| CMS Manual System | **Department of Health & Human Services (DHH)** |
|---|---|
| Pub 100-20 One-Time Notification | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 310** | **Date: JANUARY 18, 2008** |
| | **Change Request 5790** |

**Subject: Requirements for Including an 8-Digit Clinical Trial Number on Claims**

**I. SUMMARY OF CHANGES:** This Change Request (CR) instructs providers and suppliers on new requirements for voluntarily including an 8-digit clinical trial number on claims. Medicare contractor systems and various claims records must be modified to accommodate this number.

**New / Revised Material**
**Effective Date: April 1, 2008**
**Implementation Date: April 7, 2008**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | Chapter / Section / Subsection / Title |
|---|---|
| N/A | |

**III. FUNDING:**
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**One-Time Notification**

**Unless otherwise specified, the effective date is the date of service.*

# Attachment – One-Time Notification

| Pub. 100-04 | Transmittal: 310 | Date: January 18, 2008 | Change Request: 5790 |
|---|---|---|---|

**SUBJECT: Requirements for Including an 8-Digit Clinical Trial Number on Claims**

**Effective Date:** April 1, 2008

**Implementation Date:** April 7, 2008

## I. GENERAL INFORMATION

**A. Background:** The purpose of this change request (CR) is to instruct providers and suppliers on new, voluntary reporting for placing 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 Manual, Publication 100-03, section 310.1. The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is requesting to be voluntarily reported is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a new study is registered by a sponsor or investigator. Section 113 of the Food and Drug Administration Modernization Act of 1997 includes the circumstances under which sponsors shall submit information to the NLM Clinical Trials Data Bank. CMS will use this number to identify all items and services provided to beneficiaries during their participation in a clinical trial.

Furthermore, this identifier will permit CMS to meet the recommendations of the 2000 Institute of Medicine report that led to the Executive Memorandum to increase participation of Medicare beneficiaries in clinical trials and the development and implementation of the CMS clinical trials policy. Recommendations from The White House Executive Memorandum included: 1. tracking Medicare payments, 2. ensuring that the information gained from the research is used to inform coverage decisions, 3. making certain that the research focuses on issues of importance to the Medicare population, and, 4. enabling CMS to better inform Medicare beneficiaries about the clinical studies available for their participation.

**B. Policy:** Medicare contractor systems and various claims records shall be modified to accommodate an 8-digit clinical trial number. As reporting this number is voluntary, claims submitted without the clinical trial number will be paid the same as claims containing a number. Therefore, contractors shall not automatically process claims without a number as return-to-provider/return as unprocessable. CMS expects that within 90 days of publication of this instruction, contractors will have instructed providers and suppliers on the proper billing methods to use and encouraged them to voluntarily participate.

In addition, contractors shall be aware of new modifiers to differentiate between routine and investigational clinical trial items and services effective with dates of service on and after January 1, 2008. Refer to CR 5805 for detailed information.

