



## Billing and Processing for Healthy Control Group Volunteers in a Qualified Clinical Trial – JA6776

Note: JA6776 was revised to reflect a revised Change Request (CR) 6776, which was issued on September 17, 2010. The CR release date, transmittal number, and the Web address for accessing CR6776 were revised. All other information is the same.

Related CR Release Date: September 17, 2010 **Revised**

Date Job Aid Revised: September 27, 2010

Effective Date: September 19, 2010

Implementation Date: July 6, 2010

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**Key Words** MM6776, CR6776, R2052CP, Clinical , Trial

**Contractors Affected**

- Fiscal Intermediaries (FIs)
- Part A/B Medicare Administrative Contractors (A/B MACs)

**Provider Types Affected** All providers submitting inpatient and outpatient claims for qualified clinical trials to FIs and A/B MACs for healthy control group volunteers

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CR6776 corrects institutional billing requirements for clinical trial claims.

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**International Classification of Diseases, Ninth Edition Clinical Modification (ICD-9-CM) Diagnosis Code V70.7**

- Institutional providers billing inpatient and outpatient clinical trial services must report 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.

**Provider Needs to Know...** ICD-9-CM Diagnosis Code V70.5

- 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.

**Patients Enrolled in a Managed Care Plan**

- For clinical trial billing requirements for patients enrolled in a managed care plan, providers should refer to the Centers for Medicare & Medicaid Services (CMS) *Medicare Claims Processing Manual*, Chapter 32, Section 69.9, available at <http://www.cms.hhs.gov/manuals/downloads/clm104c32.pdf> on the CMS website.
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**Background**

- By definition, Healthy Control Group Volunteers 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, 2001), as the primary diagnosis instead of the secondary diagnosis, as no primary diagnosis exists.
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**Operational Impact**

N/A

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**Reference Materials**

The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6776.pdf> on the CMS website.

The official instruction (CR6776) regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R2052CP.pdf> on the CMS website.

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