OIG Approves Certain Subsidies for Clinical Trial Subjects

06-10-15 • alert • katherine leibowitz

Last week, OIG released an advisory opinion (No. 15-07) that would allow a medical device manufacturer (Requestor) to pay:

(1) the copayments for all Medicare beneficiaries participating in the Requestor's clinical trial (Study); and

(2) the costs of the medical procedure performed using the Requestor's surgical instruments (System) for certain control group patients (together, the Subsidies).

Importantly, the control group receives a sham medical procedure. According to the Requestor, the purpose of the Subsidies is to encourage patients to enroll in the Study, as otherwise, individuals may be reluctant to participate in a research study known to include a sham, or placebo, group. This advisory opinion reflects an unusual interplay between a trial sponsor's budget decisions and the study integrity, with the former directly impacting the latter.

Factual Background

The Study is designed to test the System to treat lumbar spinal stenosis through a procedure known as percutaneous image-guided lumbar decompression (PILD). The Study is a prospective, multi-center, randomized, controlled, double-blind trial. The Study control group receives a sham procedure. The Centers for Medicare & Medicaid Services (CMS) last year determined that PILD for lumbar spinal stenosis is not "reasonable and necessary" and, therefore, will not be covered; however, Medicare will cover PILD for lumbar spinal stenosis under its Coverage with Evidence Development (CED) Program if PILD is performed as part of a clinical trial that meets certain conditions. These conditions include that the study satisfies criteria established by CMS and that CMS approves the study itself.

For each Study site, the manufacturer (Requestor) has entered into a written agreement with the principal investigator and his/her medical practice and may also have written agreements with the associated hospitals or ambulatory surgical centers. The agreements address each party's Study obligations and the compensation Requestor will pay. Requestor certified that the payments are fair market value for necessary Study-related services. Further, the investigators have proper experience, and the Study includes caps on the numbers of sites and patients.

Copayments:

Medicare beneficiaries would typically be charged copayments for the facilities' services and the physicians' professional services. For beneficiaries who receive the sham procedure, it would be inappropriate to charge copayments because no items or services are rendered with therapeutic intent. Requestor states that failing to charge control group subjects who receive the sham procedure while charging subjects in the treatment group would compromise the Study design because the subjects who are not charged would realize they are in the control group.

Requestor consulted with CMS, and together they decided that the Requestor should pay the copayments for all Medicare beneficiaries, regardless of treatment group. In a footnote, OIG explains that for subjects with private insurance that denies coverage for the sham procedure, Requestor states that it covers all of the costs for which the third-party payor does not provide coverage because, otherwise, only Medicare beneficiaries would be able to enroll in the trial.

Procedure Subsidy:

The Study protocol primary endpoint is six months post-procedure. Subjects who fail to meet the primary endpoint may be unblinded to determine whether they are in the treatment group or control group. Once unblinded, control group subjects who are failures will have the opportunity to undergo the PILD procedure using the System if they wish. If the subject elects to do so, the Requestor will pay all costs of the PILD procedure using the System. (Requestor explains that Medicare will not cover the costs because of how the CED Program works.) The Requestor does not pay for any other treatments. Patients are made aware of this potential subsidized procedure in the informed consent.

The Requestor pays both the copayment and procedure Subsidies directly to the person or entity to whom the subject would otherwise owe the payment.

OIG Analysis

In the advisory opinion, OIG concludes that it will not impose administrative sanctions on the manufacturer even though the arrangement (Arrangement) implicates both Federal anti-kickback and beneficiary inducement laws. OIG's justifies its opinion as follows:

1. The Arrangement is consistent with CMS policy objectives, including the CED Program.

2. The Arrangement is a reasonable means of achieving the Study's goals because it encourages enrollment and allows for the true impact of the procedure using the System to be assessed.

3. The Arrangement does not appear to be designed to induce the investigators, other persons, or entities to use or arrange for use of the System other than as part of the Study. Supporting OIG's conclusion is the following certification by Requestor:

    a. "...the Arrangement is not dependent upon, and does not operate in conjunction with, either explicitly or implicitly, any other arrangement or agreement between or among Requestor, the participating physician investigators, the Sites, any patient who enrolls in the Study, or any other party in a position to refer or arrange for the referral of items or services reimbursable by any Federal health care program. Furthermore, Requestor certified that the compensation it pays in connection with the Arrangement is fair market value for necessary Study-related services."

4. The risk that the Arrangement will result in overutilization or increased costs to the Federal health care programs is reduced based on the following factors:

    a. Subjects must satisfy the Study protocol enrollment criteria;

    b. Subjects must sign an informed consent;

c. Investigators must comply with the protocol;

d. Investigators are subject to oversight and monitoring by an institutional review board; and

e. Subsidies may be provided only to a small, predetermined number of patients enrolled in the Study.

Conclusion

Even though the Arrangement presents fraud and abuse risk, OIG chooses instead to focus on the bona fides of the Study, such as Study design, CMS involvement and policy objectives, structures designed to ensure regulatory compliance, lack of suspect relationships, and the practical effect of the sham procedure on the overall Study feasibility. The opinion reflects the impact of the clinical trial agreement budget on the Study integrity.

The advisory opinion is limited to the facts of the Arrangement. Absent unique circumstances such as these, trial sponsors should be aware that covering copayments for Medicare beneficiaries risks violating the Federal anti-kickback and beneficiary inducements statutes. The anti-kickback statute is a criminal statute, and the penalties for violations can be severe, including fines, felony conviction punishable by imprisonment, or both, as well as possible exclusion from participation in Federal Healthcare Programs (e.g. Medicare, Medicaid, and TRICARE). As a general rule, sponsors should craft clinical trial agreement budget exhibits in a manner that reduces the risks of overutilization of or increased costs to Federal health care programs.

If you have any questions or would like more information about these developing issues, please contact the following:

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