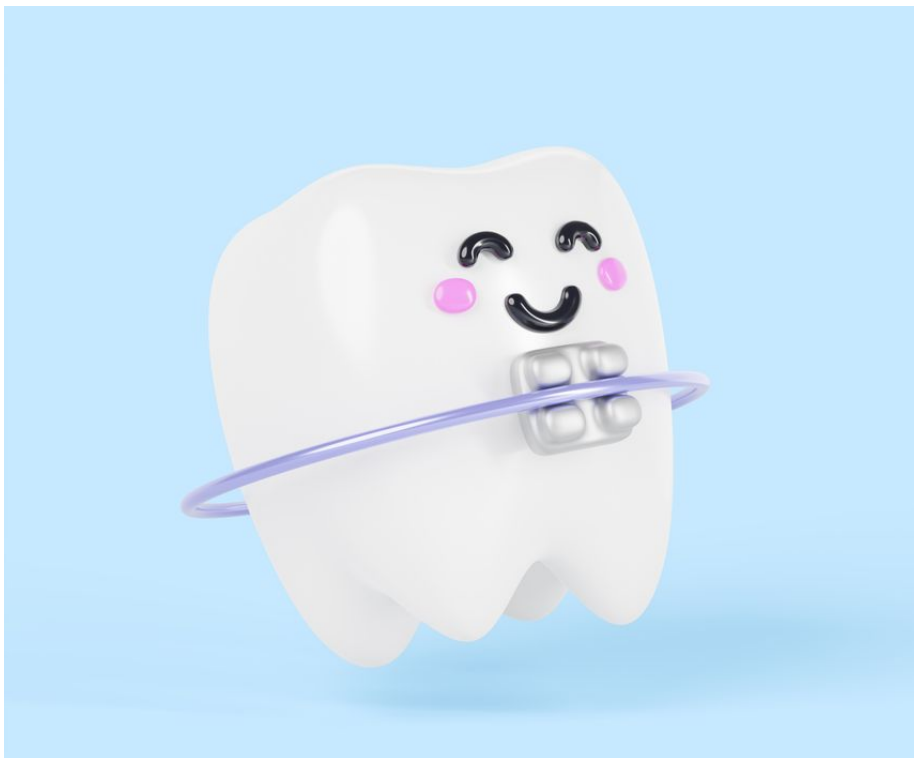


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Something to Smile About: OIG Issues Favorable Advisory Opinion on Charitable Orthodontic Care for Underserved Pediatric Patients

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The U.S. Department of Health and Human Services Office of Inspector General (the OIG) recently issued a favorable advisory opinion approving a pediatric dental and orthodontic services provider's (the Requestor) proposal to provide free orthodontic treatments to underserved pediatric patients. Although the OIG concluded that the proposed

arrangement could generate prohibited remuneration under the federal Anti-Kickback Statute (the AKS) and the civil monetary penalty provision prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP), the agency determined it would not impose administrative sanctions on the Requestor because the proposed arrangement carries a low risk of fraud and abuse.

How Would the Proposed Arrangement Work?

The Requestor proposed to provide free orthodontic treatments to up to three patients per year — one at each of the Requestor’s three locations. The treatment would span one to two years and would be valued at approximately \$4,725 per patient. The Requestor’s treating dentists and orthodontists would nominate existing patients to receive the free services based on the following guidelines:

- Patients must be between the ages of 10 and 14
- Patients must have a clinical need for orthodontics
- Patients must have financial need
- If insured, patients would need documentation that the orthodontic treatment had been denied by their insurer
- Patients must meet basic oral health requirements as determined by a licensed dental provider
- Patients must have the potential for “community impact” (e.g., foster care status or single-parent household)

To select patients, the Requestor would use a weighted scoring system considering clinical need, financial hardship, and community impact. The Requestor certified that it would not promote the free orthodontic treatments in a way designed to attract or induce new patients. Among other things, the Requestor certified that it would not publicize that it selects recipients from its patient population

and would not promote an ongoing opportunity for selection for the free services. Additionally, the Requestor certified that it would not advertise the availability of free services in its offices or through targeted messaging to its current or potential patients. Instead, the Requestor would only publicize the free services for the purpose of highlighting its community service and the positive impact on recipients. But this publicity would not include any solicitation or promotional language.

