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AFFORDABLE HEALTH CARE: PATIENTS' CO-PAYS WAIVED BY CHARITABLE PEDIATRIC CLINIC

Recently, the Department of Health and Human Services Office of Inspector General ("OIG") issued a favorable advisory opinion, Advisory Opinion 19-01, concerning a charitable pediatric clinic (the "Clinic")'s arrangement under which the Clinic waives cost-sharing amounts for a small percentage of TRICARE and Medicare beneficiaries not covered by a state insurance program (the "Arrangement"). After a fact-specific analysis, OIG determined it would not impose administrative sanctions under the federal Anti-Kickback Statute ("AKS") or the Civil Monetary Penalties Law ("Beneficiary Inducement CMP").

BACKGROUND

The Clinic is a charitable pediatric clinic that provides medical, psychiatric and dental care to children residing in the county where it is located. This area contains a disproportionately large number of children residing in poverty, and the Clinic's mission is to improve health outcomes for the area's at-risk children. The Clinic is located in Health Professional Shortage Areas ("HPSAs") for primary care, dental care and mental health care and is near a designated Medically Underserved Area.

The Clinic imposes the following eligibility criteria for patients to receive continuing services:

1. The patient must reside in the county where the Clinic is located;
2. The patient must be less than 19 years old; and
3. The patient must satisfy the Clinic's financial need standard ("Need Standard").

Fulfillment of the Need Standard involves either: 1) participation in Medicaid or other state insurance program; or 2) evidence that the patient's family income does not exceed 200 percent of the federal poverty level. The Clinic certified that of its eligible patients ("Enrolled Patients"), more than 90 percent participate in at least one of the state insurance programs. The Clinic individually verifies that any remaining Enrolled Patients fulfill the Need Standard and reevaluates the financial need of those Enrolled Patients each year. The Clinic further asserts that less than 1 percent of its Enrolled Patients have TRICARE coverage and that very few (if any) of its Enrolled Patients are covered by Medicare.

In certain scenarios, the Clinic may also provide limited health services, such as emergency dental care, to pediatric patients whose families do not meet the Need Standard ("Non-Enrolled Patients"). According to the Clinic, many of these patients do not have a household income in excess of 200 percent of the federal poverty level but do not fulfill the Need Standard because they do not participate in a state insurance program or they did not provide the Clinic with sufficient evidence of their limited income. Once the Non-Enrolled Patients are stabilized, the Clinic refers them to other providers for follow-up care. The Clinic has provided emergency dental care to less than 50 Non-Enrolled Patients over the past several years and did not anticipate a significant increase in care provided to Non-Enrolled Patients.

Under the Arrangement, the Clinic waives any patient cost-sharing amounts, including the total cost of services to uninsured patients, but bills third party payors including federal health care programs. The majority of the Clinic's patients that are federal health care program beneficiaries participate in state insurance programs that do not require cost-sharing amounts. The Clinic's TRICARE and Medicare patients would only owe federal health care cost-sharing amounts if the patient is not also covered by a state insurance program. As less than 1 percent of the Clinic's patients have TRICARE coverage and Medicare only covers a select few patients at a given time, only a small number of the Clinic's patients have federal health care cost-sharing obligations.

OIG ANALYSIS

Anti-Kickback Statute

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration in an effort to induce or reward referrals of items or services reimbursable by federal health care programs. If just one purpose of an arrangement is to induce or reward referrals, the arrangement violates the AKS.

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OIG noted that the waiver of cost-sharing amounts related to federally reimbursable items or services may invoke liability under the AKS because such waivers may constitute prohibited remuneration to induce referrals.

Civil Monetary Penalties Law

The Beneficiary Inducement CMP prohibits offering items or services to federal health care program beneficiaries when the offeror knows or is likely to know that the item or service will induce the beneficiary to choose a particular health care provider for services. The waiver of copayments and deductibles can be viewed as an item or service that may influence a beneficiary.

An exception to the Beneficiary Inducement CMP's definition of "remuneration" exists for the waiver of copayments, subject to the following requirements:

1. The waiver is not offered as part of an advertisement or solicitation;
2. The entity does not routinely waive coinsurance or deductible amounts; and
3. The entity either:
   - Waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
   - The entity fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

OIG further addresses that the Arrangement does not meet all of the requirements of the exception to the CMP for the waiver of cost-sharing amounts offered to financially needy patients, as discussed below.

In its analysis, OIG noted that the Arrangement does not satisfy all of the criteria of the Beneficiary Inducement CMP exception, as the Clinic routinely waives cost-sharing amounts (albeit under limited circumstances). These routine waivers are only applicable to a small number of patients but extend to 100 percent of said patients. Furthermore, while the Clinic verifies the financial need of some patients, it does not do so for all patients with cost-sharing obligations. Nevertheless, OIG concluded that the Arrangement presents minimal risk of fraud and abuse under the AKS and the CMP due in part to the limited extent to which the Clinic's cost-sharing waivers implicate the AKS and the CMP. OIG paid particular attention to the fact that the Clinic only waives cost-sharing amounts for a limited number of TRICARE and Medicare beneficiaries who are not covered by a state insurance program, as state insurance program beneficiaries do not have a cost-sharing obligation. Therefore, the Clinic's cost-sharing waivers apply only to a very small subset of patients. Furthermore, the Arrangement implicates the CMP to an even lesser extent, as the CMP is inapplicable to TRICARE.

Safeguards

In its analysis, OIG identified the following safeguards that the Clinic implemented pursuant to the Arrangement:

- The Clinic waives cost-sharing amounts for very few patients without individually verified need. In fact, there may be some years where no such patients exist. Most of the Clinic's patients are Enrolled Patients, and the Clinic individually verifies need for all Enrolled Patients that are not state insurance program participants.
- The provision of limited services to Non-Enrolled Patients who may not satisfy the Clinic's Need Standard constitutes a small percentage of the Clinic's aggregate services.
- The Clinic does not advertise the waiver of cost-sharing amounts.
- The Clinic does not compensate physicians, dentists or other staff in a manner based on the volume or value of services performed or referrals made and does not provide financial incentives to direct patient referrals to the Clinic or order unnecessary care.
- The overlapping HPSA areas indicate that the lacking local health care infrastructure and absence of provider options will likely draw patients to the Clinic as opposed to any improper inducement under the Arrangement.
- The Clinic implements numerous additional safeguards that minimize risks posed by the Arrangement, such as the following: 1) the Clinic does not take into account the patient's medical condition or insurance status when considering eligibility or determining a course of treatment; 2) the Clinic does not tie the delivery of services to the provision of other services reimbursed in whole or in part by a federal

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health care program; and 3) the Clinic does not claim any cost-sharing reductions or waivers as bad debt on its Medicare Cost Report.

However, due to the Arrangement's limited implications to the AKS and the CMP as well as the safeguards implemented by the Clinic, OIG stated that it would not impose administrative sanctions against the Clinic for any potential AKS-related issues.

PRACTICAL TAKEAWAYS

The waivers of copayments allow for increased access to health care for vulnerable patient populations. However, this opinion specifically suggests that infrequent waivers of copayments may still be considered routine if such waivers occur each time an applicable patient receives health care services.

When the requirements of the applicable Beneficiary Inducement CMP exception are not satisfied, OIG may consider the routine waiver of cost-sharing obligations of beneficiaries permissible under limited circumstances so long as certain safeguards are implemented. Providers that are considering waiving cost-sharing obligations should review the specific facts and circumstances at issue to ensure compliance with the applicable AKS and CMP regulations.

If you have any questions regarding this Advisory Opinion or any other fraud and abuse concerns, please contact:

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