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: November 13, 2018

Posted: November 16, 2018

[Name and address redacted]

Re: OIG Advisory Opinion No. 18-14

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a drug company's proposal to provide free product to hospitals for the hospitals to use exclusively to treat inpatients who have been diagnosed with one particular condition (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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.

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 on the facts and information presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information that we detail in Section II.B.1. We have not undertaken an independent investigation of the facts and information presented to us by [company redacted], the requestor of this opinion. This opinion is limited to the facts presented to us by [company redacted] and other publicly available information that we include in Section II.B.1.

Based on the facts certified in your request for an advisory opinion, supplemental submissions, and other publicly available information, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on [company 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

This opinion may not be relied on by any persons other than [company 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

[Company redacted] ("Requestor") markets [drug redacted] (the "Drug").[1] Requestor certified that the Drug initially was approved by the U.S. Food & Drug Administration ("FDA") in 1952 and has been used for more than 60 years to help treat patients with serious and rare conditions. Currently, there are 19 FDA-approved indications for the Drug. The Drug is an injectable drug that is frequently self-administered (or administered by a caregiver) and is dispensed through a specialty pharmacy. In some cases, however, the Drug is administered to a patient during an inpatient hospital stay. Requestor certified that, in those instances, payment for the inpatient hospital stay would include payment for the Drug (as well as room charges, diagnostic testing, nursing services, etc.); the Drug is not separately reimbursable in the inpatient setting.

One of the FDA-approved indications for the Drug is treatment of [syndrome redacted] (the "Syndrome").[2] The Syndrome is a form of epilepsy that may occur through the end of the second year of life, and Requestor estimates that approximately 2,000–2,500 new cases are diagnosed each year in the United States. Requestor certified that patients typically are diagnosed with the Syndrome in an inpatient hospital setting because diagnosis involves extensive testing, such as an electroencephalogram of the electrical activity in the patient's brain or a magnetic resonance imaging scan. Requestor certified that patients with the Syndrome present with a distinct, but sometimes subtle, seizure

[1] [Company redacted] ("Company B") acquired the rights to the Drug from [company redacted] in 2001, and Requestor acquired Company B in 2014.

[2] Requestor certified that the Drug is listed in the American Academy of Neurology Guidelines as a first-line treatment for the Syndrome.

type, which can result in delays in diagnosis. Requestor cites to various studies that suggest improved long-term outcomes for patients who had a shorter lag time to treatment after the onset of symptoms (e.g., within one month of onset). Requestor further certified that medical literature indicates that patients with the Syndrome experience a steady decline in development and graver intellectual outcomes as the length of time from the onset of symptoms to treatment increases.

Requestor certified that the Syndrome currently can be treated with only two FDA-approved treatments: the Drug and another product manufactured by a different drug company. Typically, patients with the Syndrome who are being treated with the Drug receive twice-daily injections of the Drug for two weeks, and then dosing is gradually tapered and discontinued over a subsequent two-week period. Requestor noted that terminating Drug therapy prematurely can lead to clinical complications for the patient.[3]

Requestor stated that, in the inpatient hospital setting, treating the Syndrome with the Drug typically requires a one- to five-day stay, which is influenced by factors such as the weekday of diagnosis, the nature of the patient's insurance coverage, the ability of the treating physician or institution to facilitate insurance coverage, and, sometimes, the caregiver's level of comfort with administering injections after discharge. Requestor certified that a longer inpatient hospital stay could be necessary if a patient's physician prescribes the Drug but the hospital does not stock it, thus delaying the patient's access to the Drug. Requestor explained that hospitals often refuse or are unable to stock the Drug for a variety of reasons, including the inventory risk of having an unused vial of the Drug in stock for long periods of time. In addition, Requestor certified that many hospitals are reluctant to administer the Drug to patients with the Syndrome during an inpatient hospital stay because government programs and other insurers do not provide sufficient reimbursement to cover the cost of the Drug and other services related to the inpatient stay; as noted above, the Drug is not separately reimbursable when administered in the inpatient setting. Requestor also certified that it considered significantly reducing the price for units sold to hospitals for this indication but concluded that it could not offer such a reduction "without a devastating impact on Best Price."[4]

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[3] Specifically, Requestor certified that it is critical for a patient's caregiver to follow the appropriate dosing and taper schedule as outlined in the packaging insert to prevent the development of [disorder redacted] and [syndrome redacted]. Requestor stated that immediate discontinuation of the Drug should not occur due to this risk. In addition, Requestor stated that ceasing therapy with the Drug prematurely could fail to stop the seizures, which could result in permanent brain damage or death.

