

OIG Issues Unfavorable Advisory Opinion on Free Items to Patients Tied to Reimbursable Services

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Perhaps unsurprisingly, the Office of Inspector General for the Department of Health and Human Services (OIG) **rejected** a manufacturer's proposal to provide free hearing aids to certain patients if they receive one of the manufacturer's cochlear implant devices (Proposed Arrangement). In reaching its determination, the OIG reiterated its longstanding concern about free items or services to Medicare and Medicaid beneficiaries because such arrangements could result in steering and unfair competition. Of note, the free hearing aids under the Proposed Arrangement have a retail value of \$1,180 to \$2,240 which far exceeds the \$570 limit imposed under the only potentially relevant safe harbor – the patient engagement and support safe harbor.

Proposed Arrangement

The manufacturer (Manufacturer) manufactures and distributes implantable hearing solutions, including (i) an implantable device (Device) sold to hospitals and ambulatory surgical centers (ASCs) and (ii) hearing aids. The Device is reimbursable by Medicare, but hearing aids are not covered by Medicare. According to the Manufacturer, some patients benefit from having the Device implanted in one ear and a hearing aid in the other ear with less severe hearing loss. Under the Proposed Arrangement, the Device would be purchased by a hospital or ASC at the request of the patient's provider, and the Manufacturer would provide a hearing aid for free. The free hearing aid would be conditioned on the purchase of the Device, and the Manufacturer expected that both patients and their providers would be aware of the availability of free hearing aids from the Manufacturer. The Manufacturer proposed to make the free hearing aids available to all patients or alternatively impose financial need criteria.

Analysis

The Proposed Arrangement would implicate the federal Anti-Kickback Statute (AKS) because the free hearing aids may induce patients to arrange for the ordering and purchasing of the Device, which is reimbursable by Medicare and Medicaid. Of note, the OIG analyzed the Proposed Arrangement under the relatively new patient engagement and support safe harbor, making this advisory opinion only the second time the OIG has provided guidance on this particular safe harbor since it was implemented in January 2021. (The OIG references the safe harbor in a footnote in OIG Advisory Opinion 20-08.) The patient engagement and support safe harbor protects items or services given to patients in order to improve quality, health outcomes, and efficiency. The OIG provides a non-exclusive list of examples of the types of items that can be protected to include:

- air filters and purifiers,
- temporary housing,
- broadband access,
- grocery or meal delivery services,
- vehicle modifications, and
- exercise programs.

But this safe harbor includes a number of fairly onerous requirements, including the requirement to form a value-based enterprise intended to achieve one or more value-based purposes (e.g. improving the quality of care; appropriately reducing costs for payors); the item or service furnished to patients must have a direct connection to the coordination and management of care for a patient population; and the item or service must advance certain health care goals (e.g., adherence to a treatment plan; management of a disease). Moreover, the safe harbor sets a monetary cap that is presently \$570 per beneficiary per year for 2023. (The monetary cap is **adjusted annually**.)

Unfortunately, the OIG offered minimal guidance on the safe harbor, merely noting that the hearing aids' retail value of \$1,180 to \$2,240 exceeds the safe harbor's monetary cap. Moreover, though the OIG does not raise this issue in the advisory opinion, the patient engagement and support safe harbor is not

available for certain types of entities, including device manufacturers like the Manufacturer, based on the OIG's longstanding view that these types of entities present a higher risk of offering remuneration to patients as a means to market their products rather than to improve the coordination and management of patient care.

Having dispensed with the only relevant safe harbor, the OIG determined that the Proposed Arrangement could result in inappropriate steering of patients to the Device over competitors' devices or other clinically appropriate treatment options, since patients are able to choose which manufacturer that their provider orders a device from and the patients would likely be aware of the availability of a free hearing aid from the Manufacturer. The free hearing aid from the Manufacturer could also result in unfair competition giving the Manufacturer an unfair advantage over competitors who may not be in a position to offer a similar benefit.

Conclusion

Ultimately, the OIG's determination in this advisory opinion is not particularly unexpected. While the OIG has issued a series of favorable advisory opinions on free items or services to patients, those advisory opinions involved health care providers rather than device manufacturers furnishing cash, gift cards, and other items to patients as part of their treatment plan or to incentivize patients to obtain preventive care services. In contrast to the Proposed Arrangement, these favorable advisory opinions generally entailed arrangements where the providers were using protocol-driven treatment programs to offer free items with a relatively modest retail value and the providers refrained from advertising the free items or services outside of the providers' existing patient bases. For more information on these Advisory Opinions, please see our [March 15, 2022 blog post](#).

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