OIG APPROVES WAIVER OF COST-SHARING AMOUNTS FOR FINANCIALLY NEEDY BENEFICIARIES PARTICIPATING IN CLINICAL RESEARCH STUDIES

On June 29, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") issued a favorable advisory opinion, Advisory Opinion 17-02, concerning a hospital (the "Hospital") outpatient facility's proposal to waive or reduce cost-sharing amounts owed by financially needy Medicare beneficiaries for items and services furnished in connection with a clinical research study (the "Arrangement"). After a fact-specific analysis, OIG determined it would not impose administrative sanctions under the federal Anti-Kickback Statute (“AKS”) or civil monetary penalties under the prohibition on beneficiary inducements (“Beneficiary Inducement CMP”).

BACKGROUND

The Hospital is a nonprofit regional medical center that operates an outpatient wound care center to treat chronic, non-healing wounds (the "Center"). A biomedical company (the "Company") manufacturers a Food and Drug Administration-approved wound care therapy product (the "Product"), which uses autologous platelet rich plasma ("PRP"). In 2012, the Centers for Medicare & Medicaid Services ("CMS") issued a National Coverage Determination approving the Medicare Coverage with Evidence Development ("CED") framework for the use of PRP treatments for chronic, non-healing diabetic, pressure or venous wounds in approved clinical studies. CMS approved three separate protocols under the CED framework to study the treatment of Medicare beneficiaries' chronic, non-healing wounds using the Company's Product (each, a "Study"). The Center is a participating site for the Studies.

Pursuant to the CED, Medicare covers the Product, as well as related items and services, only when they are furnished to Study-enrolled beneficiaries. Medicare beneficiaries are responsible for any co-payments owed for the items and services they receive in connection with a Study. For dual-eligible beneficiaries that are enrolled in Medicare and Medicaid, Medicaid often pays for cost-sharing for Medicare items and services to the extent the services are consistent with the Medicaid State Plan. However, Medicaid may not cover items and services provided in connection with clinical research studies and therefore, may not pay for the cost-sharing of dual-eligible beneficiaries. The Company and the Hospital asserted that the cost-sharing obligations incurred through Study participation might deter some financially needy beneficiaries, particularly dual-eligible beneficiaries, from participating.

Under the Arrangement, the Center proposed to reduce or waive applicable cost-sharing amounts owed by financially needy beneficiaries for all Study-related items and services. The determination of financial need would depend on the Hospital's existing financial need policy, which requires the beneficiary to provide the following:

- Payroll check stubs from the most recent three months;
- The most recent tax return if pay stubs are unavailable;
- Unemployment records;
- Documentation of government benefits; and
- Any other financial documentation reasonably requested by the Hospital.

Based on the documentation provided, the Hospital then uses monthly family income (as defined by the United States Census Bureau) and savings to determine the beneficiary's financial need based on a sliding scale. The sliding scale is determined using certain percentages of the Federal Poverty Level.

OIG ANALYSIS

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. In the Advisory Opinion, OIG first noted that providers who routinely waive Medicare cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship may be liable under the AKS because such waivers may constitute prohibited remuneration to induce referrals. However, due to the safeguards included in the Hospital's financial assistance policy, and the satisfaction of an exception to the Beneficiary Inducement CMP, as described below, OIG stated that it would not impose administrative sanctions against the Company or the Hospital for any potential AKS-related issues.

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. However, because the Arrangement satisfied all of the criteria of the waiver of copayments exception to the Beneficiary Inducement CMP's definition of "remuneration," OIG determined that the Company and the Hospital would not impose civil monetary penalties under the prohibition on beneficiary inducements.

The Beneficiary Inducement CMP exception for the waiver of copayments requires that:

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:
   a. Waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
   b. The entity fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

In its analysis, OIG paid particular attention to the fact that the Hospital's financial assistance policy was very robust. Notably, OIG identified the following favorable facts of the Arrangement.

- The Company would not compensate or reimburse the Center or the Hospital in any manner for reduced or waived cost-sharing amounts.
- As part of the informed consent process, a Study investigator would inform the beneficiary of cost-sharing obligations in connection with the Study.
- If the beneficiary notified an investigator that he or she lacked the resources to cover the cost sharing amounts, the Center would make a reasonable inquiry, to determine on an individual basis, whether the beneficiary satisfied the objective financial need criteria of the Hospital's financial need policy.
- The Hospital would not claim any cost-sharing reductions or waivers as bad debt on its Medicare Cost Report.
- Neither the Hospital, the Center nor the Company would advertise cost-sharing reductions or waivers.

Much of OIG's analysis turned on the application of the Hospital's financial need policy and the importance of an individualized, good faith determination of financial need. While OIG did not specify any particular method of determining "financial need," it determined the Hospital's policy, as outlined above, would result in a reasonable inquiry to determine, on an individualized and objective basis, whether the beneficiary is in need of cost-sharing assistance.

PRACTICAL TAKEAWAYS

The waiver of copayments and deductibles provides an opportunity for health care providers to increase access to health care in the communities they serve. Further, this opinion specifically suggests OIG may consider the waiver or reduction of cost-sharing obligations of Medicare beneficiaries that wish to participate in clinical research studies permissible, provided there is adherence to certain safeguards. Hospitals that are considering waiving cost-sharing obligations for Medicare beneficiaries participating in clinical research should review their charity care and financial need policies to determine whether the policies contemplate individualized assessments of objective financial need criteria in the context of clinical research.

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

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