Health Industry Alert

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OIG Approves Manufacturer Loaning Smartphones as Appropriate Patient Assistance to Support Digital Medicine

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On January 29, the Health and Human Service Office of Inspector General (OIG) released new guidance that sheds further light on the types of patient assistance that may be provided under the "Promotes Access to Care" exception to the beneficiary inducements civil monetary penalties (CMP) statute and the anti-kickback statute (AKS). In Advisory Opinion 19-02, the OIG found acceptable a pharmaceutical company's loan of a smartphone to low-income patients when used to support an innovative digital medicine therapy. This favorable opinion demonstrates a willingness of the OIG to provide greater flexibility to those companies seeking to support low-income patients with technologies that promote patient care and coordination, a goal that the administration recently expressed in its Request for Information on the AKS and the beneficiary inducements CMP published in August 2018. However, program safeguards designed to reduce the value of the technology outside of the support to be provided to eligible patients remain an important component of reduced compliance risk. Of note in Advisory Opinion 19-02:

- The smartphone would be very limited in its functionality (i.e., it would be intended to support only the digital medicine platform and would not have a camera, web browser or the ability to download apps).
- The smartphone would include a voice and data plan to enable patient support and data flow to their physicians.
- There would be a time limitation on the loan of the smartphone: no more than two 12-week terms.

The Advisory Opinion also provides helpful context for drug and device companies considering patient assistance programs. It clarifies how and when the OIG will apply the beneficiary inducements CMP to these entities, and it reiterates that when conducting its AKS analysis, the OIG will consider compliance with exceptions to the beneficiary inducements CMP. This lines up with previous OIG advisory opinions.[1]

A more detailed analysis of the Advisory Opinion and the OIG's "Promotes Access to Care" analytical framework can be found below.

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The Proposed Arrangement

The requestor is a pharmaceutical manufacturer that makes a product approved by the Food and Drug Administration and used in the treatment of patients with mental illness.[2] The OIG noted that medication nonadherence and partial adherence are a particular problem for the drug's patient population and that a lack of adherence to medication results in higher health care utilization and increased costs to the health care system. The product is a combined drug/ingestion sensor that monitors a patient's utilization of the drug by sending a signal to the patient's smartphone via an app. Patients also have the ability to add more information to the app (e.g., quality of rest and mood). With the patient's consent, the patient's physicians and caregivers can access this information through web-based portals. Use of the product requires a smartphone capable of running the app.

Under the proposed arrangement, the requestor would lend a refurbished, older-model iPhone or compatible Android device to patients who meet the following criteria:

- Possession of a prescription for the product for on-label use.
- Meeting any applicable prior authorization required by the patient's health insurance coverage.
- Having an annual income below a specific percentage of the federal poverty level.
- Not already possessing a device capable of running the app.
- Being a United States citizen or legal permanent resident.

The requestor would not advertise the proposed arrangement to patients; health care providers would screen potential applicants, based on guidance from the requestor. The OIG noted that the proposed arrangement would be available through only a specific specialty pharmacy, as would the product during an initial rollout period.

As noted above, the smartphone would have very limited capabilities. The loaner device would come preloaded with only the product app, the ability to make domestic telephone calls, and a voice and data plan to enable these functions. All other features would be disabled on the device, and the patient would be unable to download or use any other applications. Additionally, the requestor intends to loan the device for a limited period. Patients would have access to the device for only the duration of their therapy, which the requestor expects to last for 8 to 12 weeks. Patients would be eligible for one additional 12-week period with approval from their health care provider. If a patient does not return the device (or if the device is lost or stolen), the requestor would remotely disable it.

The OIG's Analysis of the Proposed Arrangement

The OIG analyzed the proposed arrangement under the beneficiary inducements CMP and the AKS. The OIG found that the smartphone would have independent value to the patient and was therefore remuneration that could implicate both the beneficiary inducements CMP and the AKS. However, under the CMP, the OIG found that, although loaning such a device could entail liability under the statute, the program contained sufficient safeguards to allow it to fit within the "Promotes Access to Care exception." Although compliance with an exception to the beneficiary inducements

CMP alone does not guarantee that the arrangement will be protected from prosecution under the AKS, the OIG concluded that "the same analysis would apply" under both statutes and that, in light of the safeguards set forth in the program, it would not subject the requestor to administrative sanctions under the AKS in connection with the proposed arrangement.

CMP Analysis. Analysis under the beneficiary inducements CMP requires the OIG to evaluate whether certain remuneration would cause a beneficiary to use a particular "provider, practitioner, or supplier" under the statute. Because manufacturers and drugs do not fall within the definition of a "provider, practitioner, or supplier," the OIG's analysis is limited to whether the smartphone would cause a patient to select a *particular prescriber or pharmacy*. The OIG found that the proposed arrangement could influence a patient's choice of provider or pharmacy, especially given the role of the provider in enrolling the patient in the program and the fact that the program would be operated through a specific specialty pharmacy. Therefore, the proposed arrangement could entail liability under the beneficiary inducements CMP.

