



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: April 30, 2018

Posted: May 7, 2018

[Name and address redacted]

Re: OIG Advisory Opinion No. 18-02

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement where a company that manufactures, distributes, and sells medical device and pharmaceutical products provides a limited number of free sample ostomy products to patients and contracts with a third party to conduct follow-up customer satisfaction surveys (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the 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”) will 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 Arrangement. This opinion is limited to the 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”) distributes and sells ostomy products, which patients who have surgically diverted biological systems must use to collect urine, fecal matter, or both. Requestor distributes and sells, but does not manufacture, [name redacted] ostomy products (the “Products”), which include two-piece coupling systems consisting of base plates that adhere to the skin and pouches that attach to the base plates to collect fecal matter or urine. While Requestor distributes and sells the Products, it does not own or operate, directly or indirectly, entities that file claims for payment for the Products, or other items and services, to the Medicare program or any State health care program. Requestor distributes and sells ostomy products that use base plates that are either pre-cut or cut-to-fit, with either closed pouches or drainable pouches. Requestor certified that, following surgery, patients typically are fitted with an ostomy product at the hospital, using the type of product purchased by the hospital. Upon discharge, patients can purchase the Products (or other ostomy products) from durable medical equipment (“DME”) suppliers, and the Products may be reimbursed under commercial insurance and State and Federal health care programs, including Medicare Part B.¹ Requestor certified that patients have options among competing products and generally face no barriers to switching among ostomy products manufactured by various DME manufacturers or sold

¹ Medicare rules require a supplier to have a written order prior to submitting a claim for ostomy products. The ordering practitioner determines whether or not to write an order that specifies the brand of ostomy products. Nevertheless, it is our understanding that even if an order specifies a brand of ostomy products, a patient could select a different brand.

by different suppliers. The Products' retail value is similar to competing products available on the market.

Under the Arrangement, Requestor provides a limited number of sample Products to patients, including Federal health care program beneficiaries, at no charge. Samples are not contingent on any future purchase obligation. A patient may request a sample Product directly, or a health care provider may request a sample Product on a patient's behalf.² Regardless of who makes the request, the sample Products are shipped directly to the patient's residence. A patient may receive a sample of a particular Product configuration and size only once, where "configuration" refers to a Product's features, such as having a closed pouch versus a drainable pouch.³ The number of Products in each sample depends on the Product configuration(s) requested, but a sample is designed to last a patient two to three days. The sample package also includes (i) a list of all authorized DME suppliers from which patients could purchase the Products, (ii) a Product brochure, (iii) a notice stating that the Products are being provided at no charge and cannot be resold or billed to any third party and that the patient is not obligated to purchase the Products or any other products, (iv) instructions for use of the sample Products, and (v) a brochure about [name redacted] (the "Educational Resource"). The Educational Resource consists of (i) a phone line to answer questions and provide product support and educational information, and (ii) a website with educational information, support resources, ostomy patient stories, and a link to request Product samples. The Educational Resource's website includes generalized marketing, such as patient testimonials. In addition, the Educational Resource's phone line operators may answer factual questions about the Products, but they do not recommend the Products or any other federally reimbursable items or services, or any particular health care providers, distributors, DME suppliers, or other Product suppliers.

The aggregate retail value of a sample package of Products ranges from approximately \$6–\$22, depending on the type of Product (i.e., one-piece or two-piece).⁴ Requestor also

² Requestor does not impose any limitations on what health care provider may request a sample Product (i.e., any health care provider may submit a sample request form).

³ If a sample is damaged, defective, or never received, the patient may request and receive a sample of the same configuration and size again.

⁴ If a patient is a "new ostomate" (a patient who had an initial ostomy surgery within the past 30–90 days), and currently is not using the Products and has not previously requested a Product sample, the sample package may include a stoma measuring device, a protective carrying bag to hold the sample Products, and a pair of medical scissors if the sample Product includes a cut-to-fit base plate ("Additional Items"). The Additional Items have a total retail value of approximately \$16. The aggregate retail value of a sample package of Products with Additional Items ranges from approximately \$15 to

makes available samples of a flow collector (which attaches to a drainable pouch to hold a larger volume of waste and has a retail value of \$7) and will make available a one-piece ostomy Product (the sample of which would have a retail value ranging from approximately \$6–\$12) once the one-piece ostomy Product becomes commercially available in the United States.

