DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

NEW product from the Medicare Learning Network® (MLN)

- "Vaccine Payments Under Medicare Part D", Fact Sheet, ICN 908764, downloadable

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| MLN Matters® Number: SE1344 | Related Change Request (CR) #: CR 8401 |
| Related CR Release Date: October 30, 2013 | Effective Date: January 1, 2014 |
| Related CR Transmittal #: 2805 | Implementation Date: January 6, 2014 |

# Further Information on 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 Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) for items and services provided in clinical trials to Medicare beneficiaries.

## Provider Action Needed

This article is related to CR 8401, which requires, effective January 1, 2014, the mandatory reporting of a clinical trial identifier 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 identifier 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.

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Since the release of CR 8401, the Centers for Medicare & Medicaid Services (CMS) has learned that some physicians, providers, and suppliers do not have the capability at this time to submit the clinical trial identifier number associated with trial-related claims. This article presents those physicians, providers, and suppliers with an alternative means of satisfying the CR 8401 requirements until January 1, 2015. At that time, such providers must fully comply with CR 8401. Make sure that your billing staffs are aware of the requirement and the implementation changes and dates.

## Background

CMS understands that implementing CR 8401 by January 1, 2014, would create an undue hardship on a number of its stakeholders. As a result, for physicians, providers, and suppliers who do not have the capacity at this time to report the clinical trials identifier number associated with trial-related claims, CMS is providing an option to submit a generic number in place of the actual National Clinical Trials (NCT) number.

Beginning January 1, 2014, and continuing no later than through December 31, 2014, those above-mentioned physicians, providers, and suppliers may instead report an 8-digit, generic number of 99999999 using the instructions in CR 8401. This will allow trial-related claims to process appropriately if they are prepared according to instructions in CR 8401. Keep in mind that trial-related claims will be returned if they do not contain either the actual clinical trial identifier number or the 8-digit generic number 99999999 – you may not leave those indicated fields blank. That said, CMS encourages those affected by CR 8401 to update their internal claims processing procedures as expeditiously as possible so they can begin reporting the actual clinical trial identifier number as CR 8401 instructs.

NOTE: This in no way precludes those already reporting and/or able to report the actual clinical trial number on clinical trial-related claims from doing so. Beginning January 1, 2015, without further notice, CR 8401 shall be fully implemented.

NOTE: For clarification, the clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED), the Medicare Clinical Trial Policy, or a CMS-approved investigational device exemption (IDE) study. For IDE trials, both the IDE and the clinical trial identifier number are required. Specifically, include the clinical trial identifier number if: the beneficiary is enrolled in an approved clinical trial; AND, the claim is for the investigational item or service, AND/OR, the costs are related to the investigational item or service, AND/OR, the costs are related to routine care for the condition in the clinical trial.

## Additional Information

The official instruction, CR 8401, issued to your MAC regarding this change, may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2805CP.pdf on the CMS website. The MLN Matters® article related to CR 8401 is available at http://www.cms.gov/Outreach-and-

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Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf on the CMS website.

Section 310.1 of the "Medicare National Coverage Determination (NCD) Manual" is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf on the CMS website.

If you have any questions, please contact your MAC 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.

News Flash - Generally, Medicare Part B covers one flu vaccination and its administration per flu season for beneficiaries without co-pay or deductible. Now is the perfect time to vaccinate beneficiaries. Health care providers are encouraged to get a flu vaccine to help protect themselves from the flu and to keep from spreading it to their family, co-workers, and patients. Note: The flu vaccine is not a Part D-covered drug. For more information, visit:

- MLN Matters® Article #MM8433, "Influenza Vaccine Payment Allowances - Annual Update for 2013-2014 Season"
- MLN Matters® Article #SE1336, "2013-2014 Influenza (Flu) Resources for Health Care Professionals"
- HealthMap Vaccine Finder - a free, online service where users can search for locations offering flu and other adult vaccines. While some providers may offer flu vaccines, those that don't can help their patients locate flu vaccines within their local community.
- The CDC website for Free Resources, including prescription-style tear-pads that allow you to give a customized flu shot reminder to patients at high-risk for complications from the flu.

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