The OIG found, however, that the arrangement satisfied the "Promotes Access to Care" exception to the beneficiary inducements CMP, meeting each of the following elements:

> **Promotes access to care.** Under this element, the OIG examined whether the arrangement "improve[s] a beneficiary's ability to obtain items and services payable by Medicare or Medicaid." The arrangement easily cleared this test; individuals without a device capable of running the app could not properly use the functions of the new digital medicine product. Therefore, the OIG found that providing a loaner device would increase access to care.
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> **Low risk of harm to patients and federal health care programs.** The OIG looked particularly at the three criteria established in the regulations codifying the "Promotes Access to Care" exception: (1) whether the remuneration is unlikely to interfere with, or skew, clinical decision making; (2) whether the remuneration is unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) whether the remuneration raises patient safety or quality-of-care concerns.[3] Looking at these criteria, the OIG found that the proposed arrangement would pose a low risk of harm to patients and federal health care programs.
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> > **Clinical Decision Making:** The OIG found that the proposed arrangement would be unlikely to interfere with clinical decision making, due to both the limited value of the device and the limiting eligibility requirements.
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> > **Costs to Federal Health Care Programs and Beneficiaries:** The OIG also found that the proposed arrangement would not likely increase costs to federal health care programs or beneficiaries. The OIG stated that the added benefit of the digital medicine product, more so than the remuneration of the loaner device, was likely to drive utilization. The OIG also noted that various safeguards in the proposed program design reduced the likelihood that the program would drive unnecessary utilization. Specifically, the OIG pointed to the fact that the requestor would not advertise the arrangement to patients and would provide the device for only a limited period. The OIG also suggested that the limited functionality of the loaner device addressed its concerns regarding inappropriate

utilization, noting that its conclusion would likely be different if the device had "additional functionality (i.e., access to an Internet browser or a camera or the ability to add other apps) such that it could relieve a patient from the burden of purchasing a smartphone or paying for a smartphone contract."[4]

Patient Safety and Quality of Care Concerns: The OIG found that the proposed arrangement most likely increased patient safety and quality of care by enabling increased use of a product that tracks adherence and communicates back to the patient's physician.

AKS Analysis. The OIG noted that, although the requestor's liability under AKS applies directly to the impact of the proposed arrangement on patients' selection of the product—in contrast to the analysis under the beneficiary inducements CMP, which looked at impact on a patient's selection of a pharmacy or health care provider—they applied "the same analysis."[5] The OIG stated that, in light of the various safeguards discussed above (i.e. the temporary nature of the program, the limiting eligibility criteria and the lack of patient advertising), the OIG would not enforce sanctions under the AKS based on the proposed arrangement.

Implications for Industry

Advisory Opinion 19-02 is one of the first to discuss the new "Promotes Access to Care" exception to the beneficiary inducements CMP, and the first guidance on its application to the provision of technological devices as part of a patient assistance program.

The Advisory Opinion indicates a willingness by the OIG to use the exception to approve potentially problematic patient assistance programs where they include extensive safeguards and mitigating factors. Here, the OIG focused on (1) the limited functionality of the device provided; (2) the limited duration of the program; (3) the limiting eligibility criteria (including having a prescription for the product, lacking a compatible smartphone and having an income below a certain threshold); and (4) the lack of patient-facing advertising.

Note, however, that the OIG approved the arrangement despite the fact that it features the provision of a smartphone with the ability to make local calls. This demonstrates the willingness of the OIG to use the "Promotes Access to Care" exception to endorse arrangements that it might not approve under the exception for the provision of free or discounted items or services to individuals with financial need, based on the OIG's prior comments in regulatory guidance.[6]

The Advisory Opinion also provides clearer evidence of the OIG's approach to patient assistance programs operated by drug and device manufacturers. First, it clarifies how the OIG applies the beneficiary inducements CMP to these programs. The Advisory Opinion states that, although the issue under the CMP is whether a program is likely to influence a patient's choice of a particular health care provider or pharmacy, where remuneration is likely to have this influence, drug and device manufacturers could still face liability. The Advisory Opinion also underscores that the OIG will consider careful compliance with exceptions to the beneficiary inducements CMP when conducting its AKS analysis, specifically stating that "the same analysis applies" in both contexts.

[1] *See, e.g.*, Adv. Op. 17-01 (Mar. 3, 2017).

[2] In accordance with regulations governing the advisory opinion process, the OIG redacted the specific disorders treated by the drug. However, based on a citation included in the opinion, it appears the drug may be used to treat mental disorders, including schizophrenia.

[3] *See* 42 C.F.R. § 1003.110; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,390-98 (Dec. 7, 2016) (final rule).

[4] Ad. Op. 19-02, at 7-8 (Jan. 29, 2019).

[5] *Id. at 8.*

[6] *See, e.g.*, 81 Fed. Reg. at 88,404; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717, 59,728 (Oct. 3, 2014) (proposed rule).