Requestor contracts with an unaffiliated third-party service provider, [name redacted] (the “Contractor”), to process sample requests and administer the user satisfaction survey. The Contractor provides consulting services to medical device and pharmaceutical companies but is not a health care provider or a DME supplier or distributor and does not sell, distribute, or supply the Products. Requestor certified that it pays the Contractor a fair market value fee for the services rendered in connection with the Arrangement and does not compensate the Contractor based on the volume or value of Product sales.⁵

A patient, or his or her health care provider, submits a sample request form. The patient’s information is transmitted directly to the Contractor; neither Requestor nor the manufacturer of the Products is able to view or access the patient’s information.⁶ Requestor certified that the Contractor has implemented a process to prevent any sample request from being processed for a patient who currently uses Products with the same configuration and size as the requested Product sample, or for any patient who previously received a Product sample with the same configuration and size as the requested sample. The sample request form also includes an agreement to participate in a user satisfaction survey. The form clearly indicates that participation in the survey is not required to receive a sample and permits a patient to opt out.

Once the Contractor receives a valid sample request, it transmits the applicable information to a third-party fulfillment center, [name redacted] (the “Fulfillment Center”),⁷ that contracts with Requestor to ship the sample Products. Requestor gives the

\$38, depending on the type of Products (i.e., one-piece or two-piece) and configuration requested (i.e., closed pouch, drainable pouch, with or without flow collector).

⁵ Requestor entered into a master services agreement with the Contractor in connection with the Arrangement. We have not been asked, and we express no opinion, about any services arrangements outside of those described herein.

⁶ However, Requestor will receive information regarding any health care provider that requests a sample on behalf of a patient.

⁷ Requestor certified that it complies, and it contractually requires the Contractor and the Fulfillment Center to comply, with all applicable privacy laws in connection with the Arrangement. We express no opinion regarding the Arrangement’s compliance with applicable privacy laws.

Fulfillment Center the Products at no charge to fill these sample requests and pays the Fulfillment Center a service fee of approximately \$5 for each sample request it fulfills, plus the cost of shipping and a flat fee of \$200 per month regardless of the number of sample requests in such month. The Fulfillment Center does not sell or otherwise distribute the Products (outside of the sample requests). Requestor does not compensate the Fulfillment Center based on the volume or value of the sales of any Products.

During the ten weeks after a patient receives the sample Products, the Contractor conducts a user satisfaction survey by telephone, computer, or both if the patient did not opt out.⁸ Requestor certified that the survey evaluates patient satisfaction with the Products; helps patients identify support services or general ostomy information that might be useful; and provides basic information about the Products, upon request. Requestor certified that it entered into a written agreement with the Contractor specifying that the Contractor does not (i) offer any additional sample Products or other products free of charge (provided that the Contractor may provide additional sample Products if there is a request for a different size or configuration of a Product), (ii) recommend the Products or any other federally reimbursable items or services, or any particular health care providers, distributors, DME suppliers, or other product suppliers, or (iii) offer anything of value in exchange for participating in the survey or purchasing the Products or any other items sold by Requestor. Requestor receives patient information gathered during the surveys in aggregate, de-identified form and uses the information for Product quality improvement and marketing purposes and to identify potential topics for further Product research.

Requestor reserves the right to audit both the Contractor and the Fulfillment Center to confirm that patients did not receive more than one sample of a particular Product configuration and size and that the sample Products shipped matched those requested. Requestor certified that it does not use any patient information collected through the sample process, except for the survey the Contractor conducts if a patient did not opt out of participation, for any future marketing or other communication. However, Requestor may use information related to health care providers who have requested a sample on behalf of a patient for future marketing and other communication with such health care providers.

