Program Memorandum Carriers

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal B-02-071 **Date: OCTOBER 25, 2002**

CHANGE REQUEST 2339

SUBJECT: Use of the National Drug Code (NDC) for Drug Claims at the Durable Medical Equipment Regional Carriers (DMERCs)

I - GENERAL INFORMATION

This Program Memorandum (PM) implements the NDC in processing claims for prescription drugs, biologicals, and vaccines (hereafter referred to as "drugs") at the DMERCs. This action is in compliance with requirements mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191).

A - Background:

On August 17, 2000, we published a final rule (65 FR 50311) that implements standards for electronic transactions in accordance with the administrative simplification provisions of HIPAA. This rule became effective on October 16, 2000. HIPAA required Medicare and other insurers to be capable of processing claims using NDCs for drugs within 24 months (by no later than October 1, 2002) after the effective date of the final rule. A subsequent law, the Administrative Simplification Compliance Act (ASCA) of December 2001, allowed covered entities to request an extension until October 16, 2003 for implementation.

For claims processing purposes, CMS considers any entity billing the DMERCs for a drug to be a retail pharmacy (noted on the NSC file with A5 indicator).

The administrative simplification provisions of HIPAA (Social Security Act, Title XI, Part C, Sections 1171 through 1179) define various terms and impose several requirements on health plans and health care clearinghouses. Those provisions also impact those health care providers that conduct electronic transactions specified in HIPAA. The selection of code sets for appropriate data elements is among the requirements. Subpart J of the final rules names the NDC as the standard code set for prescription drugs and pharmaceuticals.

The purpose of the administrative simplification provision of HIPAA is to diminish the inefficiencies in health care data interchange, including claims processing, which result from a lack of standardization, and to increase savings, which would result from standardization. Although HIPAA applies to electronic transactions, which includes electronic claims, this PM extends the new standards to include paper claims, also for reasons of administrative simplification.

Description of NDC

The NDC System was originally established as an essential part of an out-of-hospital drug reimbursement program under Medicare. The NDC serves as a universal product identifier for human drugs. The current edition of the NDC Directory is limited to prescription drugs and a few selected over-the-counter products and is maintained by the Food and Drug Administration (FDA).

The Drug Listing Act of 1972 (effective February 1, 1973) is the legal basis that provides the Commissioner of the FDA a current list of all drugs manufactured, prepared, propagated, compounded, or processed by a drug establishment registered under the Federal Food, Drug, and Cosmetic Act (FFDCA). This act requires submission of information on commercially marketed drugs and is used in the enforcement of the FFDCA.

Drug information, including the NDC Directory, can be obtained from the FDA by accessing its website at www.fda.gov. The FDA can be contacted by E-mail at DRUGPRODUCTS@CDER.FDA.GOV or by writing to the following address:

Food and Drug Administration
Information Management Team HFD-095
5600 Fishers Lane
Rockville, Maryland 20857

Specific NDC issues may be directed to (301) 594-5467. The FAX number is 301-594-6463.

DMERC Claims Processing

Claims submitted either electronic or paper by all retail pharmacies must comply with the standard formats identified in HIPAA. The NDC must be used to identify retail drugs on all claims submitted to Medicare using the National Council for Prescription Drug Programs (NCPDP) format that is being implemented by the DMERCs.

Claims submitted for all drugs from retail pharmacies to the DMERCs must be identified by a NDC and submitted on or after April 1, 2003, unless an ASCA extension has been requested. HCPCS codes submitted by retail pharmacies to the DMERCs will be rejected.

Continue to use all coverage and medical necessity rules with the NDC processing as was done with use of the HCPCS drug codes. Continue to use the edits for NDC processing that were previously associated with the HCPCS drug codes. Continue to perform all routine drug activities associated with medical review, fraud and abuse, audit, and Medicare Secondary Payer (MSP).