The OIG's Analysis: Why the Risk Is Low

According to the OIG, the proposed arrangement implicates the AKS because the Requestor would offer remuneration, in the form of free orthodontics services, to patients, including federal healthcare program beneficiaries. Those patients could then, in turn, refer themselves to the Requestor for services billable to a federal healthcare program. Similarly, the OIG determined that the proposed arrangement implicates the Beneficiary Inducements CMP because it could influence beneficiaries to select the Requestor for services reimbursable by a federal healthcare program. Yet, despite its longstanding concerns about the provision of free items or services to patients, the OIG concluded that the proposed arrangement presents a sufficiently low risk of fraud and abuse under the AKS and Beneficiary Inducements CMP for several reasons.

- 1. Reduced Risk of Patient Steering.** The proposed arrangement includes safeguards that reduce the risk that it would steer new patients to the Requestor. For example, the free services would only be available to existing patients who have already selected the Requestor for their care, the Requestor would not promote the fact that it selects from among its patient population or offers an ongoing opportunity for selection for free services, and patients would not be able to nominate themselves for the free services. These safeguards significantly reduce the risk that new

patients would be steered toward the Requestor in the hopes of being selected.

2. **Unlikely to Lead to Inappropriate Utilization or Increased Costs.** The proposed arrangement is not likely to generate inappropriate utilization or increased costs to federal healthcare programs because the Requestor would not bill any federal healthcare program for the free services. Further, the factors for selection (clinical need, financial hardship, and community impact) do not incentivize patients to increase their utilization of the Requestor's services. Additionally, recipients of the free care would not be required to obtain any additional services from the Requestor. The oral health screening included in the selection criteria could be performed by any provider of the patient's choosing, not necessarily the Requestor.
3. **Limited Publicity.** The OIG also emphasized that the Requestor would make limited public reference to the free services that would consist of general descriptions of the charitable purpose of the program, summaries of patient outcomes, and consensual testimonies from selected patients. According to the OIG, it likely would have rejected the proposed arrangement if the Requestor intended to promote the fact that it selects recipients of free services from its patient population or on an ongoing basis because of the risk that such actions would lead to patient steering and unfair competition.

Practical Takeaways for Healthcare Providers

Although the OIG's advisory opinion is only applicable to the Requestor, it offers lessons for providers seeking to provide charitable services to their underserved patients:

- **Limit eligibility to existing patients.** Charitable programs that are available only to patients who have already selected the provider significantly reduce the risk of patient steering. Providers should avoid structuring charitable programs in a

way that could attract new patients or influence patient choice.

- **Do not bill federal healthcare programs for the free service.** Not billing federal programs for the charitable services reduces the risk of inappropriate utilization and increased costs to those programs.
- **Restrict marketing and publicity.** Providers should not publicize that the charitable program selects from among the provider's own patient population or that it presents an ongoing opportunity for selection. Any public reference should be limited to highlighting the community service aspect without solicitation or promotional language.
- **Use objective, documented selection criteria.** A consistently administered, weighted scoring system based on clinical need, financial hardship, and community impact — rather than factors that incentivize utilization — reduces the risk of fraud and abuse.
- **Do not require recipients to obtain other services from the provider.** There should be no requirement or expectation that recipients obtain other services from the provider, and patients should be free to obtain related services from the provider of their choosing.
- **Keep the scope modest.** The OIG viewed the arrangement favorably in part because it contemplated only a small number of recipients per year. Providers should be cautious about scaling charitable programs beyond what is necessary for their charitable purpose.
- **Maintain records and conduct audits.** Thorough documentation of nominations, decisions, and the selection process, along with periodic audits, supports transparency and demonstrates good faith compliance.

Akerman's Healthcare Practice Group is available to answer questions you may have about setting up a charity care program.

This blog was drafted with the assistance of an Artificial Intelligence (AI) tool.