Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-01-04 **Date JANUARY 18, 2001**

CHANGE REQUEST 1441

This PM is informational only. Specific contractor claims processing instructions will follow. Currently, we are requesting comments only.

SUBJECT: Implementation of the National Drug Code (NDC) to Process Claims for Prescription Drugs and Biologicals and Request for Comments -- ADVANCE NOTICE

This Program Memorandum (PM) provides advance notice to, and a request for comments from, contractors that process Medicare drug claims of the need to prepare for the implementation of the NDC in processing claims for prescription drugs, biologicals, and vaccines (hereafter referred to as "drugs"). This action is in compliance with requirements mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191).

On August 17, 2000, HCFA 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 requires 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 that implements the administrative simplification provisions of HIPAA. No system modifications are to be made at this time. We intend to prepare a follow up PM with specific contractor instructions regarding claims processing and implementation on this subject and, therefore, request only your comments at this time.

Basis for Change

The administrative simplification provision of HIPAA (Social Security Act, Title XI, Part C, §§1171 through 1179) defines various terms and imposes 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. The Final Rule selected 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

The FDA phone number is (301) 827-5467. Specific NDC issues may be directed to (301) 594-1086. The FAX number is 301-594-6463.

The FDA maintains electronic data files of currently marketed products. The file layout description describes the content of the files. The **ZIPTEXT.EXE** file is a zipped executable file that can be downloaded and, using a PC database management system such as Access®, be formatted for query and reporting. Unless otherwise noted, the contents (both text and graphics) of the FDA World Wide Web site are *not* copyrighted. They are in the public domain and may be republished, reprinted, and otherwise used freely by anyone without the need to obtain permission from FDA.

Health care professionals, retail pharmacy, and institutional facilities will use the NDCs in reporting prescription drugs in pharmacy transactions and claims. The codes are assigned when the drugs are approved or repackaged and may be found on the packaging of drugs. This unique identifier for drugs contains 11 digits in the following order:

First 5-digits represent the manufacturer
Second 4-digits identify the product
Last 2-digits signify the package size

(NOTE: There is no universal assignment for the numbering other than what is listed above. That is, each company designates its own numbering sequence for the product and package size.)

For example, the **NDC 00300-3612-28** identifies the manufacturer as Tap Pharmaceuticals Inc. (00300), the drug as Lupron® (3612) which is the brand name product for the generic chemical known as leuprolide acetate, and finally the package size as a single unit containing 5 milligrams of drug in 1 milliliter (28).

The **NDC 00300-3612-24** identifies the manufacturer as Tap Pharmaceuticals Inc. (00300), the drug as Lupron® (3612), and the package size as a package containing 6 individual units with each unit containing 5 milligrams of drug in 1 milliliter (24).

Leuprolide acetate is the active chemical ingredient which is also referred to as the generic version of the brand name product, Lupron®. Where the brand name has only a single manufacturer with exclusive patent rights to the brand name, the generic version (available after the patent expires) may have multiple sources for its production as follows:

NDC Components	Bedford	Eon	Eon
Company I.D.	55390	00185	00185
Drug I.D.	0515	7400	7400
Package I.D.	05	14	85
Complete NDC	55390-0515-05[1]	00185-7400-14[2]	00185-7400-85[3]

[1] leuprolide acetate, single unit of 2.800 milliliters, 5 milligrams per milliliter
[2] leuprolide acetate, package of 6 units, each unit of 2.800 milliliters, 5 milligrams per milliliter
[3] leuprolide acetate, single unit of 2.800 milliliters, 5 milligrams per milliliter
(Information Source: 2000 Drug Topics Red Book)

A crosswalk between the HCFA Common Procedure Coding System (HCPCS) drug codes and the NDCs will be available for downloading either on disk, the Internet, or contractor purchase. Work has begun on developing, maintaining, updating, and distributing the crosswalks. Until further notice, contractors should continue to price NDCs in accordance with 42 CFR 405.517 and Program Memorandum AB-00-110.

