



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



*[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]*

**Issued:** January 24, 2019

**Posted:** January 29, 2019

[Name and address redacted]

**Re: OIG Advisory Opinion No. 19-02**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's proposal to loan, on a temporary basis, a limited-functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## **I. FACTUAL BACKGROUND**

[Name redacted] (“Requestor”) is an affiliate of [name redacted], the global pharmaceutical manufacturer that developed [drug name redacted] (the “Drug”). The U.S. Food & Drug Administration (“FDA”) has approved the Drug for the treatment of multiple conditions, including [disorders redacted]. The Drug also is used as an adjunctive treatment for [disorder redacted]. According to Requestor, medication nonadherence or partial adherence is a problem in these patient populations due to factors associated with the [disorders redacted] for which they are being treated. Requestor noted that lack of adherence to medication results in higher utilization of health care services and increased costs to the health care system.<sup>1</sup>

The FDA recently approved a Digital Medicine (“DM”) version of the Drug, [drug redacted] (the “DM Drug”), which consists of a tablet of the Drug embedded with an ingestible sensor (an ingestion event marker or “IEM”). When a patient ingests the DM

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<sup>1</sup> As an example, Requestor cited to an article examining medication adherence among Medicaid beneficiaries with [disorder redacted], which states that “individuals who were considered nonadherent were two and one-half times more likely to be hospitalized than those who were adherent.” Todd Gilmer et al., Adherence to Treatment with Antipsychotic Medication and Health Care Costs Among Medicaid Beneficiaries with [disorder redacted], 161 AM. J. PSYCHIATRY 692, 694-95 (2004).

Drug, the IEM gives off a mild electrophysiological signal that is detected by a wearable sensor (a “Patch”) on the patient’s abdomen. The Patch records that the patient ingested the DM Drug and also records certain indicators of the patient’s rest patterns and activity. A third component to proper use of the DM Drug is an application (the “App”), which must be accessed through the patient’s smartphone. The information collected by the Patch is transmitted via a Bluetooth® connection to the App. Patients also have the ability to add more information to the App, such as how well they rested and their current mood. The information collected by the Patch and the App is then transmitted via a secure protocol<sup>2</sup> to a secure cloud-based server. With patient consent, the patient’s health care provider(s) and caregiver(s) can access this information through web-based portals.

To use the DM Drug effectively, the patient must possess a smartphone capable of running the App. Under the Proposed Arrangement, Requestor would loan a device with highly limited functionality (a “Loaner Device”) to patients who: (1) have a prescription for the DM Drug for on-label use; (2) meet any applicable prior-authorization or therapeutic-step-edit requirements required by the patient’s insurer; (3) have an annual income below a specific percentage of the Federal poverty level; (4) do not already possess a device capable of running the App; and (5) are United States citizens or legal permanent residents. Requestor would contract with a specialty pharmacy (the “Specialty Pharmacy”)<sup>3</sup> to verify patient eligibility, and the Specialty Pharmacy would provide the Loaner Device to eligible patients.

The Proposed Arrangement would not be advertised to patients. Instead, as part of Requestor’s provider education about the DM Drug, Requestor would give information to potential prescribers on how to screen potential applicants appropriately. Prescribers would complete the enrollment forms on behalf of patients. Requestor certified that the DM Drug is ingested orally, and it does not expect that prescribers would receive any additional

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<sup>2</sup> Requestor certified that the protocol is compliant with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations. We express no opinion regarding the protocol’s compliance with HIPAA and its implementing regulations.

<sup>3</sup> Requestor certified it would have no ownership interest in the Specialty Pharmacy. In addition, during the initial rollout period (approximately two years), the DM Drug would be distributed only through the Specialty Pharmacy so that Requestor can monitor how the DM Drug functions for patients, their caregivers, and their health care providers. After the initial rollout period, Requestor anticipates that the DM Drug would be available from a range of pharmacies, including both traditional and specialty pharmacies. Any Loaner Device still would be obtained through the Specialty Pharmacy, regardless of which pharmacy a patient uses to obtain the DM Drug.

reimbursement for prescribing the DM Drug as opposed to any other treatment. Requestor also stated that providers are not expected to be separately reimbursed for the services involved in onboarding the patient onto the DM Drug, nor would Requestor provide any financial benefit to health care providers for prescribing the DM Drug or helping patients participate in the Proposed Arrangement.

