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, unless otherwise approved by the requestor(s).*]

Issued: November 10, 2021

Posted: November 16, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-16

Dear [Name redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [name redacted] ("Requestor"), regarding Requestor's arrangement to provide up to a specified number of trial units of a long-acting antipsychotic drug to certain hospitals for inpatient use (the "Arrangement"). Specifically, you have inquired whether the Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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").

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information you provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Drug

Requestor manufacturers the drug [drug name redacted] (the "Drug"), which is a long-acting injectable ("LAI") atypical antipsychotic drug approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with [disorders redacted] (each, a "Disorder"). Requestor cited to various peer-reviewed articles that indicate that medication nonadherence is common for patients with either Disorder. Requestor explained that nonadherence leads to worse outcomes among patients with either Disorder, such as an exacerbation of symptoms, increased rates of hospitalization, and longer lengths of hospital stays, all of which could increase costs to the health care system.

According to Requestor, long-acting drug formulations, like the Drug, can provide uninterrupted medication coverage for up to 30 days at a time, which reduces incidences of nonadherence and thus reduces the risk of these negative outcomes. In support of its assertion, Requestor cited to peer-reviewed studies that analyzed claims data for Medicaid patients with [disorder redacted] who were treated with either LAIs or with daily oral antipsychotics. One study showed that, after being discharged from an inpatient stay, patients treated with an LAI had a significantly lower probability of rehospitalization at the 60-day post-discharge mark than patients treated with daily oral antipsychotics. Another study showed that patients treated with a second-generation LAI were much more likely to have persisted with their treatment at the 12-month post-discharge mark than patients treated with daily oral antipsychotics. Requestor also provided information about a study comparing hospitalization rates of patients who previously used an oral antipsychotic medication and then switched to the Drug. The hospitalization rates of the patients while using the daily oral antipsychotic medication were significantly higher at the 3- and 6-month marks prior to initiating treatment with the Drug compared to those same patients' hospitalization rates at the 3- and 6-month marks after initiating treatment with the Drug.

A health care professional administers the Drug by intramuscular injection in either an inpatient or outpatient setting. When administered in an inpatient setting, it generally is not separately reimbursable by a Federal health care program; for example, under Medicare Part A, the Drug treatment is included within the overall payment for the applicable Medicare Severity Diagnosis-Related Group ("MS-DRG") for the patient's stay.[2] When administered in the outpatient setting,

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[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] Generally, Federal health care programs reimburse for inpatient services on a prospective basis, but Requestor noted that some state Medicaid programs may pay on a per diem or a cost basis, and some facility types (e.g., critical access hospitals) are paid for inpatient services based on a percentage of reasonable costs.

the Drug generally would be covered by Medicare Part B[3] and subject to cost-sharing amounts. In conjunction with the initial injection, a patient also must take oral antipsychotic treatment for 14 days, but thereafter the patient does not need to take a daily medication to treat a Disorder, as long as the monthly injection of the Drug is administered.

B. The Arrangement

Under the Arrangement, Requestor permits hospitals that do not accept and dispense Prescription Drug Marketing Act of 1987[4] ("PDMA")-compliant samples in their facilities[5] to request up to a maximum number of units of the Drug free of charge to be dispensed to inpatients. Requestor makes hospitals aware of the Arrangement via field-based sales representatives or through Requestor-approved communications sent directly to hospitals; the Arrangement is not advertised in magazines, journals, digital ads, or other mass consumption forums.

To receive the free trial units of the Drug, a hospital must enroll in the Arrangement (a "Participating Hospital"). Requestor certified that a Participating Hospital's pharmacy director or pharmacy administrator typically enrolls the hospital. The Participating Hospital must agree to comply with the terms and conditions of participation, which require, among other things, that:

- hospital employees understand the FDA-approved indications for the Drug;
- prescribing decisions are in the best interest of the patient, and there is no obligation on the part of a Participating Hospital or prescriber to prescribe, use, continue using, or recommend the Drug as a condition of receiving a trial unit;[6]

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[3] The Drug also could be covered by Medicare Part D in certain situations when it is dispensed from a setting not covered by Medicare Part B.

[4] See 21 U.S.C. § 353.

[5] Requestor provides PDMA-compliant samples to physicians at hospitals that accept such samples and to physicians in the outpatient setting through a separate program. We have not been asked to opine, and we express no opinion, on that separate program. Also, Requestor certified that hospitals have various reasons for permitting programs like the Arrangement while refusing to permit PDMA sample programs. For example, PDMA-compliant samples may be given by a sales representative to a physician, which some hospitals believe presents health and safety concerns because the samples bypass the hospital's pharmacy. In addition, the physician may not have a comprehensive record of the prescription drugs the patient is taking, which can result in problematic drug interactions and complicate the consistent application of the treatment protocols the institution may wish to apply. According to Requestor, the Arrangement minimizes these risks because the free trial units of the Drug are dispensed through the hospital's pharmacy.

