinion process, to obtain a response to a COVID-19 inquiry, providers must submit sufficient facts for the OIG to have a full understanding of the key parties and the terms of the arrangement at issue. Responses to COVID-19 inquires differ from advisory opinions which are legally binding on HHS and the requesting party or parties. FAQs in response to a COVID-19 inquiry are mere informal opinions, and according to the OIG, are not binding on HHS, the Department of Justice, or any other agency. Moreover, the COVID-19 FAQs apply only to arrangements in existence during the PHE.

Key Takeaway: While the OIG's FAQ process during COVID-19 can reduce risk related to certain

arrangements, it does not remove risk entirely and ceases to apply after the PHE ends.

Free or Discounted Lodging

On July 29, 2020, OIG advised that an oncology practice's provision of free or discounted lodging to certain financially needy federal health care program beneficiaries presents a low risk of fraud if eight (8) narrow conditions are met. These conditions include:

1. The patient resides at least 50 miles from the treatment site;

2. The patient is an established patient of the oncology practice who has already scheduled chemotherapy or radiation treatment prior to the offer of free or discounted lodging;

3. The patient's physician determines that the free or discounted lodging would facilitate access to care while the patient is receiving chemotherapy or radiation treatment;

4. The oncology practice reasonably believes that the patient would have qualified for free or discounted housing during treatment at a nonprofit lodging facility that is closed as a result of the PHE;

5. The remuneration is in-kind, such as a direct payment to a hotel or motel for the appropriate number of nights;

6. The hotel or motel is located in close proximity to the treatment site;

7. The oncology practice does not advertise the availability of free or discounted housing or otherwise use the availability of this remuneration for patient recruitment; and

8. The lodging is provided during the PHE.

Key Takeaway: If narrow requirements are satisfied, some of which are entirely outside of the control of a provider (e.g., that nonprofit lodging facilities in a provider's area are closed), there is some indication by the OIG that the provision of free or discounted lodging to financially needy federal health care program beneficiaries during the PHE poses a low risk of fraud and abuse under both AKS and the Beneficiary Inducement CMP. However, it remains unclear whether the OIG would view other arrangements similarly if, for instance, there is no nonprofit lodging facility in the area, or there is, but it is full.

Free COVID-19 Antibody Testing

Similarly, on August 4, 2020, OIG responded to a clinical laboratory inquiry concerning the provision of free COVID-19 antibody testing to patients. Typically, providing free laboratory testing to federal health care program beneficiaries implicates both the AKS and the Beneficiary Inducement CMP because the free test could be considered an inducement to the patient to select this provider for other federally reimbursable services. Notwithstanding the risk otherwise posed by such an offer, the OIG indicated in a FAQ response that it views the proposed arrangement as a positive public health initiative in that the provider will be able to identify additional potential convalescent plasma donors and share that data with the Centers for Disease Control and Prevention and other state public health agencies. Accordingly, the OIG has indicated that the proposed arrangement presents a low risk of

fraud and abuse as long as the laboratory follows five (5) safeguards, including:

1. The physicians ordering the laboratory tests, including the free COVID-19 antibody tests, would not receive any payments or anything else of value from the clinical laboratory in connection with the free antibody testing program;

2. The patients receiving the laboratory tests would not receive any payments or anything of value, other than the free COVID-19 antibody test, from the clinical laboratory in connection with the free antibody testing program;

3. The tests would be offered only to patients receiving other medically necessary blood tests as part of a medically necessary exam or treatment;

4. No payer, including the patient, a commercial insurance company, or a federal health care program, would be billed for or pay any costs in connection with the COVID-19 antibody tests; and

5. The antibody tests are cleared or approved by the U.S. Food and Drug Administration (FDA) or are subject to an FDA-issued Emergency Use Authorization.

Key Takeaway: There may be a low risk of enforcement under AKS and the Beneficiary Inducement CMP for laboratories that offer a free FDA-approved or cleared COVID-19 antibody test with another medically necessary blood test and follow the specified safeguards. However, there could be state laws that would also be implicated by the proposed arrangement, such as state kickback statutes, so providers and laboratories should proceed with caution.

Conclusion: The OIG FAQ inquiry process may be an effective option for providers who are creatively finding arrangements to best serve their patients, when those arrangements do not clearly fit within the boundaries of current laws. While OIG's opinions are not binding, they may further aid providers in rolling new innovative treatment arrangements for best serving patients.

National Law Review, Volume X, Number 223