

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



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MLN Matters® Number: MM8401

Related Change Request (CR) #: CR 8401

Related CR Release Date: August 9, 2013

Effective Date: January 1, 2014

Related CR Transmittal #: R2758CP

Implementation Date: January 6, 2014

## **Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims**

### **Provider Types Affected**

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), carriers, Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) and A/B MACs) for items and services provided in clinical trials to Medicare beneficiaries.

### **Provider Action Needed**

This article is based on Change Request (CR) 8401, which informs you that, effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.

The clinical trial number to be reported is the same number that has been reported voluntarily since the implementation of CR 5790, dated January 18, 2008. That is the number assigned by the National Library of Medicine (NLM) <http://clinicaltrials.gov/> website when a new study appears in the NLM Clinical Trials data base.

Make sure that your billing staffs are aware of this requirement.

#### **Disclaimer**

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## Background

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CR 5790, Transmittal 310, dated January 18, 2008, titled "Requirements for Including an 8-Digit Clinical Trial Number on Claims" is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3100TN.pdf> on the CMS website. The MLN Matters® Article for CR5790 is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5790.pdf> on the CMS website.

This number is listed prominently on each specific study's page and is always preceded by the letters 'NCT'.

The Centers for Medicare & Medicaid Services (CMS) uses this number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry. Furthermore, this identifier permits CMS to better track Medicare payments, ensure that the information gained from the research is used to inform coverage decisions, and make certain that the research focuses on issues of importance to the Medicare population.

Suppliers may verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry website at <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/index.html> on the CMS website.

For institutional paper or direct data entry (DDE) claims, the 8-digit clinical trial number is to be placed in the value amount for paper only value code D4/DDE claim UB-04 (For Locators 39-41) when a clinical trial claim includes:

- Condition code 30;
- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

For institutional claims that are submitted on the electronic claim 837I, the 8-digit number should be placed in Loop 2300 REF02 (REF01=P4) when a clinical trial claim includes:

- Condition code 30;
- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

For professional claims, the 8-digit clinical trial number preceded by the 2 alpha characters of CT must be placed in Filed 19 of the paper claim Form CMS-1500 (e.g., CT12345678) or the electronic equivalent 837P in Loop 2300 REF02(REF01=P4) when a clinical trial claim includes:

- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

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Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number using the messages listed below..

- Claim Adjustment Reason Code (CARC) 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either National Council for Prescription Drug Programs (NCPDP) Reject Reason Code, or Remittance Advice Remark Code (RARC) that is not an ALERT.)"
- RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."
- RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."
- Group Code-Contractual Obligation (CO).

**NOTE:** This is a reminder/clarification that clinical trials that are also investigational device exemption (IDE) trials must continue to report the associated IDE number on the claim form as well.

## Additional Information

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The official instruction, CR 8401, issued to your Medicare contractor regarding this change, may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2758CP.pdf> on the CMS website.

If you have any questions, please contact your Medicare contractor 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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