PUBLICATION

OIG Approves Subsidies to Medicare Beneficiaries Provided by a Clinical Research Study [Ober|Kaler]

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On May 28, 2015, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued an advisory opinion approving a medical device manufacturer's proposed arrangement to provide subsidies to certain patients participating in a clinical research study. In Advisory Opinion 15-07, the OIG concluded that this arrangement would potentially generate prohibited remuneration under the antikickback statute and implicate the civil monetary prohibition against inducements to beneficiaries, but the OIG would not impose sanctions under either statute based on the unique facts of this clinical research study.

The Advisory Opinion's requestor manufacturers a set of specialized instruments designed to perform minimally invasive direct decompression of the lumbar spine in patients with lumbar spinal stenosis. This procedure is referred to as percutaneous image-guided lumbar decompression (PILD). Currently, Medicare provides coverage for PILD only in limited circumstances related to clinical research.

In January 2014, the Centers for Medicaid and Medicare Services (CMS) issued Medicare National Coverage Determination (NCD) 150.13, which states that PILD for lumbar stenosis is not “reasonable and necessary” under section 1862(a)(1)(A of the Social Security Act and, accordingly, will not be covered by Medicare. Nonetheless, under NCD 150.13, Medicare will cover PILD for lumbar spinal stenosis under the Coverage with Evidence Development (CED) Program for Medicare beneficiaries who received PILD as part of a clinical research study approved by CMS. NCD 150.13 states that the clinical research study must be designed to determine whether PILD improves the function and/or quality of life in Medicare beneficiaries with lumbar spine stenosis compared to alternative treatments. NCD 150.13 also significantly limits the design of these clinical research studies, and one such limitation is that the clinical research study must include a “sham controlled arm,” where randomized participants will receive a sham surgery to try to control for the “placebo” effect.

The requestor developed a clinical research study (Study) that is not limited to Medicare beneficiaries and that has called for 120 patients to be randomly assigned to receive either PILD or the sham surgery. While the requestor was developing the Study, it encountered an issue with the patients' copayments. Upon CMS's approval of the Study and consistent with NCD 150.13, Medicare will provide coverage for the Medicare beneficiaries, including their copayments for facilities' charges and the physicians' professional charges. However, the facilities and physicians will be unable to charge and collect copayments from patients who receive the sham surgery. According to the requestor, failing to charge the patients who receive the sham surgery copayments would compromise the Study because the patients would know they are in the control group that does not receive PILD.

The requestor consulted with CMS regarding the copayment issue and, with CMS's endorsement, decided that the best solution was for it to pay the applicable copayments for all Medicare beneficiaries enrolled in the Study. The requestor will pay the copayments directly to the facilities or physicians. Additionally, the requestor will also pay for the costs of PILD for patients who received the sham surgery if these patients elect to have PILD following the end of the Study or after the patient's early exit. The requestor stated that the purpose of these two subsidies was to encourage patients to enroll in the Study.

Analysis under Antikickback Statute and Civil Monetary Penalties (CMP) Law

The OIG began by concluding that the arrangement implicated the antikickback statute and CMP. Specifically, the OIG found that because Medicare reimbursed for the PILD when the procedure was performed under the Study, which met certain conditions listed in NCD 150.13, the arrangement could generate prohibited remuneration if the requisite intent was to induce or reward referrals of federal health care program business. In spite of the antikickback implications, the OIG concluded that the arrangement presented a minimal risk of fraud and abuse for the following reasons:

The arrangement is consistent with CMS's policy objectives because the requestor has designed the Study in consultation with CMS and in accordance with the conditions listed in NCD 150.13. The Study's results will assist CMS in determining whether PILD is reasonable and necessary for Medicare to cover the procedure outside of a clinical research study setting.

The requestor asserted the subsidies were necessary to facilitate a randomized, controlled, double-blind study with appropriate comparative treatments. This assertion is consistent with CMS's requirements for the study to be double-blind. The arrangement also reasonably achieves the Study's goals because it encourages patient enrollment and it allows the Study to determine whether PILD improves the function and/or quality of life in Medicare beneficiaries with lumbar spine stenosis compared to alternative treatments.

The arrangement is not designed to induce any physician or entity to refer federal health care program beneficiaries to use the requestor's set of special instruments designed for PILD, except for purposes of the Study. Additionally, all compensation paid in connection with the arrangement is fair market value for necessary Study-related services.

To participate in the Study, patients must meet the Study protocol's enrollment criteria and execute an informed consent document. Participating physician investigators must comply with the Study's protocol while being subject to oversight and monitoring by the Institutional Review Board. Further, subsidies are provided to only a small number of patients enrolled in the Study. These three factors reduce the risk that the arrangement results in overutilization or increased costs to the federal health care programs.

For these same reasons, the OIG concluded that it would not impose sanctions under the CMP law based on the facts of this particular arrangement.

Ober|Kaler Comments

Advisory Opinion 15-07 is instructive as to how the OIG analyzes subsidies provided to patients to enroll in clinical research studies. The applicability of this advisory opinion is fairly limited given the unique facts surrounding this clinical research study.