

Insights

Recent OIG Opinion Permits Free Samples to Patients

June 19, 2018

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On April 30, 2018, the Department of Health and Human Services, Office of Inspector General ("OIG"), issued an Advisory Opinion regarding an Arrangement whereby a Company that distributes and sells medical device and pharmaceutical products provides a limited number of sample ostomy products to patients, including Federal health care program beneficiaries, at no charge (the "Arrangement").¹

The samples are not contingent on any future purchase obligation, and the sample may be obtained at the request of the patient or at the request of a health care provider on a patient's behalf. Samples are shipped directly to the patient's residence. The samples are designed to last a patient two to three days, and the patient may only receive one sample package of a particular product configuration and size. The Company also contracts with a third party ("Contractor") to process sample requests and conduct follow-up customer satisfaction surveys. The Company pays the Contractor, which is not a health care provider, a fair market value fee for the services rendered and does not compensate the Contractor based on the volume or value of product sales.

The OIG determined that the Arrangement does not constitute grounds for the imposition of civil monetary penalties (CMP) under Social Security Act §1128A(a)(5) as the remuneration (i.e., the product samples) provided would not influence a beneficiary to make any future purchases from a particular provider, practitioner, or supplier, as the Company is not a provider, practitioner, or supplier (i.e. does not file a claim for payment for the products or other reimbursable items and services).

In its analysis, the OIG determined that although the Arrangement could potentially violate the Anti-Kickback Statute if the intent to induce or reward referrals of Federal health care program business were present. Notwithstanding, the OIG indicated it would not impose administrative sanctions in connection with the Arrangement, because:

- The Arrangement should not increase costs to patients or Federal health care programs;
- 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;
- The Arrangement is unlikely to result in inappropriate utilization, as the free sample only lasts a few days; and
- The Arrangement includes safeguards to limit the risk that the Contractor is paid for product referrals, including that the Contractor is not compensated on future product sales, and the Contractor is not permitted to recommend the Products or other items sold by Company during the survey process.

Note, Advisory Opinions are issued only to the entity requesting the opinion and may not be relied on by any person other than the party requesting the opinion.

If you have any questions regarding this or other Advisory Opinions, please contact Meghan M. Linvill McNab at mmcnab@kdlegal.com, Thomas N. Hutchinson at thutchinson@kdlegal.com, or your regular Krieg DeVault attorney.

¹ A copy of Advisory Opinion 18-02 is available here: <https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-02.pdf>.