[6] According to Requestor, hospital bylaws and other systems generally require that prescribers make prescribing decisions in the best interest of the patient. Through this term of participation, Participating Hospitals agree that they will require that prescribers act in accordance with these professional standards, including making prescribing decisions in the best interest of the patient, and the Participating Hospital's understanding that neither the patient, the prescriber, nor the

- neither the Participating Hospital nor the administering practitioner bills any patient, insurer, or other third party for the free Drug or for any administration services in connection with the free Drug, and the free units may not be sold, resold, traded, or distributed for sale;
- the Participating Hospital does not accept PDMA-compliant samples, and the hospital will notify Requestor if that position changes;
- the Participating Hospital and its pharmacy must have the ability to track utilization of the Arrangement and the Drug by each patient and establish adequate controls to ensure that the Drug received under the Arrangement is appropriately segregated and tracked; and
- the Participating Hospital will conduct certain monitoring to detect irregularities, such as failure to comply with the terms and conditions of participation or to submit forms acknowledging receipt of the free trial Drug.

Participating Hospitals electronically complete and submit a request for trial units through a secure online portal. Login identifications are provided to Participating Hospital pharmacists after they have electronically signed to accept the program terms and conditions on behalf of the Participating Hospital. With each free trial unit order, the pharmacist must indicate the treating physician who requested the units. Each prescriber must already be affiliated with the Participating Hospital. The free trial units are sent directly to the pharmacy that dispenses products for a Participating Hospital's inpatient use. Upon receiving free trial units, the Participating Hospital must sign and return a shipment receipt and acknowledgement of contents to the program administrator.[7] When free trial units are sent to a Participating Hospital's designated pharmacy, the packaging includes a zero-dollar invoice that reiterates that no free units of the Drug may be sold, resold, traded, distributed for sale, or billed to any insurer or Federal health care program.

For a patient to be eligible to receive the free Drug, the patient must be diagnosed with a Disorder, and a prescriber must have ordered the Drug for the patient after independently determining that the Drug is clinically appropriate and that immediate onsite treatment increases the long-term likelihood of a positive treatment outcome. Participating Hospitals are eligible to receive up to two free units (each of which provides medication coverage for up to 30 days at a time) per eligible patient,[8] per calendar year. The Arrangement caps the amount of the Drug each Participating Hospital can receive at 60 units per year, per prescriber, with a maximum of 360 units per Participating Hospital, per year,[9] and the ordering system prevents a pharmacist from placing an

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Participating Hospital are under any obligation, at any time, to prescribe, use, continue using, or recommend the use of the Drug as a condition of receiving a trial unit.

[7] Requestor certified that an experienced third-party vendor administers the Arrangement.

[8] Any patient who has been prescribed the Drug for an FDA-approved indication as an inpatient is "eligible," as long as the per-patient and per-facility unit limits have not been reached and the patient remains an inpatient at the Participating Hospital.

[9] Specifically, each prescriber may receive 20 units per trimester or 60 units per year. A Participating Hospital can receive a maximum of 120 units per trimester or 360 units per year. This limit is based on 6 registered prescribers. If a Participating Hospital registers more than 6 prescribers, the limit remains 120 units per trimester or 360 units per year.

order that will result in any order beyond the Participating Hospital's limit. Requestor certified that, in 2019, 91 percent of Participating Hospitals received 50 or fewer units for the year.

If a Medicare beneficiary who received the free trial units as an inpatient continues to be prescribed the Drug after discharge, as noted above, the Drug generally would be covered by Medicare Part B or D, as appropriate, and subject to cost-sharing amounts. However, Requestor certified that patients are not obligated to continue using the Drug after discharge or upon conclusion of their eligibility to receive the free Drug. In addition, Requestor certified that there are no known clinical barriers to transitioning from the Drug to another LAI or oral antipsychotic medication.

II. LEGAL ANALYSIS

A. Law

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[10] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[11] For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care program.[12] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

At the outset, we note that providing drug samples is a widespread industry practice, and the PDMA governs their distribution. As we explained in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers:

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[10] Section 1128B(b) of the Act.

[11] Id.

[12] 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).

> [F]ailure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (e.g., a physician) and are used to treat [F]ederal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the Federal anti-kickback statute.[13]

The Arrangement is limited to hospitals that do not accept PDMA-compliant samples. We express no opinion regarding Requestor's potential liability under the PDMA or the False Claims Act; this opinion is limited to the OIG's administrative authorities relating to the Federal anti-kickback statute.

The Arrangement implicates the Federal anti-kickback statute because the free trial units are remuneration that Requestor offers and provides to hospitals, and hospitals are referral sources for the Drug. Specifically, hospitals could be direct referral sources for the Drug if the hospitals' employed physicians prescribe it for inpatients or outpatients. In addition, hospitals often establish formularies that limit or influence the drugs that physicians may administer or dispense to inpatients and thus are in a position to arrange for or recommend purchases of the Drug. Because there is no safe harbor available to protect the Arrangement, we evaluate all of the facts and circumstances of the Arrangement and assess risks such as overutilization, increased costs to Federal health care programs, corruption of medical decision-making, patient steering, and unfair competition. For the combination of the following reasons, we believe that the risk under the Federal anti-kickback statute is sufficiently low.

