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OIG Initiatives to Ease Provider Burdens Related to COVID-19

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The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has taken numerous steps to minimize regulatory burdens for providers who need to make their primary focus delivering patient care during the COVID-19 national emergency. These steps, along with recent steps taken by other agencies to provide temporary regulatory flexibility, provide further welcomed relief to providers who are facing a tremendous burden during this time.

1. AKS Administrative Sanctions Not Imposed for Remuneration Covered by Stark Blanket Waivers related to "COVID-19 Purposes"

As we wrote about in our prior blog post, on March 30, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued 18 blanket waivers of sanctions under the federal physician self-referral law (or "Stark Law") for remuneration and referrals related to "COVID-19 Purposes" (the "Stark Blanket Waivers"). Then, on April 3, 2020, the OIG issued a Policy Statement notifying interested parties that it "will exercise its enforcement discretion not to impose administrative sanctions under the Federal anti-kickback statute [("AKS")] for certain remuneration related to COVID-19" that is covered by certain of the Stark Blanket Waivers.

As the OIG explained in this Policy Statement, ordinarily, some financial relationships that implicate the Stark Law may also implicate, and may potentially violate, the AKS. In the Policy Statement, the OIG stated that it will not impose sanctions with respect to remuneration covered by the first 11 of the Stark Blanket Waivers, provided that all of the conditions and definitions within the Stark Blanket Waivers are met. This includes certain remuneration to or from a physician that is above or below fair market value and remuneration to a physician in the form of medical staff incidental benefits or non-monetary compensation that exceeds the limits set forth in applicable Stark exceptions (when specified requirements are met).

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Note that the remainder of the 18 Stark Blanket Waivers relates to referrals rather than remuneration. In the Policy Statement, the OIG specified that parties can submit questions via email to OIGComplianceSuggestions@oig.hhs.gov related to the application of the OIG's administrative sanctions for remuneration associated with referrals described in items 12-17 of the Stark Blanket Waivers. (The OIG did not mention the 18th Stark Blanket Waiver, which relates to compensation arrangements that do not satisfy the writing or signature requirements of an applicable Stark exception, even though various AKS safe harbors also have writing and signature requirements. Presumably, parties can also submit questions to OIG about such arrangements, although many such arrangements may not implicate the AKS based on a facts and circumstances analysis outside of safe harbor protection.)

The OIG stated that its purpose in issuing the Policy Statement was to avoid the need for parties to undertake a separate legal review under the AKS for arrangements that are covered by the Stark Blanket Waivers. The OIG cautioned, however, that the Policy Statement does not have any bearing on arrangements that are not covered by the Stark Blanket Waivers. This would include, for example, arrangements between a manufacturer and a physician, and arrangements that do not involve a physician (or immediate family member of a physician).

The Policy Statement applies to conduct occurring on or after April 3, 2020, whereas the Stark Blanket Waivers were retroactive to March 1, 2020. The Policy Statement terminates the same day that the Stark Blanket Waivers terminate (i.e., the end of the Public Health Emergency ("PHE") that was declared related to COVID-19).

2. Other Recent OIG Initiatives

In addition to the Policy Statement described above, the OIG has undertaken other notable initiatives lately related to COVID-19. Specifically:

- The OIG issued a "Message from leadership on minimizing burdens on providers" on March 30, 2020, in which it stated: "For any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when

assessing whether to proceed with any enforcement action."

- On April 3, 2020, the OIG posted a FAQ website about the application of OIG's administrative enforcement authorities (specifically, the AKS and beneficiary inducements civil monetary penalty) to arrangements connected to the COVID-19 PHE.
  - This website sets forth instructions for submitting questions and limitations on the FAQs, including how this informal feedback during the unique circumstances of the PHE differs from the legally binding OIG advisory opinion process (which remains available to interested parties).
  - Thus far, the FAQ website has one FAQ posted, in which the OIG responded to a question about whether health care providers/practitioners can furnish services for free or at a reduced rate to assist long-term care providers facing staffing shortages. The OIG stated: "In the unique circumstances resulting from the COVID-19 outbreak, we believe that these scenarios likely would present a low risk of fraud and abuse under the Federal anti-kickback statute and the Beneficiary Inducements CMP provided the services being offered are (i) necessary to meet patient care needs as a result of staffing shortages directly connected to the COVID-19 outbreak; (ii) provided for free or at a reduced cost only when necessary as a result of the COVID-19 outbreak; (iii) limited to the period subject to the COVID-19 Declaration; and (iv) not contingent on referrals for any items or services that may be reimbursable in whole or in part by a Federal health care program, either during or after the COVID-19 Declaration period."

- The OIG has a "COVID-19 Portal" website, which includes a link for submitting questions regarding OIG's authorities during the COVID-19 PHE, as well as links for information about other news and resources regarding OIG's COVID-19 initiatives.
- On April 3, 2020, the OIG published a report based on brief phone interviews (or "pulse surveys") that it conducted from March 23 to March 27, 2020 from a random sample of 323 hospitals across the country on challenges the hospitals are facing in responding to COVID-19, strategies used to address those challenges, and how the government can provide support. A summary of the report can be found here, and the complete report can be found here.

Finally, while not related to easing provider burdens during the COVID-19 PHE, we note that on March 23, 2020, the OIG alerted the public about new fraud schemes related to COVID-19. In addition, a number of recently added OIG work plan items relate to COVID-19 response matters.

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For assistance in determining whether an existing or proposed arrangement meets the criteria for waiving AKS administrative sanctions under the OIG Policy Statement described herein, or for any other questions regarding recent OIG initiatives related to COVID-19, please contact the authors or your regular Dorsey & Whitney LLP attorney. Dorsey is closely monitoring the rapidly evolving legal landscape related to the COVID-19 pandemic. You can access Dorsey's health law blog related to health law updates, available here. You can also access Dorsey's coronavirus resource center, which contains a wide variety of legal resources related to the coronavirus outbreak, available here.