MEDICARE CLAIMS PROCESSING

Claims submitted electronically by all individual providers, suppliers, and institutional providers must comply with the standard formats identified in HIPAA. The NDC must be used throughout the claims adjudication process.

You must be able to accept claims with either HCPCS drug codes or the NDC for claims with dates of service (DOS) on or after April 1, 2002, through September 30, 2002. For claims with DOS on or after October 1, 2002, only NDCs may be accepted, thereby rejecting all other codes used for drugs.

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). The implementation of the NDC will affect the Outpatient Pricer and the Outpatient Code Editor.

All Medicare providers, whether they bill electronically or on paper, must use the code sets described in the standards for electronic transactions final rule by October 1, 2002. Use the date of service for pricing the drug claims regardless of the date of submission, date of receipt, or date of processing of the claim.

Paper Claims Submitted to Carriers and DMERCs

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 HCFA-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. Carriers and DMERCs must install the required logic to assure that their scanners will be able to recognize the NDCs for appropriate processing.

Paper Claims Submitted to Fiscal Intermediaries (FIs)

The current Form HCFA-1450 (UB-92) paper claim cannot adequately accommodate the HIPAA requirement of the 11-digit NDC. The decision to accept the NDC on the UB-92 is pending with the National Uniform Billing Committee.

Claims for Influenza and Pneumococcal Vaccines

When NDC codes become effective, their use will extend to influenza and pneumococcal claims billed on paper and electronic roster claim forms, both by regular billers and centralized billers. It will be the responsibility of the contractor to make any necessary updates to paper (carriers only) and electronic roster bill formats to accommodate the NDCs. These changes must be made to coincide with the effective date of the use of the NDCs.

Electronic Claims Submitted to Carriers and Durable Medical Equipment Regional Carriers (DMERCs)

For drug claims from retail pharmacies, the NDC must be entered as follows in the National Council for Prescription Drug Programs (NCPDP) electronic format:

NCPDP V5.1, field #407 – Product Service ID

For drug claims from all entities other than retail pharmacies, the NDC must be entered as follows in the ASC X12N electronic format:

N4 SV101-1
11-digit NDC SV102-2

Electronic Claims Submitted to FIs

The NDC must be entered as follows in the ASC X12N electronic format:

N4 SV202-1
11-digit NDC SV202-2

Other HIPAA-Related Requirements for Electronic Claims

The American National Standards Institute (ANSI) chartered the X12 Accredited Standards Committee (ASC) to design national electronic standards for a wide range of business applications. In turn, an ASC X12N subcommittee was chartered to develop electronic standards specific to the insurance industry, including health care insurance. The subcommittee included health care providers, health plans, bankers, and software vendors who worked to develop standards for electronic health care transactions.

ANSI accredits standards-setting organizations to ensure that the procedures used meet certain due process requirements and that the process is voluntary, open, and based on consensus. Both the ASC X12 and the NCPDP, meeting the ANSI criteria are named as ANSI-accredited standards developers. The two types of code sets required for data elements in ASC X12N and NCPDP health transaction standards are large coding and classification systems for medical data elements which include drugs and smaller sets of codes for data elements such as type of facility. The current use of drug codes within the alpha-numeric HCPCS for claims processing will be replaced with the NDC.

ASC X12N Claims Standards

Health care claims for drugs from all entities must use the NDCs with the ASC X12N format in place of the alpha-numeric HCPC drug codes. In the Standards for Electronic Transactions Final Rule (published on August 17, 2000), the Secretary of Health and Human Services adopted the ASC X12N 837 4010 professional and ASC X12N 837 4010 institutional formats for electronic claims transactions as national standards. The implementation guides for these ASC X12N standards may be obtained from:

Washington Publishing Company
806 W. Diamond Avenue
Suite 400
Gaithersburg, Maryland 20878
Telephone: (301) 590-9337
FAX: (301) 869-9460
Internet at http://www.wpc-edi.com

NCPDP Claim Standard

The Secretary of Health and Human Services adopted the NCPDP Telecommunication Standard Implementation Guide, Version 5 Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1 Release 0, February 1, 1996, for retail pharmacy claims. The implementation specifications may be obtained from:

National Council for Prescription Drug Programs
4201 North 24th Street
Suite 365
Phoenix, Arizona 85016
Telephone: (602) 957-9105
FAX: (602) 955-0749
Internet at http://www.ncpdp.org

These standards were announced in the Standards for Electronic Transactions Final Rule (published on August 17, 2000). They are the only two formats that will be accepted from retail pharmacies for drug claims or equivalent encounter information.