First, the risk of a Participating Hospital steering inpatients to the Drug based on receipt of the Drug for free under the Arrangement is low. We note that, according to an Agency for Healthcare Research and Quality "Statistical Brief," in 2016, inpatient stays with a principal diagnosis of [disorder redacted] had a mean length of stay of 10.5 days while inpatient stays with a principal diagnosis of [disorder redacted] had a mean length of stay of 7.6 days.[14] According to the Drug's labeling, for the first 14 days after the initial administration of the Drug, a patient must receive concurrent treatment with daily oral antipsychotics—which are not provided for free under the Arrangement. Therefore, in many circumstances, neither the Participating Hospital nor the prescribing physician would gain anything financially by prescribing or dispensing the Drug under the Arrangement (i.e., the Participating Hospital provides the Drug in addition to the daily oral antipsychotic, when the daily oral antipsychotic alone could be sufficient to stabilize the patient during his or her inpatient stay). Moreover, Requestor certified that there is no known clinical barrier to switching from the Drug to another LAI or daily oral antipsychotic medication, so the patient's receipt of the free Drug in the Participating Hospital does not mean that the patient must continue receiving the Drug after discharge, when it would be billed to both patients and payors.

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[13] OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,739 (May 5, 2003).

[14] Pamela L. Owens, Ph.D. et al., Inpatient Stays Involving Mental and Substance Use Disorders, 2016 (Mar. 2019), at 11, available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb249-Mental-Substance-Use-Disorder-Hospital-Stays-2016.pdf.

Second, we believe that the Arrangement presents a low risk of overutilization. Requestor certified that Participating Hospitals must agree to permit prescribers to make an independent decision as to whether the Drug is clinically appropriate and that immediate onsite treatment increases a patient's long-term likelihood of a positive treatment outcome. In addition, the Arrangement does not give prescribing physicians any incentive to prescribe the Drug to inpatients as opposed to a competing LAI or the daily oral alternative. While a physician would be able to benefit financially from prescribing the Drug on an outpatient basis where the Drug is a billable, physician-administered drug, that benefit could occur even absent the Arrangement. The Arrangement includes only free trial units to the Participating Hospital for treatment of eligible inpatients, not any units of the Drug administered in an outpatient setting. In the outpatient setting where the Drug and its administration can be billed, the usual cost-control features, including any beneficiary cost-sharing obligations, apply.

Third, the Arrangement is unlikely to increase costs to Federal health care programs inappropriately and could save program costs over time if the Drug successfully achieves the outcomes cited by Requestor. We recognize that the Drug generally is not separately billable during the inpatient stay, which means that for those beneficiaries whose inpatient stay exceeds the 14 days where the Participating Hospital must administer the daily oral antipsychotic medication, receiving the Drug for free gives the Participating Hospital a financial benefit in which Federal health care programs do not share. Further, we recognize that the Drug could be billed to Federal health care programs if the beneficiary continues receiving it after discharge. However, Requestor certified that, under the Arrangement, Participating Hospitals agree to give the free trial units of the Drug only to patients diagnosed with a Disorder for whom a physician determined that the Drug is clinically appropriate and increases the long-term likelihood of a positive treatment outcome. As noted above, Requestor indicated that the Drug's long-acting formulation reduces incidences of nonadherence and provided information about peer-reviewed studies showing that LAIs, like the Drug, reduce the risk of negative outcomes, such as hospitalizations. To the extent that treatment using LAIs, such as the Drug, could reduce incidences of nonadherence and the risk of negative outcomes, such as hospitalizations, aggregate costs to Federal health care programs and beneficiaries could decrease over time.

Fourth, the Arrangement includes a number of safeguards to minimize the risk that the free trial units will be misused. For example, the Participating Hospital must agree that the trial units cannot be sold, resold, traded, distributed for sale, or billed to any patient or payor. Participating Hospitals can receive only a limited number of trial units per year and per patient. By participating in the Arrangement, Participating Hospitals agree that (i) they will require that prescribers act in accordance with professional standards, including making prescribing decisions in the best interest of the patient; and (ii) understand that neither the patient, the prescriber, nor the Participating Hospital are under any obligation, at any time, to prescribe, use, continue using, or recommend the use of the Drug as a condition of receiving a trial unit. In addition, the Participating Hospital must indicate the treating physician who has requested each unit and must execute documentation upon receiving it.

For the combination of the foregoing reasons, we conclude that the Arrangement presents a sufficiently low risk under the Federal anti-kickback statute.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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 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.

- We express no opinion herein regarding the liability of any person 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 Requestor with respect to any action that is part of the 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 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 Requestor with respect to any action that is part of the 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