[4] In brief, under the Medicaid Drug Rebate Program, manufacturers are required to give state Medicaid programs the "best price" given to any other purchaser. Subject to certain exclusions and special rules, "best price" means the lowest price available from a

Under the Proposed Arrangement, Requestor[5] would give free doses of the Drug to hospitals for the hospitals to use exclusively for inpatients who are diagnosed with the Syndrome and are prescribed a course of therapy with the Drug. Requestor would stock the Drug at participating hospitals on a consignment basis, at no cost to the hospital or any payor. If a physician diagnoses an inpatient with the Syndrome and desires to prescribe the Drug, the physician would submit a referral to the Drug's reimbursement hub and then would initiate therapy using the free vial.[6] A single vial is equivalent to three to five days of treatment. During this initial treatment time, the reimbursement hub would complete a benefits investigation on the patient's behalf and facilitate shipment of additional vials of the Drug to the patient's caregiver for the caregiver to administer at home following discharge. If the contents of the entire free vial have been administered to the patient before the patient has been discharged from the hospital, Requestor would provide a second free vial (or further subsequent vials) to the hospital for that patient. If the patient's caregiver is unable to secure insurance coverage for the Drug, then the patient would continue to receive the Drug for free until either coverage is obtained or the therapy (including, as necessary for safe treatment termination, the two-week taper period) is complete.

Requestor stated that it would inform participating hospitals, prescribers, and patient caregivers that receiving the free vial(s) is not contingent on any future obligation to purchase either the Drug or any of Requestor's other products. Requestor would require the specialty pharmacy that would distribute the Drug to participating hospitals, prescribers, and patient caregivers to sign statements acknowledging that the Drug provided under the Proposed Arrangement is free and may not be resold or billed to a third-party payor. With respect to qualified Medicaid patients, Requestor would notify the patients' Medicaid plans that the free Drug was provided outside of the Medicaid benefit, and no claim would be filed with a Medicaid plan or by a Medicaid patient for the Drug. Requestor certified that it would not advertise the Proposed Arrangement on

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manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. See section 1927(c)(1)(C) of the Act. "Best price" is calculated for each drug and is not indication-specific.

[5] Requestor certified that a specialty pharmacy would distribute the free doses of the Drug to hospitals. The specialty pharmacy is affiliated with a third-party vendor with which Requestor would contract to administer the Proposed Arrangement. Requestor certified that the specialty pharmacy is not and would not be included in Requestor's existing network of pharmacies.

[6] Title to the Drug would not pass to the hospital until the Drug is dispensed for an inpatient diagnosed with the Syndrome and prescribed the Drug.

third-party websites or magazines commonly read by potential enrollees (e.g., patient caregivers) or prescribing physicians, nor would Requestor send direct-to-consumer advertisements. Requestor also would prohibit physicians and hospitals from marketing their participation in the Proposed Arrangement. Requestor might, however, include information about the Proposed Arrangement on its own website and distribute information about the Proposed Arrangement to health care providers. In addition, Requestor would include information about the Proposed Arrangement in certain public relations materials that are intended to inform the public and Requestor's shareholders that the company provides free product as part of its commitment to patients in urgent need of care.

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 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.

B. Analysis

Requestor seeks to provide free vials of the Drug to hospitals for inpatients diagnosed with the Syndrome and potentially to continue to provide the Drug for free to patients who are unable to secure insurance coverage for the Drug after they are discharged. We previously have approved arrangements under which drug manufacturers provide free drugs to patients.[7] However, as discussed below, those opinions, which apply only to those specific arrangements, are distinct from the Proposed Arrangement in a number of material ways. In addition, certain publicly available information that relates to the subject of this request for an advisory opinion illuminates our analysis of the fraud and abuse risks posed by the Proposed Arrangement. Typically, we examine only those facts provided to us and certified by a requestor when analyzing a particular arrangement. However, if we are aware of additional relevant and material facts that might bear on the risks of a particular arrangement, we cannot ignore those facts simply because a requestor does not present them to us in its advisory opinion request. Therefore, we first provide additional context—otherwise available to the public—in this analysis.

