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CMS Clarifies Certain Medicare Payments for Routine Costs in Clinical Trials

The Centers for Medicare and Medicaid Services recently issued a special edition of its publication *MLN Matters* to clarify certain of its positions on the payment of routine costs in the clinical trial context.

As has been discussed in previous Honigman Alerts, CMS maintains a detailed policy whereby it will make payments to providers for routine costs related to a Medicare beneficiary's participation in a qualifying clinical trial. This special edition article addresses three specific concerns with the payment of such routine costs in a question/answer format, which is summarized here:

1. If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from any insurance company (including Medicare), is Medicare obligated to pay for these routine costs?

Answer: NO. If the routine costs are furnished without regard to the beneficiary's ability to pay and without expectation of payment from any other source, Medicare payment cannot be made and the beneficiary cannot be charged. Further, if private insurers deny the routine costs and the provider does not pursue these patients for payment after denials (even when the patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs.

2. If the research sponsor pays for the routine costs provided to an indigent non-Medicare patient (the provider has determined that the patient is indigent due to a valid financial hardship) may Medicare payment be made for Medicare beneficiaries?

Answer: YES. If the routine costs of the clinical trial are not billed to indigent non-Medicare patients because of their inability to pay (but are being billed to all other patients in the clinical trial who have the financial means to pay even when his/her private insurers denies payment for the routine costs), then a legal obligation to pay exists and Medicare payment may be made and the beneficiary (who is not indigent) will be responsible for the applicable Medicare deductible and coinsurance amounts. Note that CMS clarifies the term "indigent" to include "medically indigent" which means "patients whose health insurance coverage, if any, does not provide full coverage for all of their medical expenses and that their medical expenses, in relationship to their income, would make them indigent if they were forced to pay full charges for their medical expenses."

3. May a research sponsor pay Medicare copays for beneficiaries in a clinical trial?

Answer: Generally, NO, this is viewed by CMS as a potential fraud and abuse problem.

The clarification contains additional helpful references and can be accessed at:
<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0822.pdf>

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