B - Policy:

1. Every claim for a drug submitted by a pharmacy to a DMERC must identify the drug by its NDC code.

2. DMERCS must accept the NDC code as the identifier for each drug for which a claim is submitted.

3. Reject as unprocessable a claim that does not identify the drug by its NDC code.

4. DMERCs must adjudicate claims based on date of receipt.

II - BUSINESS REQUIREMENTS

Req. #	Requirements	Resp.
1	DMERCs and Standard Systems Maintainer (SSM) must accept the NDC for each drug on a claim.	DMERC/ SSM
2	Reject as unprocessable a claim that does not identify the drug by its NDC.	DMERC/ SSM
3	DMERCs must adjudicate claims based on date of receipt.	DMERC
4	DMERCs, SSM, CWF, and NCHF must accept a decimal point in the drug units field. The field must be able to accept 7 numbers to the left and 3 number to the right of the decimal point. Use the metric decimal quantity.	DMERC/ SSM/ CWF/NC HF
5	DMERCs remain responsible for maintaining a NDC/HCPCS crosswalk file.	DMERC
6	SSM must crosswalk the NDC to the appropriate HCPCS code for determining the proper payment amount. For remittance advice and Medicare Summary Notice (MSN), SSM must crosswalk the HCPCS code back to the NDC.	DMERC/ SSM
7	CWF and NCHF must capture both the NDC and HCPCS codes.	CWF
8	Both remittance advices (RAs) and MSNs must specify the NDC code. For re-association purposes, the remittance advice or any COB transaction that references the actual drug must reflect only the NDC. The SSM must retain submitted NDCs, and return NDCs rather than drug HCPCS codes on any outgoing transaction.	SSM
9	Utilization review must continue to be performed using the HCPCS code.	DMERC/ SSM
10	Continue to use all coverage and medical necessity rules with the NDC processing as was done with use of the HCPCS drug codes. Continue to use the edits for NDC processing that were previously associated with the HCPCS drug codes. Continue to perform all routine drug activities associated with medical review, fraud and abuse, audit, and MSP.	DMERC
11	There will be instances in which the use of paper claims is unavoidable. Paper claims are capable of containing the 11-position NDC. The Health Insurance Claim Form, Form CMS -1500, is able to accommodate the 11-position drug code in field 24D (CPT/HCPCS -- MODIFIER). A modifier cannot be included in item 24D if an NDC is entered. The modifier, if appropriate, and supporting documentation, if any, must be supplied in item 19. The supplier must put the line number in front of the modifier in block 19. DMERCs must install the required logic to assure that their scanners will be able to recognize the NDCs for appropriate processing.	DMERC/ Supplier

12	Each NDC will be reported on the claim in the units prescribed by the NCPDP standard. Volume measures (e. g., liter, milliliter) must be converted on an individual NDC basis to the corresponding unit of weight of HCPCS codes for pricing purposes. **See attached chart**.	SSM
13	The DMERCs must maintain a current NDC/HCPCS crosswalk file for the purpose of implementing these instructions. DMERCs must include the individual NDC conversion factor from volume to weight (e.g., mg per ml).	DMERC
14	For drug claims from retail pharmacies, the NDC must be entered as follows in the NCPDP electronic format: NCPDP V5.1, Product/Service ID (Field 407-D7)	Pharmacy
15	The CMS will provide to each DMERC (and to the SADMERC and SSM a crosswalk of HCPCS codes to NDC for all drugs for which claims are submitted to DMERCs. A crosswalk for testing will be provided on or before November 1, 2002. The final crosswalk will be provided on or before December 1, 2002, and will be current as of November 1, 2002. The crosswalk is for advisory purposes only.	CMS

III - Supporting Information and Possible Design Considerations

A – Other Instructions:

X-Ref Req. #	Instructions
1 – 15	The DMERCs must publish this information in their bulletins, on their Web sites and on listservs by January 1, 2003. The DMERCs must educate pharmacy providers during their regular training efforts.

B – Design Considerations: N/A

X-Ref Req. #	Recommendation for Medicare System Requirements

C - Interfaces: N/A

D - Contractor Financial Reporting /Workload Impact: N/A

E - Dependencies: N/A

F - Testing Considerations: N/A

IV - Attachment(s): **NDC Units Conversion Chart** attached.

Version: 8/14/02 **Implementation Date: April 1, 2003** **Discard Date: April 1, 2004** **Post-Implementation Contact:** **Angie Costello at (410) 786-1554** **acostello@cms.hhs.gov**	**Effective Date: April 1, 2003** **Funding: No additional funding** **Pre-Implementation Contact:** **Angie Costello at (410) 786-1554** **acostello@cms.hhs.gov**