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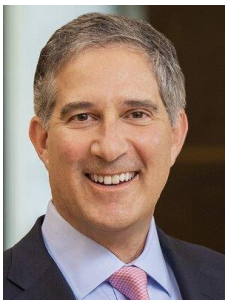
HHS Advisory Highlights Free Product Inducement Risks

By **Howard Young, Sydney Swanson and Scott McBride** (December 21, 2023, 4:25 PM EST)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In its Oct. 25 Advisory Opinion No. 23-08, the U.S. Department of Health and Human Services Office of Inspector General rejected a proposed arrangement from a cochlear implant device manufacturer — the requester — that would provide a free hearing aid to certain qualified patients who received a cochlear implant.

The OIG concluded the proposed arrangement could generate prohibited remuneration under the federal Anti-Kickback Statute and the Civil Monetary Penalty Law's beneficiary inducement prohibitions — the beneficiary inducement law — and could violate those laws if the requisite intent were present.

Under the proposed arrangement, the manufacturer would offer a bundle consisting of a cochlear implant made by the manufacturer and a free hearing aid manufactured by a third party for certain qualified patients.

More specifically, the cochlear implant would be purchased by a hospital or ambulatory surgical center for implantation. For certain bimodal hearing candidates, a hearing aid would be provided for free to the patient along with the cochlear implant. While hearing aids are not covered by most federal healthcare programs, or FHCPs, cochlear implants may be covered.

Importantly for its analysis, in a footnote, the OIG observed that the cochlear implant manufacturer was also a Medicare-enrolled durable medical equipment, or DME, supplier "for the limited purpose of furnishing repair services and replacements for the [cochlear implants'] external sound processors." As such, the OIG observed that the requester submits claims to Medicare and other FHCPs for external sound-processor servicing and repairs.

The advisory opinion was, however, silent on whether FHCP beneficiaries were aware that the cochlear implant manufacturer served as a vendor for external sound-processor servicing and repairs.

This is notable because as a general legal principle, the beneficiary inducement law does not apply to device manufacturers, as discussed in the OIG's August 20023 special advisory bulletin on gifts and inducements.

In the bulletin, the OIG stated that drug manufacturers are not typically providers, practitioners or suppliers for the limited purposes of Section 1128A(a)(5) of the Social Security Act.

A drug manufacturer may be considered a provider, practitioner, or supplier if the drug manufacturer also owns or operates, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment with FHCPs. Though not specified in the OIG bulletin, it is reasonable to assume this distinction applies to device manufacturers as well as drug manufacturers.

Here, however, the OIG applied the beneficiary inducement law to the requester's proposed arrangement even though there was no assessment of whether the DME service and repair business was a material aspect of the requester's business.

In its legal analysis, the OIG determined that the proposed arrangement implicated the AKS because the manufacturer would provide remuneration in the form of a free hearing aid that may induce patients and providers (e.g., ambulatory surgical centers) to purchase the manufacturer's cochlear implant, which is reimbursable by FHCPs.

The OIG reasoned that the value-based enterprise safe harbor for arrangements for patient engagement and support was inapplicable since the value of the hearing aids exceeded the safe harbor's $570 monetary cap, as the hearing aids were valued at $1,180 or more.

Furthermore, the OIG found that the proposed arrangement would also implicate the beneficiary inducement law because the manufacturer would provide remuneration in the form of a free hearing aid that may induce patients and providers located in states where the manufacturer bills Medicaid and Medicaid-managed care to purchase the cochlear implant reimbursable by FHCPs.

The OIG also concluded — in what may appear as a bit of speculation — that the hearing aid may influence a beneficiary to select the requester manufacturer's cochlear implant, which could in turn result in the manufacturer, in its role as a DME supplier, furnishing an increased number of repair or replacement services for the external sound processor that would be reimbursable under FHCPs.

The OIG made this observation without exploring whether beneficiaries seek to influence the hospitals or ambulatory surgical centers, or rendering physicians, in the selection and purchase of the cochlear implant.

The OIG assessed that the promoting access to care exception to the beneficiary inducement law would not apply because the hearing aid is not required for the cochlear implant to work properly. The OIG also decided that the financial need-based exception would not apply because the hearing aid would be conditioned on the purchase of the cochlear implant, and not on an individual's financial need.

The Oct. 25 advisory opinion highlights the OIG's concern that valuable free products and other inducements offered by manufacturers may create real or perceived risks that patients and providers are inappropriately influenced to select one manufacturer's product over another, notwithstanding that such free healthcare products benefit the beneficiaries.

As it often does, the OIG also expressed concern about unfair competition if free hearing aids were offered only by manufacturers with greater financial resources to attract business.

Although the AKS was not enacted to protect level playing field competition, the OIG often applies that

standard in its AKS analyses, particularly in its advisory opinions, and this provides competitors with ample room to argue that competition would be harmed by such arrangements.

Despite the tenuous connection between the manufacturer's role as a DME supplier offering external sound-processor servicing and repair and the offer of free hearing aids, the OIG leveraged that connection to apply the beneficiary inducement law to the manufacturer. This is perhaps one of those rare situations when a manufacturer is also enrolled in Medicare or Medicaid as a supplier, and, thus, the beneficiary inducement law may apply for free items or services.

It is dubious whether the bundled cochlear implant and hearing aid would serve as an incentive to individual beneficiaries who may not appreciate or even be cognizant of which entity handles the servicing or product repairs of external sound processors associated with the cochlear implants.

Further, it seems unlikely that the manufacturer's furnishing of free hearing aids to certain eligible patients would materially increase the rate at which the manufacturer provides repair and replacement services for external sound processors or, in turn, materially affect the revenue the manufacturer — in its capacity as a DME supplier — receives from FHCPs.

Nevertheless, the OIG's analysis in this advisory opinion indicates that the agency is willing, in the context of an advisory opinion request, to make that connection — even when tenuous.

Healthcare industry participants, including manufacturers that do not usually concern themselves with the beneficiary inducement law, should examine whether they also qualify as a Medicare or Medicaid provider or supplier, and assess whether the provision of free products complies with both the AKS and the beneficiary inducement law.

As manufacturers with specialized servicing and repair expertise consider whether to directly enroll with Medicare or Medicaid as a DME supplier, they should be aware of the additional legal risk associated with the beneficiary inducement law, although that particular civil monetary penalty statute has seen limited enforcement by the OIG and affords no private right of action.

The AKS risks must be separately analyzed.

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