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Clarification of Medicare Payment for Routine Costs in a Clinical Trial

Note: **This article was revised on May 16, 2018, to update Web addresses. All other information remains the same.**

Provider Types Affected

All physicians, providers, and suppliers who submit claims to Medicare contractors (carriers, Medicare Administrative Contractors (A/B MACs), durable medical equipment Medicare Administrative Contractors (DME MACs), fiscal intermediaries (FIs), and regional home health intermediaries (RHHIs)) for services provided to Medicare beneficiaries in clinical trials.

Provider Action Needed

This Special Edition article provides clarification regarding Medicare payment of routine costs associated with clinical trials. Be sure your billing staff is aware of this information.

Background

The Centers for Medicare & Medicaid Services (CMS) reminds providers that the policies for payment of the routine costs of the clinical trial are outlined in chapter 16, section 40 of the Medicare Benefit Policy Manual. The policy in the manual states:

Program payment may not be made for items or services which neither the beneficiary nor any other person or organization has a legal obligation to pay for or provide. This exclusion applies where items and services are furnished gratuitously without regard to the beneficiary's ability to pay and without expectation of payment from any source, such as free x-rays or immunizations provided by health organizations. However, Medicare reimbursement is not precluded merely because a provider, physician, or supplier waives the charge in the case of a particular patient or group or class of patients, as the waiver of

charges for some patients does not impair the right to charge others, including Medicare patients. The determinative factor in applying this exclusion is the reason the particular individual is not charged."

Key Points of SE0822

There are two concerns addressed in this article regarding "Payment for Routine Costs in a Clinical Trial" and they are addressed in the following questions and answers:

1. **Question:** 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: 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 the other patients in the clinical trial who have the financial means to pay even when his/her private insurer denies payment for the routine costs), then a legal obligation to pay exists. Therefore, Medicare payment may be made and the beneficiary (who is not indigent) will be responsible for the applicable Medicare deductible and coinsurance amounts. As noted at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/FAQ_Uninsured.pdf** "nothing in the Centers for Medicare & Medicaid Services' (CMS') regulations or Program Instructions prohibit a hospital from waiving collection of charges to any patients, Medicare or non-Medicare, including low-income, uninsured or medically indigent individuals, if it is done as part of the hospital's indigency policy. By "indigency policy" we mean a policy developed and utilized by a hospital to determine patients' financial ability to pay for services. By "medically indigent," we mean 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. In addition to CMS' policy, the Office of Inspector General (OIG) advises that nothing in OIG rules or regulations under the Federal anti-kickback statute prohibits hospitals from waiving collection of charges to uninsured patients of limited means, so long as the waiver is not linked in any manner to the generation of business payable by a Federal health care program – a highly unlikely circumstance

   Thus, the provider of services should bill the beneficiary for co-payments and deductible, but may waive that payment for beneficiaries who have a valid financial hardship.

   2. Question: May a research sponsor pay Medicare copays for beneficiaries in a clinical trial.
   Answer: If a research sponsor offers to pay cost-sharing amounts owed by the beneficiary, this could be a fraud and abuse problem. In addition to CMS' policy, the

Office of Inspector General (OIG) advises that nothing in OIG rules or regulations under the Federal anti-kickback statute prohibits hospitals from waiving collection of charges to uninsured patients of limited means, so long as the waiver is not linked in any manner to the generation of business payable by a Federal health care program.

The citations include 42 U.S.C. 1320a-7(a)(i)(6); OIG Special Advisory Bulletin on Offering Gifts to Beneficiaries (***http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf***) and OIG Special Fraud Alert on Routine Waivers of Copayments and Deductibles (***http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html***).

Additional Information

Chapter 16, Section 40 of the Medicare Benefit Policy Manual is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf**.

If you have any questions, please contact your MAC at their toll-free number, which is available at **http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html**.

Document History

- September 26, 2008 – Initial article released.
- January 7, 2009 – The article was revised to delete the first question and answer that was previously on page 2. All other information remains the same.
- May 16, 2018 – The article is revised to update Web addresses. All other information remains the same.