The NDC is the required code set for reporting drugs in the NCPDP standard formats. Although the NCPDP formats will be used only by the DMERCs within Medicare, FIs and carriers may wish to become familiar with these formats in anticipation of a proposed national Medicare prescription drug program.

Common Working File (CWF)

The CWF must make appropriate changes to accommodate the NDC for edits and data collection as previously associated with the HCPCS drug codes.

Testing

The goal of internal testing is to ensure that all changes work as intended and that existing systems functionality is not impeded. Refer to PM Transmittal AB-00-25, dated April 2000 for guidance on your testing responsibilities.

Reporting

When the NDC is implemented, you must comply with all reporting requirements for drugs using the NDC instead of the HCPCS drug codes.

Outreach

You must conduct the necessary training in using the NDC for providers to assure a smooth migration to the NDC from HCPCS drug codes. Use routine methods, such as newsletters, for initial notification. Survey other outreach methods depending on the intensity of training needed. Convey to providers that they may begin submitting claims with NDCs on April 1, 2002, and may only use NDCs on claims submitted on and after October 1, 2002. Beginning October 1, 2002, reject as unprocessable a claim for a prescription drug or biological that does not contain an NDC.

Questions and Comments Received

The following comments and questions were received in response to the original distribution of the PM. The comments include those, which refer to Parts A and B. Where answers were available, they are included in this section. Some comments and questions require greater review. Answers to the comments and questions under review will be included in the follow up PM.

1. The change to NDCs from HCPCS will require the revision of several regional medical review policies to reflect the transition to NDCs from HCPCS. *(HIPAA legislation mandates the use of NDCs for drug billing. All actions must be accomplished to comply with the law.)*

2. Internal medical review guides will require revision to reflect the change to NDCs. *(See response to comment #1.)*

3. The potentially numerous NDCs for each drug HCPC creates a new volume of drug codes that will create a huge undertaking to implement at all levels. *(The regulation defines a timeframe of 24 months from the effective date of the regulation to accomplish the needs to comply with HIPAA.)*

4. Having the NDC go on the remit to the supplier and on the Medicare Summary Notice to the beneficiary entails changes in both internal and external education. *(This issue will is under review.)*

5. If the NDC is required throughout the entire claims processing, every edit (EAR, AFN, rule) currently built with the capacity for a HCPCS code would need to be changed. All logic within the system would have to be changed. *(See response to comment #1.)*

6. In regard to paper claims, what about HCFA-1490's? We cannot expect the beneficiary to know an NDC code. There will be more manual efforts to correctly look up the NDC code in order to manually key the claim properly. *(What do beneficiaries currently do with HCPCS? The Form HCFA-1490S requires the beneficiary to attach itemized bills from the doctor or supplier. These sources should be aware of NDCs, especially after the outreach provided by contractors to initiate them to the NDC use.)*

7. Will HCFA routinely notify contractors of new NDCs covered by Medicare? *(This issue is currently under review.)*

8. Will contractors be provided an initial master list of covered NDCs with routine updates? *(The most likely scenario is that there will be a HCPCS/NDC crosswalk available by disk or on a website.)*

9. Will the system be required to maintain and retain each quarter's fee update in order to process drug claims based on date of service? *(Presently, our thinking is to process claims based on the date of service to preclude holding claims awaiting potential drug price increases.)*

10. Current fees match units as described by HCPCS. The NDCs reflect a more extensive breakout of pricing development associated with many strengths, dosages, and package sizes. *(The pricing methodology will comply with 42 CFR 405.517. The step to price based on HCPC descriptor will be eliminated.)*

