



MLN Matters Number: SE0822 Revised **Related Change Request (CR) #: N/A**
Related CR Release Date: N/A **Effective Date: N/A**
Related CR Transmittal #: N/A **Implementation Date: N/A**

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

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

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

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

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.

Copyright © 2017, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

The American Hospital Association (the “AHA”) has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.

Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.