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

⁸ The user satisfaction survey may consist of multiple communications.

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 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 section 1128A(a)(5) as including “transfers of items or services for free or for other than fair market value.”

B. Analysis

Under the Arrangement, Requestor offers one free sample package of a particular Product configuration and size upon request and receives aggregated, de-identified results of customer satisfaction surveys of patients who did not opt out of participation. The Arrangement does not implicate Section 1128A(a)(5) of the Act because the remuneration provided under the Arrangement would not influence a beneficiary to make any future purchases from a particular provider, practitioner, or supplier. Requestor certified that it does not own or operate, directly or indirectly, any entity that files claims for payment for the Products, or other reimbursable items and services, to the Medicare program or State health care programs. The OIG has previously stated that we do “not

believe that drug manufacturers are ‘providers, practitioners, or suppliers’ for the limited purposes of section 1128A(a)(5) of the Act, unless the drug manufacturers also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.”⁹ While Requestor does not manufacture the Products, it does not own or operate, directly or indirectly, entities that file claims for payment for the Products, or other items and services, to the Medicare program or any State health care program. As a consequence, Requestor is not a provider, practitioner, or supplier for the purposes of Section 1128A(a)(5) of the Act.

However, the remuneration—in the form of free samples—may be intended to induce Federal health care program beneficiaries to self-refer to the Products in the future, and therefore, the Arrangement implicates the anti-kickback statute. For the combination of the following reasons, we conclude that the Arrangement presents a low risk of fraud and abuse under the anti-kickback statute.

First, the Arrangement should not increase costs to patients or Federal health care programs. Importantly, Requestor informs patients receiving Product samples that they are not permitted to bill a third-party payor for the sample Products. In other words, under the Arrangement, neither patients nor Federal health care programs should incur any costs for the sample Products furnished by Requestor.

Second, the risk of inappropriate patient steering to the Products under the Arrangement is low because future purchases of ostomy products remain an exercise of each patient’s personal preferences. As an initial matter, the Product sample is not contingent on any future purchase obligation. In addition, Requestor certified that patients generally face no barriers to switching among ostomy products manufactured by different DME manufacturers or sold by different suppliers and that the Products’ retail values are similar to those of available, competing products. Further, each sample is relatively small—providing only a few days’ supply of the Products—and of relatively low retail value. These factors are in contrast to problematic “seeding” programs in which, for example, a manufacturer offers a patient a free drug—which might be more expensive than competing drugs or which might be dangerous for the patient to cease using—with the goal of having the patient obtain subsequent supplies that would be billed to Federal health care programs. Here, although a patient might choose the Products after testing the Product samples, nothing from a clinical perspective requires the patient to continue using the Products instead of a competitor’s products (either of which the patient may use for the rest of his or her life). Finally, the patient’s decision to order the Products over a competitor’s products likely has a minimal impact on Federal health care program

⁹ OIG, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

expenditures, further reducing the risks posed by the Arrangement vis-à-vis problematic seeding programs.

Third, the Arrangement is unlikely to result in inappropriate utilization. The free sample lasts only a few days, after which patients need to purchase their own supplies. Although Federal health care programs may reimburse future purchases of the Products, patients are subject to applicable cost-sharing obligations and restrictions on the quantity of ostomy supplies reimbursed by Federal health care programs.

Finally, the Arrangement includes safeguards to limit the risk that the Contractor is paid for Product referrals. The Contractor that conducts the survey does not sell the Products and is not compensated based on future Product sales. In addition, the Contractor is not permitted to recommend the Products or any other items sold by Requestor during the survey process. Moreover, Requestor receives patient data from the survey only in an aggregated and de-identified form, which limits its ability to use the data to target future marketing efforts to particular patients.

For the foregoing reasons, we conclude that the Arrangement presents a low risk of fraud and abuse under the anti-kickback statute, and thus, we will not impose administrative sanctions on Requestor under the anti-kickback statute in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the 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 will 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 Arrangement. This opinion is limited to the 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 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 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 [name redacted] 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/

Assistant Inspector General for Legal Affairs