PUBLICATION

OIG Approves Cost-Sharing Arrangement Involving Clinical Research Study

July 2017

The U.S. Department of Health and Human Services, Office of the Inspector General (OIG), issued a favorable advisory opinion, No. 17-02, regarding a proposed arrangement under which the cost-sharing amounts owed by financially needy Medicare beneficiaries would be reduced or waived for items and services furnished in connection with a clinical research study. In the advisory opinion, issued June 29, 2017, the OIG concluded that the proposed arrangement would not constitute grounds for the imposition of sanctions under the civil monetary penalty against beneficiary inducements (Beneficiary Inducements CMP), or under the anti-kickback statute (AKS).

The requestors were a non-profit hospital's (Hospital) outpatient facility (Center) that furnishes wound care services, and a biomedical company (Biomedical Company) that manufactures a Food and Drug Administration-approved wound care therapy system (Wound Care System). The Biomedical Company's Wound Care System and related items and services, if furnished in connection with a CMS-approved clinical study, are eligible for Medicare coverage based on the Medicare Coverage with Evidence Development (CED) framework approved by an August 2012 National Coverage Determination from the Centers for Medicare & Medicaid Services (CMS). CMS approved three studies (Study(ies)) using the Wound Care System to study the treatment of Medicare beneficiaries' chronic, non-healing wounds. The Center was designated as a participating site.

Although the Wound Care System was approved for Medicare coverage in connection with each Study, Medicare beneficiaries who enroll in a Study are responsible for copayments owed for services or items received. The Requestors' concern, however, was that Medicare beneficiaries who are also Medicaid beneficiaries (dual-eligible beneficiaries) may be deterred from participating in a Study because Medicaid (in the state the Center is located) may not pay for Medicare items or services provided in connection with a clinical research study and therefore may not pay for any associated cost-sharing. To address this concern, the Requestors proposed to reduce or waive the cost-sharing amounts for financially needy Medicare beneficiaries participating in the Studies.

The OIG first concluded that the proposed arrangement implicated the Beneficiary Inducement CMP, as its definition of *remuneration* includes the waiver of coinsurance and deductible amounts. However, the OIG then analyzed an exception to this definition and determined that the proposed arrangement satisfies all of the elements of the exception. The OIG explained that the cost-sharing reduction or waiver:

1. Will not be offered in any advertisement or solicitation. Additionally, the beneficiary will be informed of the potential waiver or reduction only once the Study investigator notifies the beneficiary that he or she may have cost-sharing responsibilities and the beneficiary then informs the Study investigator that he or she may not have the financial resources to cover the cost-sharing amount;
2. Will be contingent on the beneficiary's inability to pay the amounts owed, based on the Center's determination on a case-by-case basis, using the Hospital's financial need policy and substantiated through required documentation; and
3. Will be offered only once the Center determines, in good faith, that the individual is in financial need.

Finally, the OIG concluded that it would not impose administrative sanctions under the AKS even though the proposed arrangement could potentially generate prohibited remuneration.

Baker Donelson's Comments

Over the years, the OIG has publically expressed its long-standing concern with *routine* waivers of coinsurance and deductibles. *See*, e.g., Dep't of Health and Human Servs., Office of Inspector General, Special Fraud Alert (Dec. 19, 1994). As analyzed in the advisory opinion, however, the regulatory and Beneficiary Inducement CMP's definition of *remuneration* explicitly carves out an exception for non-routine waivers of coinsurance and deductibles based on individualized, good faith assessments of financial hardship. Therefore, it is no surprise the OIG determined that, under the facts presented, this proposed arrangement satisfied the necessary criteria and did not constitute prohibited remuneration.