OIG APPROVES ARRANGEMENT TO PROVIDE FREE DME SAMPLES

On May 7, 2018, the Department of Health and Human Services Office of Inspector General ("OIG") published Advisory Opinion 18-02, which approved an arrangement allowing a durable medical equipment ("DME") distributor to provide patients with product samples at no cost to the patient. OIG stated that it would not impose sanctions against the parties for violations of the Anti-Kickback Statute ("AKS") because the arrangement contains appropriate safeguards or the Civil Monetary Penalties law ("CMP") because the requesting entity is not a "provider, practitioner, or supplier" for purposes of the CMP.

BACKGROUND

Requesting Party

The requesting party ("Requestor") is a distributor and seller of certain DME products, including ostomy products ("Products"). However, Requestor does not own or operate entities that bill Medicare or any state health care programs for Products. Requestor certified that patients may purchase Products from DME suppliers and that the Products are typically reimbursed by Medicare, Medicaid or commercial insurance programs. Requestor also certified that patients are free to switch among Product manufacturers and/or suppliers.

Proposed Arrangement

Patients and/or their health care provider may request a Product sample on the patient's behalf. Under the proposed arrangement, Requestor will provide Product samples to patients, which may include Medicare and Medicaid beneficiaries, at no charge to the patient. The patients are not committed to any future purchases in exchange for receipt of the Product sample. Patients may only receive one sample per Product configuration and size. A Product sample is intended to last the patient two to three days. When a patient receives a Product sample, the sample package includes the following:

- A list of all DME suppliers of the Product;
- A Product brochure;
- A notice stating that the Products are provided to the patient at no charge and cannot be resold or billed to third parties;
- Instructions for use of the Product sample; and
- A brochure about the Product manufacturer. The retail value of the Product sample package ranges from $6-$22 depending upon the specific Product provided.

Requestor utilizes a third party service provider to process Product sample requests and to administer user satisfaction surveys to patients who receive Product samples. This third party does not sell, distribute or supply Products. The third party is paid fair market value for services provided to Requestor and such compensation is not based upon the volume or value of Product sales.

Pursuant to the proposed arrangement, in order for patients to receive Product samples, the following must occur:

1. Patient (or the patient's health care provider) submits a Product sample request form to Requestor.
2. Patient information is communicated directly to the third party service provider.
3. The third party service provider has implemented protocols to ensure that patients do not receive more than one Product sample of the same Product size and configuration.
4. The third party service provider then submits the information to an unaffiliated fulfillment center that contracts with the Requestor to ship the Product samples. The Requestor compensates the fulfillment center via a fee of $5 per fulfilled sample request plus shipping costs. The fulfillment center also receives a flat fee of $200 per month regardless of the number of Product samples that it fills each month. The fulfillment center does not sell or distribute Products outside of the sample requests.

5. The third party service provider then conducts patient satisfaction surveys over the next ten weeks. Requestor has certified that patients are not offered any additional Product samples, recommendations for future Products or other items of value as a part of this process or in exchange for their participation in the patient satisfaction surveys.

Further, Requestor has the right to audit both the third party service provider and the fulfillment center to confirm that patients did not receive more than one Product sample and that the samples shipped are those requested by the Patients.

OIG ANALYSIS

Civil Monetary Penalties Law

The CMP prohibits the offer or transfer of items or services for free or less than fair market value to Medicare and/or Medicaid beneficiaries that the offeror knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier for items or services that are reimbursable by federal health care programs.

OIG determined that the samples provided by Requestor would not influence a beneficiary to make future purchases from any particular provider, practitioner or supplier. Further, Requestor certified that it does not own or operate any entities that submit claims to Medicare or Medicaid; therefore, it is not a "provider, practitioner, or supplier" for purposes of this analysis. As such, the CMP does not apply to the proposed arrangement. However, because the Product samples may influence a patient to self-refer to the Products in the future, the proposed arrangement may implicate the AKS.

Anti-Kickback Statute

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by federal health care programs. If just one purpose of an arrangement is to induce or reward referrals, the arrangement violates the AKS.

Due to the safeguards implemented by Requestor pursuant to the proposed arrangement and absence of any appearance of improper intent, OIG concluded that the proposed arrangement presented a low risk of fraud and abuse under the AKS.

Safeguards

In making its determinations regarding the proposed arrangement, OIG enumerated several safeguards that the Requestor implemented in order to reduce the risk of the arrangement. The following safeguards were relied upon by OIG and should be implemented where possible in any similar arrangements:

- The proposed arrangement did not increase costs to patients or federal health care programs such as Medicare or Medicaid.
- Patients retain the ability to make future purchases of Products based on personal preference and patient choice. This reduces the risk of steering patients towards particular Products. OIG noted that this was in contrast to "seeding" programs that incentivize patients to choose more expensive products so that the patient will seek out the more expensive products when receiving reimbursable items in the future.
- The Product samples are low in value and provide only a few days' worth of use.
- Because the Products are very similar in price to competitors' products, a patient's decision to choose the Products has a nominal financial impact on federal health care programs.
- Patients are required to purchase their own supplies after utilizing the Product sample for only a few days, which makes the proposed arrangement unlikely to lead to excess utilization.
- The third party service provider that conducts the patient surveys does not sell the Products and is not compensated in a manner that takes into account current or future Product sales.
- The third party service provider does not recommend Products or any other items sold by Requestor to patients during the survey process.
- Requestor only receives de-identified aggregate survey data from the third party service provider, which minimizes Requestor's ability to

engage in targeted marketing efforts to patients.

PRACTICAL TAKEAWAYS

The provision of items or services to patients for free or less than fair market value should only be considered after a thorough analysis of the facts and circumstances of the program at issue. Although the Requestor in Advisory Opinion 18-02 was not a "provider, practitioner, or supplier" for purposes of OIG's CMP analysis, many health care organizations looking to implement such programs would be subject to these regulations and such arrangements may warrant additional scrutiny.

Further, the scope of entities subject to the AKS considerations discussed above are much broader than the scope of entities subject to the CMP regulations. As such, health care organizations should ensure that any programs offering free samples or other items and services to patients are structured in a manner to limit risk via the implementation of as many of the above safeguards as possible.

If you have any questions or would like additional information about this topic, please contact:

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