



Clarification on Use of National Drug Codes (NDCs) in 837 Institutional Billing – JA6330

Note: MLN Matters® article MM6330 was revised to provide a Web address for accessing electronic billing information, including flat file formats. That address is in the Reference Materials section below. All other information remains the same.

Related CR Release Date: February 13, 2009 **Revised**

Date Job Aid Revised: July 14, 2009

Effective Date: July 1, 2009

Implementation Date: July 6, 2009

Key Words MM6330, CR6330, R446OTN, NDC, Drug

Contractors Affected

- Part A/B Medicare Administrative Contractors (A/B MACs)
- Regional Home Health Intermediaries (RHHIs)
- Fiscal Intermediaries (FIs)

Provider Types Affected Hospitals, home health agencies, and other providers who bill Medicare FIs, RHHIs, or A/B MACs for drugs, especially new drugs provided under the Outpatient Prospective Payment System (OPPS)



- Change Request (CR) 6330 specifies how quantities of drugs are to be reported and then processed by Medicare when the NDC is used for institutional billing. Specifically, it requires Medicare contractors to accept decimal values for NDC quantities.
- CR6330 also adds to CR3287, regarding the reporting of drugs that have not yet been approved by the Food and Drug Administration (FDA).

Provider Needs to Know...

- Effective for claims with **dates of service on and after July 1, 2009**, hospitals billing for drugs/biologicals that have received FDA approval but which have not yet received product-specific drug/biological Healthcare Common Procedure Coding System (HCPCS) codes will not only specify the NDC of the drug/biological, but will also specify the quantity of that drug/biological using the CTP segment in the ANSI X-12 837 I (in Loop 2410 LIN 03).
- The Units Field, while adequate to define quantities when HCPCS codes are used to describe drugs and biologicals, is not adequate to describe the quantities of a drug or

biological identified only by an NDC.

- Medicare contractors are required to accept decimals to specify the quantity in this new quantity field.
 - Medicare's systems are required to retain this information in the repository and forward it to a subsequent payer (although the decimals may be rounded to whole numbers for actual claims processing).
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Background

- CR3287 issued on May 28, 2004 (MMA-Hospital Outpatient Billing and Payment under Outpatient Prospective Payment System for New Drugs or Biologicals After FDA Approval but Before Assignment of a Product-Specific Drug/Biological HCPCS Code), provided that Medicare hospitals, subject to the OPPS, may use HCPCS code C9399 to report drugs that have been approved by the FDA, but that do not yet have a product-specific drug/biological HCPCS code.
 - CR6330 builds on the instructions provided in CR3287 and adds some additional requirements for providers billing Medicare contractors for drugs provided under the OPPS.
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**Operational
Impact**

N/A

**Reference
Materials**

The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6330.pdf> on the CMS website.

The official instruction (CR6330) issued regarding this change may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R446OTN.pdf> on the CMS website.

Providers may review the MLN Matters® article relating to CR3287 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3287.pdf> on the CMS website.

Information on electronic claim formats, including the flat file formats, is available at http://www.cms.hhs.gov/ElectronicBillingEDITrans/08_HealthCareClaims.asp on the CMS website.