## II. BUSINESS REQUIREMENTS TABLE

*Use"Shall" to denote a mandatory requirement*

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5790.1 | Effective for claims received on and after April 1, 2008, | X | | X | | | X | | | X | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| | contractor systems shall accept the numeric, 8-digit clinical trial registry number (when reported) in the value amount for value code D4 on the paper claim UB-04 (Form Locators 39-41) or the electronic claim equivalent, 837I (Loop 2300, HI - VALUE INFORMATION segment, qualifier BE). | | | | | | | | | | |
| 5790.2 | Effective for claims received on and after April 1, 2008, contractor systems shall accept the numeric, 8-digit clinical trial registry number (when present on the claim) preceded by the 2 alpha characters "CT" when placed in Field 19 of the paper Form CMS-1500. For example, CT12345678.<br><br>NOTE: The "CT" prefix is only to be used on the paper claim to distinguish the 8-digit number from any other information that may be placed in Item 19. | X | X | | X | | | X | X | X | |
| 5790.2.1 | Contractors shall transmit the 8-digit clinical trial number when reported on the Form CMS-1500 to the Common Working File (CWF). | X | X | | X | | | X | X | | |
| 5790.2.2 | Contractors shall not transmit the "CT" prefix when reported on the Form CMS-1500 to CWF. | X | X | | X | | | | | | |
| 5790.3 | Effective for claims received on and after April 1, 2008, contractor systems shall accept the numeric, 8-digit clinical trial registry number when placed on the electronic 837P in Loop 2300 REF02(REF01=P4). | X | X | | X | | | X | X | X | |
| 5790.4 | Contractors shall ensure that the numeric, 8-digit clinical trial registry number (when reported) appears on the HUBC record going to CWF. | X | | | X | | | X | | | |
| 5790.5 | Contractors shall ensure that the numeric, 8-digit clinical trial registry number (when reported) appears on the HUDC record going to CWF. | | X | | | | | | X | | |
| 5790.6 | CWF shall accept and expand the appropriate record to accept the numeric, 8-digit clinical trial registry number (when present on the claim record) for Parts A, B, and DME and transmit the number to NCH. | | | | | | | | | X | |
| 5790.6.1 | CWF shall generate one monthly report according to the attached layout and transmit it to the CMS data center. This report shall contain monthly claim adjustments as applicable. | | | | | | | | | X | |
| 5790.7 | NCH shall accept the numeric, 8-digit clinical trial registry number when transmitted by the CWF record. | | | | | | | | | | NCH |
| 5790.8 | Contractors shall not create and/or modify existing edits to process claims without a clinical trial registry number as return-to-provider/return as unprocessable. | X | X | X | X | | X | X | X | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5790.9 | Contractors shall instruct providers and suppliers on the proper billing methods to use and encourage them to voluntarily include the 8-digit clinical trial registry number on claims. | X | X | X | X | | X | X | X | | |

**III. PROVIDER EDUCATION TABLE**

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5790.10 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | X | X | | | | | | |

## IV. SUPPORTING INFORMATION

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| 5790.1-5790.9 | Institutional clinical trial claims are identified through the presence of all of the following elements:<br>• Value Code D4 and corresponding 8-digit clinical trial number (when present on the claim)<br>• ICD-9 diagnosis code V70.7 |

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | • Condition Code 30<br>• HCPCS modifier Q1: outpatient claims only - Refer to CR 5805<br><br>Practitioner/DME clinical trial claims are identified through the presence of all of the following elements:<br><br>• ICD-9 diagnosis code V70.7<br>• HCPCS modifier Q1 - Refer to CR 5805<br>• 8-digit clinical trial number (when present on the claim) |

**B. For all other recommendations and supporting information, use this space:**

## V. CONTACTS

**Pre-Implementation Contact(s):**

National Coverage Determination: Leslye Fitterman, leslye.fitterman@cms.hhs.gov, 410-786-3669
Institutional Claims Processing: Joe Bryson, joseph.bryson@cms.hhs.gov, 410-786-2986 or Valeri Ritter, valeri.ritter@cms.hhs.gov, 410-786-8652
Physician Claims Processing: Vera Dillard, vera.dillard@cms.hhs.gov, 410-786-6149
DME Claims Processing: Tracey Hemphill, tracey.hemphill@cms.hhs.gov, 410-786-7169

**Post-Implementation Contact(s):** Regional Office

## VI. FUNDING

**A. *For Fiscal Intermediaries and Carriers*:** No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**B. *For Medicare Administrative Contractors (MAC)*:** The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

## Clinical Trial Number Monthly Report

1/17/2008

The following report should be prepared monthly from CWF claims received by CMS.

The report will contain each unique clinical trial number reported on claims and will also report for those claims the number that contain the new HCPCS modifiers designed to differentiate between routine and investigational services in clinical trials.

| Clinical Trial Numbers | Clinical Trial HCPCS Modifiers | Number of Claims | Number of Patients |
|---|---|---|---|
| (As specified in Requirement Number XXXX.3, 3.1, and 3.2) | | | |
| Unique clinical trial numbers | Claims with HCPCS modifier Q0 and not Q1 | | |
| | Claims with HCPCS modifier Q1 and not Q0 | | |
| | Claims with HCPCS modifiers Q0 and Q1 | | |
| | Claims with neither HCPCS modifiers Q0 or Q1 | | |

# Clinical Trial Number Monthly Report

1/17/2008

**Medicare Payment Amount**