PUBLICATION

OIG Approves Charitable Pediatric Clinic's Cost-Sharing Waivers in Advisory Opinion 19-01

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On January 9, in its first Advisory Opinion of 2019 (OIG Advisory Opinion 19-01), the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), issued a favorable opinion regarding an arrangement under which a charitable pediatric clinic waives any patient cost-sharing amounts while seeking to improve the health care of a large number of at-risk children living in its service area. The OIG concluded that the arrangement presents minimal risk of fraud and abuse under the Anti-Kickback Statute (AKS). In addition, although the arrangement did not fall squarely within an exception to the civil monetary penalty provision related to beneficiary inducements (Beneficiary Inducements CMP), the OIG concluded that the arrangement posed a minimal risk of generating prohibited remuneration and that it would not impose sanctions under the Beneficiary Inducements CMP.

The pediatric clinic requesting the advisory opinion offers medical, psychiatric, and dental care services to its pediatric patients in an area where census data shows close to 60 percent of the city's children reside in households reporting at or below federal poverty level (FPL). The clinic rests within designated Health Professional Shortage Areas for its specialties and is also situated a short distance outside a designated Medically Underserved Area.

To qualify for the clinic's health services, patients are required to meet certain residency, age, and financial need standards established by the clinic. The financial need standards require that a patient must either:

- participate in Medicaid;
- participate in a state health care program; or
- present evidence of household income at or below 200 percent of FPL.

Patients who meet the financial need standards are designated as "Enrolled" patients, while those who have not satisfied the financial standards are designated as "Non-Enrolled." The clinic certified that it annually reevaluates the financial need of Enrolled patients, and that many Non-Enrolled patients meet FPL guidelines; however, they do not meet its financial need standards due to lack of participation in state health insurance programs or lack of adequate proof of income. In limited instances (e.g., emergency dental care), the clinic will provide services to Non-Enrolled patients. In those instances, the clinic will stabilize the patient's condition and then refer him or her to other providers for medically necessary follow-up care.

The clinic's arrangement involves waiving any applicable patient cost-sharing amounts as well as waiving total service costs to uninsured patients. The clinic submits claims and receives payment reimbursements from third-party payors, which include federal health care programs. While the majority of patients participate through state health insurance programs that carry no cost-sharing amounts, the clinic does provide limited health care services to patients covered by TRICARE and Medicare. In practice, the clinic routinely waives all cost-sharing obligations for patients covered under these federal health care programs; however, such waivers constitute a small percentage of the total services rendered by the clinic.

- A patient's medical condition and insurance status (whether government or other payor) are not determining factors in any patient's course of treatment or financial need eligibility.
- Cost-sharing waivers are not offered as a part of any clinic advertisement or solicitation.
- Physicians, dentists and other staff (employees or independent contractors) are not compensated in any manner that varies based on the volume or value of services performed or referrals made.
- The delivery of services are never tied, either directly or indirectly, to the provision of other items or services reimbursed by any federal health care program.
- No cost-sharing amounts waived by the clinic are ever claimed on cost reports as bad debts.
- No cost-sharing amounts waived by the clinic are ever shifted in a manner that creates an additional cost burden to third-party payors, including federal health care programs.

Legal Analysis

The OIG acknowledged the arrangement's failure to satisfy the elements set forth in the cost-sharing waiver exception that protects waivers of cost-sharing amounts offered to the financially needy only if such waivers are:

- Not offered as part of any advertisement or solicitation;
- Not routine; and
- Made following an individual determination of financial need.

In its analysis, the OIG first noted the limited extent to which the arrangement implicates the AKS with respect to the relatively few services it provides TRICARE and Medicare patients, and also the more limited extent to which it implicates the Beneficiary Inducements CMP through services provided to Medicare beneficiaries. (The Beneficiary Inducements CMP does not apply to TRICARE.) The OIG noted, however, it does not consider the waivers less "routine" simply because such waivers are applicable to only a small portion of the total patient population, since 100 percent of the clinic's patients still receive such waivers.

The number of implicated federal health care program patients was additionally reduced by the dual coverage from the state's health insurance programs. In a typical case, most cost-sharing amounts under federal programs are alleviated by the clinic patient's concurrent coverage under the state's programs. Thus, waivers of TRICARE or Medicare cost-sharing amounts would be applicable only when the clinic's services were not covered by the state's programs.

In addition to the limited application of the waivers, the OIG recognized the clinic's certification that such waivers are not advertised and that no financial incentives are available to health care providers as further reducing the risk surrounding the arrangement. The absence of advertising distinguished the arrangement from others involving routine waivers, and the lack of incentives safeguarded against patient steering and overutilization.

The OIG's risk analysis also took into account the circumstances particular to the clinic's location, including the low availability of health provider resources and the patient population. Observing the area's limited resources and the disproportionately large volume of children at or below FPL, the OIG reasoned that a lack of options, rather than any kind of improper inducements, would more likely be the force behind patients' attraction to the clinic. At the same time, the OIG emphasized that a lack of other health care providers by itself would not validate the use of routine cost-sharing waivers.

The combination of the above reasons in the particular context presented, as well as other safeguards that further reduced the risk of providing medically unnecessary services and increasing federal program costs, led the OIG to conclude that the arrangement posed a minimal risk under the AKS and that it would not impose sanctions under the Beneficiary Inducements CMP.

Additional Perspectives on Cost-Sharing Waivers

The OIG has consistently articulated its concern with routine waivers of cost-sharing amounts being used as an inducement to influence a patient's selection of a provider, practitioner, or supplier of health care items and services. This Advisory Opinion does not represent a retreat from this long-held position; however, it falls in line with other OIG guidance recognizing that waivers may be permissible in limited circumstances such as where there is a demonstrated financial need or where the waiver satisfies all elements of the CMP exception for waivers of cost-sharing amounts (*see* OIG Advisory Opinion 17-02 as addressed in Health Law Alert, July 2017.) While the waivers addressed in this Opinion were determined to be routine (i.e., 100 percent of the time) and did not fall into an exception, the OIG noted a number of other factors that led to its determination not to impose sanctions, including the unique circumstances of this clinic being located in overlapping HRSA-designated HPSAs, and the large number of area children in poverty. Thus, this Advisory Opinion is based on the very unique circumstances of the clinic involved.

It remains to be seen whether the OIG will add additional safe harbors or protections for waivers of copayments and deductibles as part of its regulatory sprint to coordinated care. The OIG's recent Request for Information seeks, among other things, input on how relieving cost-sharing amounts might improve care and suggested safeguards to include in any potential safe harbor for cost-sharing waivers. *(See* OIG Releases RFI Focused on Removing Barriers to Value-Based Care, Sept. 19, 2018.)