CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 446	**Date: February 13, 2009**
	Change Request 6330

Subject: Clarification on Use of National Drug Codes (NDCS) in 837 I Billing

I. SUMMARY OF CHANGES: This CR instructs FISS to add the NDC number to its internal claim record and specifies how quantities of drugs are to be reported when the NDC is used for institutional billing. The CR also requires contractors to accept decimal values for NDC quantities, although these may be rounded for actual claims processing. It also requires passing the NDC information to CWF and NCH.

NEW / REVISED MATERIAL
EFFECTIVE DATE: *July 1, 2009
IMPLEMENTATION DATE: July 6, 2009

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. 100-20	Transmittal: 446	Date: February 13, 2009	Change Request: 6330

SUBJECT: Clarification on Use of National Drug Codes (NDCs) in 837 I Billing.

EFFECTIVE DATE: July 1, 2009

IMPLEMENTATION DATE: July 6, 2009

I. GENERAL INFORMATION

A. Background: This CR instructs FISS to add the NDC number to its internal claim record and specifies how quantities of drugs are to be reported when the NDC is used for institutional billing. The CR also requires contractors to accept decimal values for NDC quantities, although these may be rounded for actual claims processing. It is necessary for contractors to accept claims with decimal values for NDCs. These decimals must be retained in the repository for later crossover of the claim to a subsequent payer. Rounding may be used for claims processing purposes, but the decimal values must be transmitted to subsequent payers. Use of the Units Field, while adequate to define quantities when HCPCS codes are used to describe drugs and biologicals, are not adequate to describe the quantities (administered to beneficiaries) of a drug or biological identified only by an NDC. This CR provides direction in using the LIN segment to identify a drug or biological using the NDC code and the CTP segment to specify the unit of measurement and the metric decimal quantity of the drug or biological. Units need to be billed at the appropriate metric/unit of measure that is standard for the NDC code.

B. Policy: Medicare hospitals subject to the OPPS report drugs that have been approved by the FDA, but that do not yet have a product-specific drug/biological HCPCS code, using HCPCS code C9399. CR 3287, transmittal 188, issued May 28, 2004 provided the instructions to Medicare providers and claims processors. This CR builds on those instructions and adds some additional requirements for providers, the shared system maintainer, and Medicare claims processors (FIs, RHHIs, and A/B MACs). Effective July 1, 2009, hospitals billing for drugs/biologicals that have received FDA approval but which have not yet received product-specific drug/biological HCPCS codes shall not only specify the NDC of the drug/biological, but shall also specify the quantity of that drug/biological using the CTP segment in the ANSI X-12 837 I. In addition, Medicare contractors must allow decimals in the specification of quantity. The CMS is aware that most drug/biological pricing is performed using whole numbers. However, it is necessary for FISS and contractors to accept decimals in the quantity field for the drug, store this information in the repository, and forward it to a subsequent payer. The companion guide to the 837 I will be updated after issuance of this CR.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)						
		A/B	DME	FI	CAR	RHH	Shared-System Maintainers	OTHER

							FISS	MCS	VMS	CWF	
6330.1	FISS shall carry the NDC code on its internal claim record, at the line level, when present on an incoming 837 I, in Loop 2410 LIN 03.						X				
6330.1.1	FISS shall modify DDE screens to accept the NDC number, at the line level, for each iteration of HCPCS code C9399.						X				
6330.1.2	FISS shall also apply appropriate edits to insure that valid combinations of HCPCS codes and NDC codes trigger appropriate messaging.						X				
6330.2	FISS shall associate the quantity of a drug administered to a Medicare beneficiary with the value in CTP, and the qualifier specifying the units in which the drug is administered. This data must be accepted for both DDE and hard copy claims. NOTE: This information may be placed in the "Remarks" section on hard copy claims. FISS shall decide where and how this information shall come in for DDE claims.						X				
6330.2.1	For DDE, if HCPCS code C9399 is present, FISS shall ensure that all of the following are also present: the NDC code itself, the quantity qualifier, CTP quantity, and price (S9(8)V99.						X				
6330.2.2	FISS shall use information found in the CTP segment to provide information specific to the NDC provided in LIN03.						X				
6330.2.3	FISS shall use the information parallel to that in the CTP segment when it is necessary to provide information specific to each NDC number on the claim.						X				
6330.2.4	FISS shall change the 837 I, v. 4010A1flat file record type 630 field 5 (Units) Cobol picture from 9(15) to 9(7)V999 and add 5 bytes of filler immediately following field 5, to match the pic from the DME MAC for NDC units.						X				
6330.3	Contractors shall allow decimal values for quantity, although these may be rounded to a whole number for claims processing and pricing. Note: Contractors may have to multiply the decimal quantity to achieve a whole number and later divide the payment amount by the same number to achieve accurate pricing.	X		X		X	X				
6330.3.1	FISS shall provide the ability to manually price based upon the NDC code and appropriate units of measure and pass the resulting payment and code information to CWF.						X				
6330.3.2	CWF shall accept and pass NDC, related unit/quantity, as									X	NCH

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	
	well as payment information to NCH.										
6330.3.3	NCH shall accept and store incoming NDC information from CWF.										NCH
6330.3.4	FISS shall store and forward the incoming decimal amount associated with the NDC for COB purposes.						X				COBC

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	
6330.4	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					

IV. SUPPORTING INFORMATION

Section 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:
3287	Hospital Outpatient Billing and Payment under OPPS for New, Unclassified Drugs or Biologicals Approved by the FDA After January 1, 2004, But Before Assignment of a Product-Specific Drug/Biological HCPCS Code

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

V. CONTACTS

Pre-Implementation Contact(s): Cindy Murphy, cindy.murphy@cms.hhs.gov, Maria Durham, maria.durham@cms.hhs.gov

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers,* use only one of the following statements:

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),* include the following statement:

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.