The Loaner Device would be a refurbished, older-model iPhone or compatible Android device<sup>4</sup> and charger. The Loaner Device would come preloaded only with the App and functionality to make domestic telephone calls. Requestor certified that all other features would be disabled, and the patient would be unable to download or use any other applications (including, but not limited to, text messaging applications, music applications, a camera, games, or an internet browser). Requestor certified that telephone capability is necessary for patients to access support for the DM Drug system. Requestor would maintain an umbrella voice and data plan for Loaner Devices.

Patients would use the Loaner Device for the duration of their DM Drug therapy, which Requestor projects would last for 8 to 12 weeks.<sup>5</sup> At the 11-week mark, Requestor would require reauthorization from the patient's health care provider for the patient to continue taking the DM Drug rather than switching to a different drug (such as a different oral drug, or a long-acting injectable drug). A patient would be eligible to keep the Loaner Device for no more than two 12-week periods. At the end of the second 12-week period, or earlier, if the patient is switched to a different drug, the Specialty Pharmacy would send a preaddressed mailer bag for return of the Loaner Device. If a patient does not return the Loaner Device (or if the Loaner Device is lost or stolen at any time), Requestor would remotely disable it.

## **II. LEGAL ANALYSIS**

### **A. Law**

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services

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<sup>4</sup> As of the time of publication of this advisory opinion, the App runs only on the iOS and Android platforms. The term "Loaner Device" includes any later-approved device that corresponds to the description herein with respect to its limited functionality.

<sup>5</sup> Requester certified that the DM Drug is intended to be a temporary intervention, typically for 8–12 weeks, until a patient's healthcare provider can assess if the patient should stop using the DM Drug and switch to a non-digital generic version of the Drug, a long-acting injectable medication, or other therapy.

reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.

Section 1128A(i)(6) of the Act defines “remuneration” for purposes of the Beneficiary Inducements CMP as including “transfers of items or services for free or for other than fair market value.” Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term “remuneration” does not apply to “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)” (the “Promotes Access to Care Exception”). We have interpreted this provision to apply to:

[i]tems or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to

Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by — (i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns[.]

42 C.F.R. § 1003.110 (2017) (defining “remuneration”).

## **B. Analysis**

The Proposed Arrangement would involve loaning limited-use smartphones to patients, including Federal health care program beneficiaries, to enable the patients to use the DM Drug’s features. Although the App alone would not necessarily have independent value, and most of the features of the smartphone would be disabled, the device would have the ability to make domestic telephone calls. Therefore, the Loaner Device would provide something of value to the patients receiving it and would be remuneration to the patient. Thus, we must examine the Proposed Arrangement under both the Beneficiary Inducements CMP and the anti-kickback statute.

### **1. The Beneficiary Inducements CMP**

Under the Beneficiary Inducements CMP, we must determine whether the remuneration would be likely to influence a Medicare or State health care program beneficiary to select a particular provider, practitioner, or supplier. Specifically, we analyze whether Requestor’s provision of a Loaner Device would be likely to influence a patient to select a particular prescriber or pharmacy.<sup>6</sup> Because a prescriber would complete the paperwork for a patient to obtain the Loaner Device, a patient reasonably could conclude that he or she must

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<sup>6</sup> We note that the Beneficiary Inducements CMP prohibits remuneration that is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier. Thus, we do not analyze whether the Loaner Device would influence a patient to select the DM Drug because the DM Drug is an item. In addition, we do not analyze whether the Proposed Arrangement would influence a beneficiary to select Requestor because the OIG does not consider drug manufacturers to be “providers, practitioners, or suppliers” for the purposes of the Beneficiary Inducements CMP, unless the drug manufacturer also owns or operates, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. See Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

continue receiving care from that provider to be able to continue using the Loaner Device. Likewise, a patient reasonably could believe that he or she must use the Specialty Pharmacy to obtain the DM Drug (even after the DM Drug becomes available from other pharmacies) if the patient uses a Loaner Device. As a result, we conclude that the Proposed Arrangement would implicate the Beneficiary Inducements CMP. However, for the following reasons, we conclude that the Proposed Arrangement would satisfy all of the criteria of the Promotes Access to Care Exception.

