



**News Flash** - As of January 1, 2009, eligible professionals can participate in the E-Prescribing Incentive Program by reporting on their adoption and use of an e-prescribing system by submitting information on one e-prescribing measure on their Medicare Part B claims. For the 2009 e-prescribing reporting year, to be a successful e-prescriber and to qualify to receive an incentive payment, an eligible professional must report one e-prescribing measure in at least 50% of the cases in which the measure is reportable by the eligible professional during 2009. There is no sign-up or pre-registration to participate in the E-Prescribing Incentive Program. For more information, visit <http://www.cms.hhs.gov/ERxIncentive/> on the CMS website.

MLN Matters® Number: MM6431 **Revised**

Related Change Request (CR) #: 6431

Related CR Release Date: June 26, 2009

Effective Date: For claims with dates of service on or after January 1, 2008 and processed after September 28, 2009

Related CR Transmittal #: R1761CP

Implementation Date: September 28, 2009

## Billing Routine Costs of Clinical Trials

**Note:** This article was revised on June 29, 2009, to reflect a revised CR 6431, issued by the Centers for Medicare & Medicaid Services (CMS) on June 26, 2009. The transmittal number, CR release date (see above), and the Web address for accessing CR 6431 have changed. In addition, the implementation date was changed to September 28, 2009. All other information is the same.

### Provider Types Affected

Physicians and non-physician practitioners submitting claims to Medicare Administrative Contractors (MACs) and carriers for clinical trials

### Provider Action Needed

This article is based on Change Request (CR) 6431 that alerts providers that they should continue to report the International Classification of Diseases diagnosis code V70.7 (Examination of participant in clinical trial) on clinical trial claims. **It is no longer necessary to make a distinction between a diagnostic and therapeutic clinical trial service on the claim.**

#### 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.

## Background

CR 6431 revises the Medicare *Claims Processing Manual*, Chapter 32, Section 69.6 (*Requirements for Billing Routine Costs of Clinical Trials*). The revised manual section is attached to CR 6431. The Centers for Medicare & Medicaid Services (CMS) is clarifying that there no longer remains a need to make a distinction between a diagnostic versus therapeutic clinical trial service on the claim.

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, your Medicare contractor **will not** consider the service as having been furnished to a diagnostic trial volunteer. Instead, they will process the service as a therapeutic clinical trial service.

- Effective for claims processed after September 28, 2009 with dates of service on or after January 1, 2008, claims submitted with either the modifier QV or the modifier Q1 will be returned as unprocessable if the diagnosis code V70.7 is not submitted on the claim.
- Providers will see the following messages from their Medicare contractor with the returned claim:
  - Claims adjustment Reason Code 16 – Claim/service lacks information which is needed for adjudication; **and**
  - As least one Remark Code, which may be comprised of either:
    - The Remittance Advice Code (M76, Missing/incomplete/invalid diagnosis or condition) **or**
    - National Council for Prescription Drug Programs Reject Reason Code.

**Note:** Healthcare Common Procedure Coding System (HCPCS) codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30;
- Report a secondary diagnosis code of V70.7; and
- Identify all lines that contain an investigational item/service with a HCPCS modifier of:
  - QA/QR for dates of service before January 1, 2008; or

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- Q0 for dates of service on or after January 1, 2008.
- Identify all lines that contain a routine service with a HCPCS modifier of:
  - QV for dates of service before January 1, 2008; or
  - Q1 for dates of service on or after January 1, 2008.

### **Additional Information**

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If you have questions, please contact your Medicare MAC and/or carrier at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

The official instruction (CR6431) issued to your Medicare MAC, or carrier is available at <http://www.cms.hhs.gov/Transmittals/downloads/R1761CP.pdf> on the CMS website.

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