

OIG Offers an Alternative to Advisory Opinions for Emergency Arrangements During the Public Health Emergency

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May 2020

In an effort to ensure that health care providers have the regulatory flexibility they need to adequately respond to COVID-19 concerns during the current public health emergency, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has begun accepting inquiries regarding how it would apply its administrative enforcement authorities to arrangements that are directly connected to the COVID-19 public health emergency. In particular, OIG is accepting inquiries related to arrangements that implicate the federal anti-kickback statute¹ and the civil monetary penalty provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP).² OIG may publish responses to the questions it receives on a new FAQ site.³

Historically, OIG has offered guidance on the application of its administrative enforcement authorities to specific arrangements exclusively through the advisory opinion process. Although the advisory opinion process remains available to interested parties, requesting an advisory opinion can be a time-consuming process that may not be well-suited to address the emergent and pressing issues some providers are facing during the public health emergency. Consequently, and in furtherance of its mission to promote “economy, efficiency, and effectiveness in HHS programs,” health care providers and individuals can now request guidance regarding the application of OIG’s administrative enforcement authorities by submitting questions to OIGComplianceSuggestions@oig.hhs.gov.

While both advisory opinions and the FAQ site address the application of OIG’s enforcement authorities to specific arrangements, the responses OIG posts on the FAQ

¹ 42 U.S.C. § 1320a-7b(b).

² 42 U.S.C. § 1320a-7a(a)(5).

³ See <https://oig.hhs.gov/coronavirus/authorities-faq.asp>. OIG states that “[t]he receipt of a question does not obligate OIG to take action, including responding to the question, making questions public, or issuing public guidance.”

site differ from advisory opinions in several important ways. Most significantly, the feedback OIG provides on the FAQ site is informal; as such, it is not binding on HHS, the U.S. Department of Justice, or any other agency, nor does it provide prospective immunity or protection from OIG administrative sanctions or under federal criminal law. OIG expresses no opinion with respect to any other federal or state law in its FAQ site responses, including the physician self-referral law⁴ (a/k/a the Stark Law), or the Eliminating Kickbacks in Recovery Act (EKRA).⁵ In addition, the feedback applies only to arrangements in place during the COVID-19 public health emergency. Despite these drawbacks, submitting a question using the FAQ site has several advantages, including the relative speed with which OIG has been issuing responses, as well as the fact that the FAQ site does not require requestors to certify as to the facts they present and permits anonymous submissions.

While individuals and entities cannot rely upon the responses that OIG posts on the FAQ site to provide them with prospective immunity or protection from OIG administrative sanctions with respect to their own arrangements, they can look to the various safeguards OIG cites in its FAQ site responses for guidance. As of the date of publication of this Client Alert, the FAQ site had last been updated on May 1, 2020. As of May 1, 2020, OIG had evaluated several arrangements under which entities had proposed to provide remuneration to federal health care program beneficiaries. Safeguards to which OIG cited when concluding that such arrangements would pose a low risk of fraud and abuse under the federal anti-kickback statute and the Beneficiary Inducements CMP included:

- The remuneration is necessary as a result of COVID-19 outbreak and is provided only during the period of the public health emergency;
- The beneficiary receiving the remuneration is financially needy;
- The remuneration is in-kind and is necessary to access medically necessary services;
- The entity providing the remuneration does not advertise the arrangement and provides the remuneration only to established patients; and
- The entity providing the remuneration does not determine a beneficiary's eligibility for assistance in a manner related to the volume or value of federal health care program business.

OIG also evaluated several arrangements pursuant to which an entity would provide remuneration to an actual or potential referral source. Safeguards to which OIG cited when concluding that such arrangements would pose a low risk of fraud and abuse under the federal anti-kickback statute included:

- The remuneration is necessary to meet patient care needs as a result of the COVID-19 outbreak and is provided only during the period of the public health emergency;
- The remuneration is used only to provide medically necessary services;

⁴ 42 U.S.C. §1395nn.

⁵ 18 U.S.C. § 220 (applying to recovery homes, clinical treatment facilities and laboratories).

- The parties documented the arrangement in a written agreement that describes the arrangement's material terms;
- The remuneration is not conditioned on the volume or value of federal health care program business, either during or after the period of the public health emergency;
- The remuneration is offered to eligible providers on an equal basis; and
- The arrangement does not require the person or entity receiving the remuneration to refer patients to a particular individual or entity or restrict the receiving person or entity's referrals.

Individuals and entities that wish to provide or receive remuneration to enable health care providers to adequately respond to patient needs during the COVID-19 public health emergency should consider incorporating the above safeguards into their own arrangements, when feasible and appropriate.

As mentioned above, parties that include some or all of the above safeguards in their arrangements are not guaranteed prospective immunity or protection from OIG administrative sanctions or penalties under federal criminal law. Nevertheless, the anti-kickback statute is an intent-based, criminal statute, and the Beneficiary Inducements CMP has a knowledge standard that requires that the person offering the remuneration "knows or should know" that the remuneration is likely to influence the beneficiary to order or receive items or services from a particular provider. Consequently, absent evidence to the contrary, parties that structure their arrangements consistent with the safeguards upon which OIG has relied in its FAQ site responses would be unlikely to be found to have had the requisite intent to violate the anti-kickback statute or the Beneficiary Inducements CMP. Finally, it is worth noting that OIG's evaluation and analysis of arrangements described on the FAQ site are valid only during the COVID-19 public health emergency, and OIG cautions that "given the unique circumstances surrounding the public health emergency, OIG may take a different position on arrangements that are the same or similar in nature that existed before the effective date of the COVID-19 Declaration or after the time such COVID-19 Declaration ends."

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This Client Alert was authored by [Melissa L. Jampol](#) and [Jennifer E. Michael](#). For additional information about the issues discussed in this Client Alert or if you have any questions or concerns, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.

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