1. Additional Publicly Available Background Information

First, the Drug's list price has increased significantly in the past 15 years. Company B purchased rights to the Drug in 2001. According to various publicly available sources,[8] the cost of one vial of the Drug in 2001 was approximately $40. In 2007, Company B raised the list price from $1,650 to over $23,000 per vial[9]—an almost 1,300 percent increase. Requestor's website reports the current list price as $38,892 per vial.[10] The

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[7] Each of these opinions involved outpatient drugs (e.g., OIG Advisory Opinions 06-03, 06-21, and 07-04, which involved free outpatient prescription drugs to financially needy Medicare Part D enrollees entirely outside of the Part D benefit; OIG Advisory Opinion 08-04, which involved free samples to patients under a program that complied with the Prescription Drug Marketing Act of 1987; and OIG Advisory Opinion 15-11, which involved giving a free supply of an anti-neoplastic drug if a patient experienced a delay in receiving a coverage determination from his or her insurer of at least five business days).

[8] See, e.g., Press Release, U.S. Federal Trade Commission ("FTC"), [Title redacted] [date redacted], https://www.ftc.gov/news-events/press-releases/2017/01/[Title redacted] ("FTC Press Release").

[9] Company B, Annual Report (Form 10-K), at 30 (Mar. 18, 2008).

[10] See https://www.[Requestor].com/about/[the Drug]/ (last visited Oct. 30, 2018).

2015 Medicare Drug Spending Dashboard[11] shows that the Drug has the highest total annual spending per user and the second highest price per unit among drugs that CMS examined that met certain criteria. Similarly, the 2015 Medicaid Drug Spending Dashboard shows the Drug as the second highest cost drug in the "Total Spending Per Prescription Fill" category among the drugs examined.[12] According to Requestor's most recent 10-K filing, net sales for the Drug reached $1.195 billion for 2017.[13] In contrast, Company B's previous 10-K filings showed 2006 net sales (before the substantial price increase) to be $12.1 million;[14] 2007 net sales, which included a partial year with the substantially increased price, to be $48.7 million;[15] and 2008 net sales, which included a full year with the substantially increased price, to be $95.2 million.[16] Given that net sales for the Drug were more than ten times higher in 2017 than they were in 2008, whereas the number of patients diagnosed with the Syndrome remains approximately the same from year to year, the market for the Drug's other indications—for which Federal health care programs may pay—appears to have expanded.

Second, the Drug is not a new drug and has long been used to treat the Syndrome. As Requestor explained, the FDA approved the Drug in 1952. The FDA approval process at that time was based on safety data but did not examine efficacy. In the intervening decades, FDA requirements for drug approval and marketing have become more stringent.[17] Various SEC filings provide an overview of changes that Company B made to modernize the Drug's approved labeling. For example, Requestor's most recent 10-K states that:

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[11] Centers for Medicare & Medicaid Services ("CMS"), 2015 Medicare Drug Spending Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015Medicare.html.

[12] CMS, 2015 Medicaid Drug Spending Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/2015-Medicaid-Drug-Spending/2015-Medicaid-Drug-Spending.html.

[13] Requestor, Annual Report (Form 10-K), at 50 (Feb. 27, 2018).

[14] Company B, Annual Report (Form 10-K), at 4 (Mar. 29, 2007).

[15] Company B, Annual Report (Form 10-K), at 5 (Mar. 18, 2008).

[16] Company B, Annual Report (Form 10-K), at 4 (Mar. 16, 2009).

[17] For example, the 1962 Kefauver-Harris Drug Amendments (Pub. L. 87-781) to the Federal Food, Drug, and Cosmetic Act required manufacturers to prove both safety and effectiveness for the product's intended use.

> In 2010, in connection with its review of a supplemental [New Drug Application ("NDA")] for use of [the Drug] in treatment of [the Syndrome], the FDA again reviewed evidence of safety and efficacy of [the Drug], and added [the Syndrome] indication to the label of approved indications while maintaining approval of [the Drug] for treatment of [indication redacted] and 17 other indications. In conjunction with its decision to retain these 19 indications on a modernized [Drug] label, the FDA eliminated approximately 30 other indications from the label. The FDA review included a medical and scientific review of [the Drug] and each indication and an evaluation of available clinical and non-clinical literature as of the date of the review. The FDA did not require additional clinical trials for [the Drug].[18]

The FDA's Action Memo[19] recommending approval of that NDA for the Syndrome acknowledged that, "[t]hough not approved for the treatment of [the Syndrome] ([the Drug] was approved in 1952 and has been approved subsequently for numerous indications), [the Drug] has been the treatment of choice for [the Syndrome] for many years." In other words, the Drug already existed and was being used to treat the Syndrome and other indications before Company B purchased the Drug, and before Requestor acquired Company B.