11. Changes from the current pricing procedures, fee calculation programs, and increase number of fees to maintain will require numerous system changes to maintain and price claims. *(Various architectures to develop and maintain the allowable drug prices are under review.)*

12. There are numerous budgetary concerns. *(Budgetary requirements are currently being reviewed.)*

13. Maintaining drug HCPCS following total implementation of NDCs would be cumbersome and should not be considered. *(The need to maintain HCPCS files in addition to the NDCs is contrary to the purpose of HIPAA Administrative Simplification. An update of the HCPCS file, theoretically, should not be needed after full implementation of NDCs. An archived HCPCS file up to the date of full implementation may be needed for appeals purposes.)*

14. Implementation of the NDC will have workload impacts on a variety of functions including tying medical review edits to each NDC; crosswalking HCPCS, CPTs, and NDCs; comparing generics and brand names of similar drugs, the multiple number of NDCs per HCPC require additional person-hours for pricing activities; manual loading of new Master Procedure Record screens; modify pricing procedures to convert allowable determined for a specific drug unit to the number of units included in each NDC; develop and implement a process to catch and any overutilization of drugs that exceed monthly parameters outlined in policy; manual review for paper claims with NDC plus a modifier, and updating all claims processing manuals with new NDC codes and appropriate processing policies. *(See response to comment #1.)*

15. There will be significant impact on costs to implement the NDC. *(See response to comment #12.)*

16. Intensive training will be needed throughout the provider community for this change. *(Outreach is important facet to the success of NDC implementation.)*

17. Contractors should maintain a HCPCS drug list after total implementation of NDCs for appeals actions. *(See response to comment #13.)*

18. There will be a temporary increase in provider inquiries. *(This is expected with any new initiative. Your responsibility will include determining and estimating staff requirements and budget impact.)*

19. There needs to be adequate lead-time for provider notifications to be released in order for providers to make system changes. *(The reason for this advance informational PM is to provide an early start by making you aware of the HIPAA requirements.)*

20. There is concern about duplicate billing for the same drug once under a HCPC and once under an NDC. *(This issue is currently under review.)*

21. Carrier intelligent character recognition (ICR) systems must be updated to recognize new code configuration for Part B. *(Our understanding is that DMERCs have installed logic for the scanners to recognize the 11-digit NDCs which are submitted by suppliers and processed by the DMERCs for oral anticancer drugs, oral antiemetic drugs, and anticancer Prodrugs.)*

22. CWF must be ready to accept the new codes on time. *(CWF is aware of HIPAA requirements and timeframes.)*

23. Instructions should be made available for processing unprocessable claims after the implementation date for NDCs. *(This issue is being reviewed.)*

24. In order to process the new 11-digit procedure codes, major system enhancements would need to begin for all standard systems. Many files and functions that interact with the NDC field will need to be reprogrammed. *(See response to comment #1.)*

25. Should carriers assume that only ANSI 837 version 4010 should be used to report NDC codes? *(This issue will be forwarded to appropriate staff for a response.)*

26. Should the original NDC code be reported back to the provider on electronic remittance if there is a change in NDC code? *(This issue is currently under review.)*

27. Billing instructions will be needed for crossover companies receiving different versions of the ANSI 837. *(This issue will be forwarded to appropriate staff.)*

28. Optical Character Recognition logic will need to be able to identify the difference between a procedure with modifiers and a NDC#. *(This issue is currently under review.)*

Comments on this implementation should be directed to Marvin Stoogenke (Mstoogenke@hcfa.gov) and Wendy Knarr (Wknarr@hcfa.gov) or at 7500 Security Blvd (C4-10-07), Baltimore, Maryland 21244 and are due by February 9, 2001.

There is no effective or implementation date at this time.

This PM may be discarded after January 2, 2002.

If you have any questions, contact Marvin Stoogenke on (410) 786-9867 (DMERCs), Leslie Trazzi on (410) 786-7544 (carriers), or Vicki Collett on (410) 786-8787 (FIs).