PUBLICATION

OIG Advisory Opinion 18-02: Medical Device Distributor Can Provide Free Samples and Patient Surveys

May 29, 2018

On May 7, 2018, the OIG issued a favorable advisory opinion, No. 18-02, regarding an arrangement that would allow a medical device distributor (Requestor) to provide free sample ostomy products to federal health care program patients and permit a third-party contractor to conduct follow-up user satisfaction surveys (the Arrangement). While this Arrangement may implicate the Anti-Kickback Statute (AKS) in the form of free sample products to federal health care program patients, the OIG concluded the Arrangement presents a low risk of fraud and abuse because of the representations made by the Requestor and the safeguards implemented with the Arrangement.

Factual Overview

The Requester is a company that sells and distributes ostomy products but does not manufacture the products or file claims for payment with Medicare or any other federal health care program. Under the Arrangement, the Requestor provides, at the request of the patient or the patient's health care provider, ostomy product samples at no charge to patients following surgery. The sample product supply is limited to three days and the retail value of the sample package is $6 to $22 ($15 to $38 if certain additional items are included). The provision of samples is not conditioned upon future purchases from the Requestor. After a certain time period, a third-party contractor follows up with the patient to conduct a user satisfaction survey by telephone or computer but does allow the patient to opt out of the survey. The third-party contractor aggregates the survey data and de-identifies it before sending it to the Requestor.

Legal Analysis

As an initial matter, the OIG recognized that the Arrangement does not implicate the beneficiary inducement prohibition (42 C.F.R. § 1320a-7a(a)(5)) because the Requestor does not own or operate entities that file claims for payment for the products to any federal health care program. The OIG has historically recognized that drug manufacturers are not "providers, practitioners, or suppliers" for purposes of the beneficiary inducement prohibition.

The OIG nevertheless recognized that, by providing free samples to federal health care program patients, the Arrangement could implicate the AKS to the extent the Arrangement induces patients to purchase products in the future. The OIG concluded, however, the Arrangement posed a low risk of fraud and abuse for the following reasons outlined below.

1. The Arrangement does not increase federal health care program costs because neither the patient nor the Requestor bills for the sample products.
2. There is a low risk of patient steering because patients retain full discretion to make any future purchases of ostomy products from any supplier and there are no clinical barriers to switching between ostomy products. The OIG contrasted the Arrangement with controversial "seeding" programs in which a drug manufacturer provides free samples of expensive drugs or drugs that create adverse health issues if discontinued – in anticipation of inducing future purchases.
3. The patient's choice of the Requestor's products over competitors' products has minimal impact on federal health care program expenditures. The samples provided to patients contain a small supply of low retail value.

4. Inappropriate utilization is unlikely because the sample supply is small, limited to only a few days. With respect to any future purchases, patients are subject to applicable cost-sharing obligations and quantity restrictions for products reimbursed by federal health care programs.
5. The contractor who conducts the customer satisfaction survey is not compensated on future sales and is not permitted to recommend products sold by the Requestor during the survey process.
6. The Requestor receives the survey results only in an aggregated and de-identified form, limiting the Requestor's ability to use the data to market to particular patients in the future.

Baker Donelson's Comments

OIG advisory opinion 18-02 adds to the growing list of opinions that offer insight into the OIG's view of the provision of free samples by drug manufacturers and distributors. While, as with all advisory opinions, the OIG's determination is limited to the proposed Arrangement at issue, the opinion provides insight into the types of safeguards that should be applied when considering these types of arrangements. It is important to note that the OIG contrasted this relatively low-value program with controversial "seeding" arrangements involving samples of free drugs that effect clinical barriers to switching between products.