Third, in January 2017, Requestor, without conceding to the allegations—all of which related to Company B's alleged conduct—agreed to pay $100 million to settle FTC charges that:

> [W]hile benefitting from an existing monopoly over . . . [the Drug], . . . [Company B] illegally acquired the U.S. rights to develop a competing drug [by] outbidding several other companies that were seeking to acquire the rights to [the competing synthetic drug substance]. Those alternative bidders were interested in developing the drug and had plans to sell it at a significant discount to [the Drug's] price, capturing a substantial amount of [Company B's] business. . . . [Company B's] acquisition of [the competing synthetic drug substance] stifled competition and eliminated the possibility that an alternative bidder would make the drug available in the U.S. market and compete with [the Drug].[20]

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[18] Requestor, Annual Report (Form 10-K), at 30 (Feb. 27, 2018).

[19] Memorandum from Russell Katz, M.D., Director, Division of Neurology Products/HFD-120, FDA, to File, NDA [number redacted] [date redacted], https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/[number redacted].pdf.

[20] See FTC Press Release.

The FTC further charged that Company B's acquisition preserved its monopoly, thereby allowing it to maintain extremely high prices for the Drug. The FTC noted that, in other parts of the world including Europe and Canada, doctors treat patients with the Syndrome with the competing synthetic drug substance, "which is available at a fraction of [the Drug's] price in the United States."[21] The FTC's order also required Requestor to grant a license to develop the competing synthetic drug substance to treat certain conditions, including the Syndrome, to a licensee approved by the FTC. We recognize that, in entering into this settlement, Requestor did not concede to the allegations, and we express no opinion on the allegations. We include this information here to highlight another treatment possibility for the Syndrome that is used elsewhere in the world and that is now able to be developed in the United States.

The facts above give additional background and provide context that is important to our fraud and abuse analysis. To examine a proposed arrangement under the Federal anti-kickback statute, we must assess the risk that a person or entity would offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. In particular, we examine risks such as overutilization, increased costs to Federal health care programs, corruption of medical decision-making, patient steering, and unfair competition. Our anti-kickback statute analysis is below.

2. Federal Anti-kickback Statute Analysis

Under the Proposed Arrangement, Requestor would provide the Drug for free to hospitals for the hospitals to use exclusively for their inpatients who have been diagnosed with the Syndrome, some of whom may be Federal health care program beneficiaries. The free Drug would be remuneration that Requestor would provide to hospitals, which could serve as referral sources for the Drug. 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 at the hospitals and thus are in a position to arrange for or recommend purchases of the Drug. If a hospital refuses to stock a drug for a certain reason (e.g., if the Drug is too expensive when dispensed for inpatients), then it may be difficult for a doctor to prescribe the Drug for any hospital patient. Giving the Drug for free to hospitals for inpatients diagnosed with the Syndrome could induce the hospitals to arrange for or recommend future purchases of the Drug. The Proposed Arrangement therefore would implicate the anti-kickback statute.

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[21] Id.

As noted above, we previously have approved arrangements to give free outpatient drugs directly to patients when those arrangements had certain safeguards or features that benefitted patients and Federal health care programs. Furthermore, we recognize the Drug is a first-line treatment for the Syndrome in the United States and that research shows the importance of receiving some form of treatment for the Syndrome as soon as possible after diagnosis. However, we cannot analyze the Proposed Arrangement in a vacuum and, for the combination of the following reasons, we conclude that the Proposed Arrangement would present more than a minimal risk of fraud and abuse under the anti-kickback statute.

First, the Proposed Arrangement would relieve a hospital of a significant financial obligation that the hospital otherwise would incur if it were to acquire the Drug when a physician prescribes it for a hospital inpatient. According to Requestor, most patients diagnosed with the Syndrome receive that diagnosis in hospitals as inpatients, and hospitals are reluctant to stock the Drug. Given that the Drug has been used to treat the Syndrome for decades, it is likely that the substantial price increases for the Drug that are described above factor into hospitals' reluctance to stock it. Giving the Drug for free to a hospital would remove the hospital's reason for refusing to stock the Drug, paving the way for the Drug to be administered to inpatients diagnosed with the Syndrome at the hospital.

Second, the Proposed Arrangement would not result in any savings for the Federal health care programs. Requestor would provide the Drug for free only to hospitals to use only for inpatients diagnosed with the Syndrome, and the amount a Federal health care program would reimburse a hospital for an inpatient stay would not be reduced even if the hospital received the Drug for free. Consequently, no portion of the significant savings from which a hospital would benefit under the Proposed Arrangement would be passed on to the Federal health care programs.

