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HHS OIG: Smartphone loaner to needy patients may not violate Anti-Kickback Statute

February 1, 2019

On Tuesday, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Advisory Opinion No. 19-02, advising that OIG would not pursue enforcement under the Anti-Kickback Statute (AKS) or the beneficiary inducement provision of the Civil Monetary Penalties Law (beneficiary inducement CMP) regarding a pharmaceutical manufacturer's proposal to loan a limited-function smartphone to financially needy patients to facilitate collection of drug-adherence data. Although OIG's guidance is limited to the narrow facts presented by this proposal, the advisory opinion shows the government engaging with new questions presented by the integration of technology and medicine, and by companies' increased involvement in patient management. Drug and device manufacturers and others considering how to incorporate technology into their products or how to engage more deeply with patients should take a careful look at this and future guidance from the government on the potential fraud and abuse implications of such initiatives.

Advisory Opinion No. 19-02 involves a "digital" version of an FDA-approved drug: a drug tablet embedded with an ingestible sensor (an ingestion event marker or IEM), a wearable patch, and a smartphone app. When the tablet is ingested, it gives off a signal that is detected by the patch, which in turn signals to the app that the drug has been ingested. Collection of these data – which reflect patient adherence to the drug regimen – requires a device capable of running the app. The pharmaceutical manufacturer requesting the OIG opinion proposed to loan a limited-function smartphone (loaner device) at no charge to financially needy patients who do not already own a compatible device.

OIG concluded that the arrangement would not violate either the AKS or the beneficiary inducement CMP. First, OIG determined that the arrangement satisfies an exception under the beneficiary inducement CMP for "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs." Second, OIG concluded that appropriate safeguards are in place to minimize the risk that the loaner device would constitute a kickback by influencing a beneficiary to select an item or service that is reimbursable by federal health care programs. OIG applied a similar analysis to each law, and the following factors weighed heavily in OIG's favorable conclusion.

- **The loaner device promotes access to care.** OIG concluded that the loaner device promotes a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. It reasoned that, without a device capable of running the adherence app, the patient is unable to access the full scope of benefits of the "digital" drug.
- **Only patients who meet certain conditions would be eligible to receive a loaner device.** To be eligible, patients must have been prescribed the digital drug for an on-label use, must have met any prior authorization or step audit requirements, must demonstrate financial need (i.e., an annual income below some unspecified percentage of the federal poverty level), and must not already own a device that can run the app.
- **The loaner device offers a limited benefit outside the purpose of promoting adherence.** The loaner device would be preloaded only with the adherence app and the functionality to make domestic phone calls, which is necessary for patients to access support for the digital drug system. OIG noted, however, that it likely would have reached a different conclusion if the smartphone "had additional functionality (e.g., 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."
- **The arrangement is unlikely to increase costs to federal health care programs or beneficiaries.** The availability of the loaner device is not advertised to patients. OIG noted that instead of advertising to patients, the manufacturer educates potential prescribers on how to screen potential applicants appropriately for eligibility. Because the arrangement is not advertised to patients, it is unlikely to create patient requests for a prescription for the digital drug.
- **Providers do not receive any additional reimbursement or financial benefit for prescribing the digital drug.** OIG noted that providers are not expected to be separately reimbursed for the services involved in onboarding the patient onto the digital drug. It also noted that the manufacturer does not provide any financial benefit to health care providers for prescribing it or helping patients participate in the proposed arrangement (we note that OIG did not analyze whether a provider could bill separately for monitoring information from the app that the patient might consent to share).
- **The loaner device is unlikely to skew a prescribing decision.** OIG reasoned that prescribers may select the drug based on its ability to transmit data, but they are unlikely to do so simply because certain patients may be loaned a limited-function smartphone.

Health care companies continue to explore integration of tracking, monitoring, and other digital functionality into their products, often with the stated purpose of engaging with patients or providers to improve adherence or clinical outcomes. Such initiatives may present new and unexplored fraud and abuse questions, and companies considering these initiatives should consider carefully the factors identified in Advisory Opinion No. 19-02 and any future guidance. In particular, consider that OIG analyzed the benefit to the patient under both the AKS and the beneficiary inducement CMP using the factors laid out in the "access to care" exception of the CMP statute, which may suggest that similar programs meeting the requirements of that exception would present lower risk under the AKS, at least as to any inducement to the patient (any risk of enforcement based on an inducement to a provider or other person would need to be analyzed separately).

If you have questions about the import of this advisory opinion, or if you are considering similar arrangements, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

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