

CLIENT ALERT

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THE OIG'S FAQs RELATED TO COVID-19

by Jeremy Belanger and Ralph Levy, Jr.

The Office of the Inspector General ("OIG") for the Department of Health and Human Services ("HHS") has developed a process for interested parties to obtain regulatory compliance guidance from the OIG prior to pursuing arrangements related to COVID-19. The OIG has dubbed this process *FAQs—Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*.¹ Parties looking to engage in conduct which could implicate the Federal Anti-kickback Statute² or the Civil Monetary Penalties Beneficiary Inducement provision ("Beneficiary Inducement CMP")³ can obtain guidance from the OIG on whether the proposed arrangement would pose a risk under either or both statutes by submitting a description of the proposed arrangement to the OIG via email: OIGComplianceSuggestions@oig.hhs.gov.

BACKGROUND

The Federal Anti-Kickback Statute prohibits the knowing and willful solicitation, receipt, offer, or payment of "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in return for referring a patient for any item or service paid for in whole or in part by a federal health care program (e.g., Medicare, Medicaid, Tricare, etc.).⁴ The Anti-Kickback Statute requires the "ill intent" to pay or receive remuneration in return for a referral; however, the Anti-Kickback Statute is violated if even one purpose of the remuneration was or is to induce a referral, even if there are other valid reasons, including medical necessity, for the referral.⁵

The Anti-Kickback Statute has certain statutory exceptions and regulatory exceptions, which are known as "safe harbors." An arrangement that meets the strict requirements of a regulatory safe harbor is automatically protected. However, because there has to be ill intent, failure to meet the requirements of a safe harbor does not make an arrangement illegal, but it does lose the automatic protection granted by the safe harbor.

The Beneficiary Inducement CMP prohibits the offer or transfer of remuneration to any person that receives Medicare or Medicaid when the person making the offer knows or should know the offer is likely to influence the patient to order or receive an item or service from a particular provider, practitioner, or supplier.⁶ Unlike the Anti-Kickback Statute, the Beneficiary Inducement CMP is a civil law, not a criminal one, so it does not require the "ill-intent" to pay or receive a kickback. However, the Beneficiary Inducement CMP requires "knowledge" that the offer or transfer of the remuneration would influence the beneficiary. Also, like the Anti-Kickback Statute, the Beneficiary Inducement CMP contains certain statutory and regulatory exceptions which, if met, would protect the arrangement. However, failure to meet an exception does not create liability if the offeror can show that it did not know and should not have known the offer would induce a beneficiary in making his or her choice.

Because both the Anti-Kickback Statute and the Beneficiary Inducement CMP require either intent or knowledge before they are violated, in the past interested parties could submit their proposed arrangement to the OIG for an "Advisory Opinion," which would evaluate it and determine whether the arrangement met a safe harbor or, if it did not, whether it posed a low risk under those statutes such that the OIG would not impose any penalties or sanctions, so long as the parties continued to adhere to the circumstances in the request for the Advisory Opinion.

Recognizing the cost and length of time it may take to obtain an Advisory Opinion and the need for regulatory flexibility and quick guidance, in light of the COVID-19 pandemic, the OIG has developed the FAQ process to offer timely compliance guidance. This process supplements the Advisory Opinion process by allowing parties to obtain guidance from the OIG; however, it does not supplant the Advisory Opinion process nor does it offer the protections of the Advisory Opinion process. The FAQ process offers only regulatory guidance; this guidance is not binding.

THE OIG FAQs

In order to submit a request for an arrangement related to COVID-19, a party needs to send an email to OIGComplianceSuggestions@oig.hhs.gov with sufficient information to permit OIG to know the identity of the parties, the key terms of the arrangement, and how it relates to COVID-19. Some of the more recent FAQs have discussed are: (1) provision of free COVID-19 antibody tests to beneficiaries receiving other services; (2) paying a pharmacy a fee for operating a COVID-19 test collection site; and (3) providing free transportation to and from an office for patients when the patient's usual office is closed. It is important to note that not all arrangements have to be directly related to COVID-19 services or treatments. Questions concerning new arrangements related to COVID-19, such as free transportation for patients due to closures or loss of income, would also be considered. Because this is a voluntary process on behalf of OIG, there is no guarantee OIG will respond to a specific request or when an answer will be given.

This FAQ process has several drawbacks. First, the informal guidance provided is not binding on the OIG, HHS, or any other agency. Second, OIG will not provide an opinion as to whether the conduct complies with any other federal, state, or local statute, rule, regulation, ordinance, or other law, including the False Claims Act or the Stark Law, or rules related to billing, claims submission, cost reporting, or related conduct. Finally, the informal guidance will only be in effect during the term of public health declaration of an emergency by the Secretary of HHS. Any favorable opinion given would end once the declaration is lifted.

The OIG FAQs will be a useful tool as providers continue to assess and respond to the COVID-19 pandemic. However, even with this guidance, the best protection for health care providers will be to work with experienced and responsible counsel to assess the legal compliance of their arrangements. Dickinson Wright PLLC's health care attorneys are uniquely prepared to advise and counsel health care providers on their health care arrangements.

ABOUT THE AUTHORS



Jeremy Belanger is an Associate in Dickinson Wright's Troy office. He can be reached at 248.433.7542 or jbelanger@dickinsonwright.com.



Ralph Levy, Jr. is Of Counsel in Dickinson Wright's Nashville office. He can be reached at 615.620.1733 or rlevy@dickinsonwright.com.

1. <https://oig.hhs.gov/coronavirus/authorities-faq.asp> (last visited August 17, 2020).
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. § 1320a-7a(a)(5).
4. 42 U.S.C. § 1320a-7b(b).
5. See *United States v. Greber*, 760 F.2d 68, 72 (3d Cir.1985).
6. 42 U.S.C. § 1320a-7a(a)(5).