The first step in an analysis under the Promotes Access to Care Exception is to determine whether the remuneration would promote access to care, *i.e.*, whether it would improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. Here, the DM Drug requires certain items to detect the signal sent by its IEM. One of those necessary items is a device capable of running the App; without such a device, a patient cannot properly use the DM Drug's features. Therefore, the Loaner Device would improve a qualifying beneficiary's ability to access the full scope of benefits of the DM Drug, which is an item payable by Medicare and Medicaid.

The second step is to determine whether the remuneration would pose a low risk of harm by (i) being unlikely to interfere with clinical decision making, (ii) being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization, and (iii) not raising patient safety or quality-of-care concerns. We conclude that the Proposed Arrangement would satisfy these requirements.

The Proposed Arrangement would be unlikely to interfere with clinical decision making. While we think a prescriber might select the DM Drug for a patient based on its ability to transmit data, we do not believe the fact that a limited-use smartphone would be loaned to certain low-income patients who do not already have a compatible device would be likely to skew a prescribing decision. Moreover, only patients who meet certain conditions would be eligible for the Loaner Device. For example, any patient who already has a smartphone capable of running the App would be ineligible for the Proposed Arrangement, as would patients who exceed the financial-need criteria.

The Proposed Arrangement also would be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization. As noted above, the ability to collect and track data might be appealing to prescribers. However, we believe this added functionality, and not the fact that a limited-use smartphone would be loaned to certain low-income patients who do not already have a compatible device, likely would be the determining factor prescribers consider when deciding whether to order the DM Drug in lieu of a less expensive alternative. The Proposed Arrangement would not be advertised to patients, so patients would be unlikely to specifically request the DM Drug for the sake of obtaining a Loaner Device. Patients would not be permitted to keep the Loaner

Device for more than two 12-week periods, which is a safeguard against patients requesting to continue using the DM Drug for a longer term in an effort to retain the Loaner Device. We note that, 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, then our conclusion likely would be different.<sup>7</sup>

Finally, we do not believe that the Proposed Arrangement would pose patient safety or quality-of-care concerns. In fact, for those patients who qualify for the Loaner Device, the Proposed Arrangement could increase patient safety and quality of care by enabling the patient to use a drug that would track adherence and communicate that data back to the prescriber.

## 2. The Anti-kickback Statute

Under the anti-kickback statute, we must consider not only whether the remuneration might influence a beneficiary to select a particular provider, practitioner, or supplier, but also whether it could influence a person to select an item or service that is reimbursable by Federal health care programs. Although this additional risk is not discussed in the above analysis of the Promotes Access to Care Exception, the same analysis applies. Essentially, the Loaner Device would be integrally related to the DM Drug and would be available, on a temporary basis, only to those patients for whom their provider deemed the DM Drug necessary and who otherwise would not be able to use the DM Drug because they lack compatible technology. The Proposed Arrangement would not be advertised to patients, so patients would be unlikely to request the DM Drug for the sake of obtaining a Loaner Device. In light of the safeguards set forth above, we conclude that we would not subject Requestor to administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

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<sup>7</sup> According to the Pew Research Center, 95 percent of Americans have some sort of cellphone. See Mobile Fact Sheet (Feb. 5, 2018), <http://www.pewinternet.org/fact-sheet/mobile/>. The Loaner Device would be a smartphone in name only; the App would be the only functionality other than the telephone. For anyone who has a cellphone, or a smartphone that is not capable of running the App, the Loaner Device bestows no new benefit (and might require the patient to carry two devices). The primary benefit that extends beyond the App (i.e., the telephone capability) would run only to those few people who currently do not have any type of cellphone.



### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti  
Assistant Inspector General for Legal Affairs