

MLN Matters® Number: MM6776 **Revised**

Related Change Request (CR) #: 6776

Related CR Release Date: September 17, 2010

Effective Date: September 19, 2000

Related CR Transmittal #: R2052CP

Implementation Date: July 6, 2010

Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial

Note: This article was updated on November 20, 2012, to reflect current Web addresses. This article was previously revised on September 21, 2010, to reflect a revised CR 6776, which was issued on September 17, 2010. In this article, the CR release date, and the Web address for accessing CR 6776 were revised. All other information is the same.

Provider Types Affected

All providers submitting inpatient and outpatient claims for qualified clinical trials to Fiscal Intermediaries (FI) and Part A/B Medicare Administrative Contractors (A/B MAC) for healthy control group volunteers are affected.

Provider Action Needed

This article is based on CR 6776, which corrects institutional billing requirements for clinical trial claims. Institutional providers billing inpatient and outpatient clinical trial services must report International Classification of Diseases, Ninth Edition Clinical Modification (ICD-9-CM) Diagnosis code of V70.7 (Examination of participant in clinical trial) in the secondary position (**or in the primary position if the patient is a healthy, control group volunteer**) and a condition code 30 regardless of whether all services are related to the clinical trial or not. (Note: For claims with dates of service on or after September 19, 2000 through December 31, 2001, V70.5 should be used for the primary diagnosis.) Please be sure that your billing staffs are aware of these changes.

Background

Healthy Control Group Volunteers, by definition, do not have any underlying conditions. Therefore, providers need to report ICD-9-CM Diagnosis code, V70.7 (V70.5 for dates of service on or after September 19, 2000 through December 31,

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2001), as the primary diagnosis instead of the secondary diagnosis, as no primary diagnosis exists.

Note: For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to the Centers for Medicare & Medicaid Services (CMS) Medicare Claims Processing Manual, chapter 32, section 69.9, available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf> on the Centers for Medicare & Medicaid Services (CMS) website.

Additional Information

The official instruction, CR 6776, issued to your FI or A/B MAC regarding this change, may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2052CP.pdf> on the CMS website. If you have questions, please contact your Medicare A/B MAC or FI at their toll-free number which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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