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Healthcare Alert

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OIG provides opinion on cost-sharing subsidies that would increase socio-economic diversity of clinical research subjects

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OIG issues an advisory opinion on subsidies of cost-sharing obligations in sponsored clinical trial to expand socio-economic diversity in clinical research participants, including Medicare beneficiaries.

What's the Impact?

- Provides insight on safeguards and socio-economic diversity factors that may be incorporated into clinical trial programs to attempt to lower the risk of fraud and abuse scrutiny by the OIG

On March 11, 2022, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion No. 22-05 finding that a medical device manufacturer's program permitting certain Medicare cost-sharing obligations in the clinical trial would pose minimal risk under federal fraud and abuse regulations. OIG reviewed the arrangement in the context of a clinical trial with the intent to create socio-economic diversity in the subjects.

Background

Proposed Arrangement

A medical device manufacturer (the Requestor) manufactures a device used for investigational therapy. The Requestor is sponsoring a clinical trial to study the safety and effectiveness of the therapy in patients at roughly 40 sites with each participating site to meet certain requirements and comply with all federal and state laws and regulations, including oversight and monitoring by an Institutional Review Board.

The Requester submitted an inquiry to the OIG as to whether certain subsidies provided under a proposed arrangement (the Proposed Arrangement) would trigger sanctions under the federal Anti-Kickback Statute (AKS), the provision prohibiting inducements to Medicare beneficiaries under the Civil Monetary Penalties Law (CMPL), or the OIG's exclusion authority. Through the Proposed Arrangement, the Requestor would provide remuneration to study sites and/or investigators by providing an opportunity to bill Medicare for items and services related to the study, and guaranteed payment of beneficiaries' cost-sharing obligations (i.e., patients' copays, co-insurance, deductibles, etc. would be covered by the manufacturer). The Requestor would provide the same subsidy to study participants regardless of how such services are reimbursed (i.e., commercial, Medicaid, or Medicare).

Cost-sharing intent

The Requestor stated that the proposed cost-sharing subsidies will serve three purposes for the study:

- *Reduce financial barriers for eligible study participants and reduce study participant attrition during the study's course*: The projected costs for the study, which will be conducted over a two-year period requiring nine visits, would likely total $1,300 per beneficiary, which may otherwise be cost-prohibitive for a large population of beneficiaries otherwise eligible to participate. By providing the subsidies, the Requestor would more likely be able to attract, enroll, and maintain the study participants necessary and appropriate to complete the study.
- *Facilitate socio-economic diversity of study participants*: The subsidies would reduce potential financial barriers to enroll socio-economically diverse study participants that would otherwise not occur if the cost-sharing obligations are imposed upon beneficiaries.
- *Preserve blinding of study participants*: By not billing for items and services provided during the study, control group recipients would not be alerted that they did not receive any therapeutic benefit from the study. Subsidizing the cost-sharing obligations for both groups prevents study participants from becoming aware of their status in the study.

Legal analysis

The OIG determined that the Proposed Arrangement would implicate the AKS because the Requestor's payment of the subsidy may inappropriately encourage Medicare beneficiaries to

participate in the study to receive billable healthcare items and services reimbursed through the Medicare program. The OIG determined that the CMPL would also be implicated because the subsidies may influence the beneficiary's decision to obtain Medicare-billable items and services from the Requestor. The OIG further determined that the Proposed Arrangement failed to meet the AKS safe harbors and CMPL remuneration exceptions. The exception applies to a "waiver" of cost-sharing obligations. In this case, the Requestor would pay investigators and sites the cost-sharing amounts they otherwise would have collected from beneficiaries rather than a waiver of cost-sharing amounts by the provider.

Notwithstanding, the OIG concluded that the Proposed Arrangement presented minimal risk under the AKS and the CMPL for the following key reasons:

Attracting and retaining socio-economically diverse subjects

The Proposed Arrangement appeared to the OIG to be a reasonable way to attract participant enrollment for the study, including a socio-economically diverse group of participants, by eliminating the financial burdens associated with participation. The subsidy would also likely reduce attrition in the study period, which included a two-year period requiring nine visits. Further, since 40% of participating Medicare beneficiaries would be in the control group, they would not have the potential to receive any therapeutic benefit under the study. The OIG found that the out-of-pocket costs to participate in the study would be cost prohibitive for many Medicare beneficiaries who otherwise would participate in the study.

Low likelihood of overutilization

The Proposed Arrangement presented a low likelihood for overutilization or impermissible utilization of items and services billed to Medicare. Although the OIG recognized the possibility that utilization of services may increase, there were several safeguards in place, including: the subsidies would not be advertised; participants are required to meet specific enrollment criteria for participation and receipt of the subsidy; and the study would be limited to 260 participants. The OIG found the regulatory framework related to the clinical trial as protective of overutilization because investigators must comply with the study protocol and are subject to oversight and monitoring by the IRB.

Medicare coverage for the study

The Centers for Medicare & Medicaid Services (CMS) approved the study as a Category B IDE study, meaning Medicare will provide reimbursement for the items and services provided during the study. CMS's approval of the study as a Category B IDE study involved an evaluation and determination that appropriate patient protection mechanisms are in place under the study. To be approved for Medicare coverage, a study must meet a number of criteria, including, for example, that:

- the principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients;

- the rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; and
- the study results are not anticipated to unjustifiably duplicate existing knowledge.

When establishing these approval criteria, CMS explained that where Medicare coverage is sought, these criteria help to ensure that the study design is appropriate to answer questions of importance to the Medicare program and its beneficiaries and to reduce the risk of harm to individuals.

Small likelihood of future use

The Proposed Arrangement could be distinguished from other arrangements, including those where device manufacturers offer subsidies to lure participants into using the item or service moving forward. Under the Proposed Arrangement, even though study participants may receive future services reimbursable by Medicare, the OIG found that the Requestor would not benefit from such future services.

Looking ahead

In Advisory Opinion 22-05, the OIG found that a device manufacture's subsidies for cost-sharing in the context of a clinical trial had low fraud and abuse risk based on the intent to creating socio-economic diversity in the trial by recruiting and retaining participants throughout the two-year trial. This finding was based on factors such as recruitment goals, the small enrollment numbers, the enrollment criteria, regulatory compliance with clinical research laws and the protocol including oversight by IRB and that subsidies would not be advertised.

Medical device manufacturers should look to the Opinion's insights on safeguards and socio-economic diversity factors that may be incorporated into clinical trial programs to attempt to lower the risk of fraud and abuse scrutiny by the OIG.

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