Third, the Proposed Arrangement could function as a seeding arrangement. As noted above, a hospital could influence or arrange for a physician to prescribe the Drug for inpatients when the hospital receives the Drug for free. Once patients are discharged, if their insurance covers the Drug, then insurers (including Federal health care programs) and patients would be charged for the Drug.[22] Moreover, giving the Drug for free to this specific patient population in the inpatient setting facilitates Requestor's high price for the Drug's other indications; Requestor represented in a certified submission to the OIG

[22] Patients would get the Drug for free outside of the inpatient setting only if they could not secure insurance coverage for the Drug. Thus, this aspect of the Proposed Arrangement would not save money for Federal health care programs either (because if a Federal health care program would pay for the Drug, Requestor would not provide it for free).

that it could not offer a discounted price for the Drug for the Syndrome because "such a discount could not be taken without a devastating impact on Best Price." In other words, rather than reducing the price of the Drug for patients with the Syndrome (which also would reduce costs for Federal health care programs because of the best price requirements), Requestor seeks to give the Drug for free to hospitals for a narrowly defined subset of patients and to retain the higher price for all other patients who use the Drug (for any of its indications) and all payors, including Federal health care programs.

Fourth, the Proposed Arrangement could result in steering or unfair competition. Requestor acknowledged that one other FDA-approved drug to treat the Syndrome already exists. In addition, we understand that [drug type redacted] or other drugs are often used off-label to treat the Syndrome.[23] Furthermore, the FTC recently required Requestor to license the right to develop yet another drug, which currently is used to treat patients with the Syndrome elsewhere in the world, that potentially could treat patients with the Syndrome in the United States if it is developed and approved. Therefore, prescribers have various treatment options, including but not limited to the Drug, to consider, and hospitals have a choice of which drugs to stock. It is possible that hospitals could influence prescribers to consider the Drug as a first option, either directly or through formulary decisions, as a result of the Proposed Arrangement.

Fifth, one of the primary justifications that Requestor presents for giving the Drug for free to hospitals for patients diagnosed with the Syndrome is that any delay in treatment (e.g., if the hospital does not have the Drug immediately available) presents increased risk to the patient. Under the Proposed Arrangement, Requestor would stock the Drug at the hospital on a consignment basis. It is unclear why, if Requestor would stock the Drug on a consignment basis, Requestor also would have to give the Drug to the hospital for free. Simply consigning the Drug onsite, requiring a purchase only if the hospital actually used it,[24] would eliminate two barriers identified by Requestor: not having

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[23] See, e.g., Gary Rex Nelson, Management of [the Syndrome], 4 TRANSLATIONAL PEDIATRICS 260–70 (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/[identifier redacted]/; Jithangi Wanigasinghe MBBS, DCH, MD et al., The Efficacy of Moderate-to-High Dose [drug redacted] Versus Low-to-Moderate Dose [drug redacted] for Improvement of [symptom redacted] in [syndrome redacted]: A Randomized, Single-Blind, Parallel Clinical Trial, 51 PEDIATRIC NEUROLOGY 24–30 (2014), available at http://www.pedneur.com/article/[identifier redacted]/pdf.

[24] We further note that consigning the Drug onsite and requiring a purchase only if the hospital actually used it would not be the only acceptable method of ensuring a patient receives the Drug. For example, in OIG Advisory Opinion 07-04, we approved of an

immediate access to the Drug and the hospital's unwillingness to bear the risk of buying the Drug and having it go unused. Giving the Drug to the hospital for free goes one step further and could induce the hospital to recommend or arrange for prescriptions of the Drug.

Finally, Requestor's certification that receipt of the free vial of the Drug is not contingent on future purchases rings hollow. Requestor certified that a course of treatment with the Drug for the Syndrome cannot be discontinued without potential adverse consequences to a patient's health. Although Requestor stated that it might continue to provide free vials of the Drug through the entire course of therapy, it would do so only when a patient could not obtain insurance coverage for the Drug. Therefore, patients who have insurance coverage for the Drug would make future purchases of the Drug in order to avoid potential adverse medical consequences. In essence, the receipt of the free vial would be contingent on future purchases of the Drug for patients with insurance coverage for the Drug.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion, supplemental submissions, and other publicly available information, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [company 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [company redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

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arrangement under which a drug manufacturer gave its drug to financially needy patients for the remainder of the coverage year. If Requester had presented facts that included giving the Drug for free to patients and payors for the full course of treatment of the Syndrome, the outcome of this opinion could have been different, even if treatment began in the inpatient setting.

- This advisory opinion may not be introduced into evidence by a person or entity other than [company 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 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.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs