Program Memorandum Carriers

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

Transmittal B-02-052 **Date: JULY 31, 2002**

CHANGE REQUEST 2255

SUBJECT: Implementation of the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard Version 5.1 and the Equivalent Batch Standard Version 1.1 for Retail Pharmacy Drug Transactions

The Secretary of Health and Human Services has established, under part 162 of title 45 of the Code of Federal Regulations, the NCPDP Telecommunications Standard Version 5.1 and Batch Standard 1.1 as the standard for electronic retail pharmacy drug claims and coordination of benefits (COB). This standard will be used by all health plans, including durable medical equipment regional carriers (DMERCs) that process retail pharmacy drug transactions. All other claims submitted to Medicare by pharmacies, other than retail pharmacy drug claims, must be sent in the American National Standards Institute Accredited Standards Committee (ASC) X12N 837 version 4010 Health Care Claim format. In order to comply with the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification provisions, DMERCs and, their standard system must complete implementation of these NCPDP standards by October 16, 2003. Further information on the HIPAA standards requirements in general may be obtained at *http://aspe.hhs.gov/admnsimp*.

This Program Memorandum (PM) instructs DMERCs and VMS to begin systems analysis, programming and testing of the NCPDP batch standard version 1.1 for retail pharmacy claims, and the outbound COB transaction. The VMS and DMERCs will use the NCPDP batch version 1.1 exclusively for these retail pharmacy drug claims. The batch transaction format is intended to provide a file transmission standard for submission in a non-real-time mode of the telecommunications standard transaction. The DMERCs will not accept retail pharmacy drug claims that are not submitted as batch transactions.

The NCPDP standard was designed for prior authorization and eligibility verification, as well as for claim submission and COB. The DMERCs are not required to implement the NCPDP transaction for prior authorization since Medicare does not require prior authorization for these drug claims. The CMS is not requiring DMERCs to implement the NCPDP transaction for eligibility verification at this time.

Documentation

The HIPAA implementation guide for the NCPDP standards may be obtained through www.ncpdp.org. The NCPDP provides free Internet access to NCPDP members. There is a fee of $550.00 for membership in the NCPDP, which includes access to the implementation guides. Funding was recently issued to each DMERC to cover this membership fee. Members may photocopy the implementation guides for exclusive use by their internal personnel.

These instructions will be carried out over 3 releases.

The following product(s) or task(s) will be in release 1 and must be completed by October 1, 2002:

- Inbound Translator - The VMS will develop and provide to each DMERC an NCPDP inbound translator. The translator must validate the syntax compliance of the inbound NCPDP standard and translate it into an NCPDP-based flat file for use by the standard system.

- Response Report – An NCPCP standard response will be created to report standard syntax errors detected in the transaction. A standard response will not be generated simply to acknowledge receipt of a compliant transaction.

The following product(s) or task(s) will be in release 2 and must be completed by January 1, 2003:

- Coding – All standard system coding for inbound processing will be completed and delivered to the DMERCs.

- Unit Testing – The VMS and the DMERCs will perform beta and Carrier Acceptance Testing (CAT) testing concurrently.

- Edits – The VMS will develop implementation guide and Medicare program edits. The DMERCs will provide documentation to explain what the edits are and how to address them.

- Response Report – The VMS will use the existing, proprietary report for rejections made as a result of NCPDP Implementation Guide edits, Medicare program edits and DMERC-specific edits.

The following product(s) or task(s) will be in release 3 and must be completed by April 1, 2003:

- Outbound translator - The outbound VMS-created NCPDP translator must create a HIPAA-compliant COB transaction and must include incoming NCPDP drug claim data, except as modified during adjudication such as for beneficiary address correction, as well as adjudication data.

- Coding – All coding for COB processing will be completed and delivered to the DMERCs.

REQUIREMENTS FOR IMPLEMENTING THE NCPDP STANDARD

Specialty Code on the inbound NCPDP claim - Retail pharmacies will be identified by a value of A5 in the specialty code as received by the National Supplier Clearinghouse. Only DMERC suppliers with an A5 specialty code may use the NCPDP standard. NCPDP claims received with a specialty code other than A5 will be rejected

National Drug Codes (NDCs) – The DMERCs, their EDI submitters, and their other trading partners are required to transmit the NDCs in the NCPDP standards for identification of prescription drugs dispensed through a retail pharmacy. NDCs replace the drug HCPCS codes for retail pharmacy drug transactions billed to DMERCs via the NCPDP standards. The VMS will convert NDCs to HCPCS codes for internal claim processing. The CMS will provide the HCPCS codes for these drugs and an NDC to HCPCS crosswalk for the use by the VMS and the DMERCs. A crosswalk for testing will be provided on or before September 1, 2002. The final crosswalk will be provided on or before October 1, 2002, and will be current up to September 15, 2002. After September 15, 2002, Medicare contractors must maintain the crosswalk file. The CMS will not provide a drug-pricing file. Medicare contractors remain responsible for this task. For re-association purposes, the remittance advice or any COB transaction that references the actual drug must reflect only the NDC. The VMS must retain submitted NDCs, and return NDCs rather than drug HCPCS codes on any outgoing transaction.

The NDC will only be used on the NCPDP standard for billing retail pharmacy drugs. The DMERCs will reject NCPDP claims for services and supplies submitted with NDC codes. These claims must be billed with ASC X12N 837 using HCPCS codes.

Certificate of Medical Necessity (CMN) – The CMN for Parenteral Nutrition (HCFA Form 852) and the DMERC Information Form for Immunosuppressive Drugs (DMERC Form 08.02) will continue to be required. As with other electronic formats, CMN data must be submitted within the valid

transaction. As of the effective date of this PM for claims submitted in NCPDP format, the CMN data must be included in the prior authorization segment, which includes a 500 position narrative

field to hold data not located elsewhere in this segment. Data will also be obtained from the claim or from claim history. By September 1, 2002, CMS will issue additional instructions to ViPS and the DMERCs on extracting the data from the claim or claim history. These additional instructions will also explain how to format the narrative segment of the NCPDP standard and how to identify a claim containing CMN information. After receipt of this information, the DMERCs must publish the information, along with directions for proper claims submission in the NCPDP format, in their next scheduled provider bulletins.

For claims submitted on the CMS-1500, retail pharmacies will continue to supply hard copy CMNs when required

Translator

The translator will edit both the batch header segment and the transaction header segments. This will enable immediate rejection of an interchange or transaction set that is non-compliant. The translators will also:

1. Convert lower case to upper case;

2. Pass all spaces to the NCPDP-based flat file for fields that are not present in the inbound NCPDP version 5.1;

3. Map "Not Used" data elements based upon each segment's definition, i.e., if a data element is never used, do not map it. However, if the same data element is "required" or "situational" in some segments but not used in others, then it must be mapped;

4. Accept multiple interchanges within a single transmission;

5. Convert an NCPDP format file (previously uploaded to the mainframe) into a flat file format for processing by the DMERC standard system;

6. Verify the integrity of the file to ensure that the file is of the proper format and the fields are syntactically correct. For example, numeric defined fields are numeric, fields do not exceed length maximums, etc.;

7. For any rejected file, produce a Response file in the NCPDP format containing one Transaction Header and one Transaction Trailer with the appropriate syntax error noted in the message field.

A HIPAA-compliant NCPDP transaction may include Medicare data (data used by the VMS to process a claim) and non-Medicare data (data not needed or retained in Medicare history). Transactions may not be rejected for submission of otherwise compliant data that is not needed by Medicare. The DMERCs must accept at least the basic ASCII character set on an inbound NCPDP transaction, plus lower case and the @ sign which are part of the extended character set and all special characters designated in the NCPDP standard.

Misdirected Claims

Under the DMERC contract, DMERCs are required to forward claims to the appropriate DME regional carrier for processing when it is determined that the claim submitted is for a beneficiary that resides in a state that is outside the receiving DMERCs processing area. These claims are referred to as misdirected claims. When these claims are submitted in the NCPDP format they will be forwarded to the appropriate DMERC carrier in NCPDP flat file format. These forwarded claims will not be re-translated. The NCPDP flat file format output will be produced by the VMS system, and it will be the responsibility of the DMERC receiving these claims to move these claims through the Medicare Data Communication Network (MDCN) to the appropriate DMERC. The misdirected claims will be subjected to all levels of editing at the original receiving DMERC. Only those claims that are determined to be HIPAA NCPDP format compliant will be forwarded.

Coordination of Benefits (COB)

1. The DMERCs must accept all data permitted in the NCPDP implementation guides on an incoming NCPDP claim (you do not have to process non-Medicare data).

2. The VMS must store that data in the data repository.

3. The VMS must re-associate the data repository data with Medicare claim and payment data in order to create a compliant outbound NCPDP COB transaction.

4. The VMS must create a "minimum data set" transaction when the outbound NCPDP COB transaction is for a paper claim. The minimum data set must contain at least each "required" NCPDP COB segment and applicable post-adjudicated Medicare data, but it is not feasible to report every data element that might have been expected on an electronic, NCPDP-compliant claim.

5. The DMERCs must report the Medicare data, rather than data received on a claim, if post-adjudicated Medicare data, and data used from history and reference files differs and there is no location to report both received and changed data. The NDC submitted on the claim, however, must be returned on the outbound COB transaction.

6. The VMS must retain the data in the VMS data repository for a minimum of 6 months after the adjudication of the claim in order to process appeal and adjustment requests. The adjudication date is the date the X12N 835 remittance advice was originally issued.

7. The VMS must archive the data deleted from the data repository.

Generating an Outbound COB NCPDP Transaction when Required Data is Missing or Invalid

An inbound retail drug claim received on paper, or in a non-NCPDP electronic format pre-October 16, 2003, could lack data elements, or contain data that do not meet the data attribute (alpha-numeric, numeric, minimum and maximum lengths, etc.) requirements needed to prepare a compliant outbound NCPDP COB transaction. In most cases, claims with invalid data are rejected, but paper claims or claims received prior to the date by which NCPDP formats must be used exclusively could be accepted and adjudicated even though they may lack some data needed to build a compliant outbound NCPDP COB transaction. It is also possible to receive data from the Common Working File (CWF) that may not meet the NCPDP requirements for COB. Electronic retail drug COB transactions issued by Medicare must adhere to the data attribute requirements in the NCPDP IG to be HIPAA-compliant. The flat file created by the VMS for COB must have all of the required and applicable conditional data elements that DMERCs need in order to produce a compliant NCPDP outbound COB transaction.

To remedy this the VMS must "gap fill" data when issuing an outbound NCPDP COB transaction, unless data is available from history, the data repository or reference files. To "gap fill" unavailable data, VMS must enter meaningless character(s) that meet the data element minimum length requirement of an outbound NCPDP COB transaction. The VMS must consult with the DMERCs to determine which characters will be used to gap fill required data elements in this situation. The selected meaningless character(s) must be useable with every type of data where this situation could occur, e.g., with alphanumeric (AN), decimal (R), identifier (ID), date (DT), and other data types as appropriate. The values may not include any special characters, low values, high values, or **all** spaces since this could cause problems with a DMERC trading partner's translator. It is not generally advisable to use zeroes as the meaningless characters as these may be eliminated when data is compressed during translation. The DMERCs must share this information with their trading partners to alert them as to when and why these characters will appear in an outgoing transaction.

Testing and Implementation

- The DMERCs will not be required to certify their NCPDP compliance with an external company, but will be required to thoroughly test the programming and operation of their

systems and self-certify their compliance. The DMERCs will follow the testing guidelines as described in CR1704.

- The DMERCs must begin testing the inbound translator by September1, 2002.
- The DMERCs must complete internal testing of the of the NCPDP Inbound Claim and COB Processing by March 31, 2003.
- The DMERCs must conduct provider beta testing of the NCPDP standard with a small number of providers involving a small number of claim batches by no later than April 30, 2003.
- The DMERCs must be able to begin COB beta testing if requested of the NCPDP standard with providers and COB trading partners by April 30, 2003.

PKZIP

You do not need to support PKZIP for NCPDP transactions. Compression is permitted between you and your data center; however, the NCPDP-based flat file when presented to your standard system must not be compressed.

Free Billing Software

DMERCs are not required to offer free billing software to support the submission of claims in the NCPD format.

ADDITIONAL INSTRUCTIONS

1. The VMS will process the NCPDP transactions in batch mode only with up to 4 transactions per transmission.
2. The VMS will process the inbound NCPDP billing record (transaction code B1) and will produce an outbound billing record with COB segments in NCPDP formats.
3. The X12N 835 version 4010 transaction set will be the only remittance advice format used for NCPDP standard claims as of October 16, 2003. Adhere to the requirements previously issued by CMS for generation of ASC X12N 835 version 4010 transactions for use of the 835 with NCPDP claims.
4. The VMS will not process the drug utilization review transaction (transaction code N1).
5. Partial fills of retail pharmacy claims will not be supported.
6. The VMS will not support HRI and UPC codes.
7. The VMS will not process the rebilling transaction (B3 transaction code) or the reversal transaction (B2 transaction code).
8. The VMS will split NCPDP input between data that passed the edits, and data that did not to allow claims that are edit-free to be processed and reject only those that did not pass the edits.
9. The VMS will make necessary changes to the core VMS system to bring in the NCPDP claims.
10. The VMS will make changes to core VMS system to allow identification of an NCPDP claim within the core system.
11. The VMS will develop new edits to the VMS core system to prevent non-drug lines on NCPDP claims.
12. The VMS will change the core VMS system to identify outbound claims that must be in NCPDP format.
13. The VMS will develop new processes to produce an NCPDP standard outbound file.

Provider Outreach

For the purpose of identifying retail pharmacies, the VMS and DMERCs will use the NCPDP definition: " Any duly licensed entities that deliver pharmaceutical goods or services for sale to or use by the final consumer".

By January 3, 2003, DMERCs must notify their pharmacies and their third party billing services, clearinghouses, and vendors that for retail pharmacy drugs covered by Medicare:

1. Each pharmacy that has elected to transmit retail drug claims electronically must begin using the NCPDP batch version 1.1 supporting Telecommunications version 5.1 for the NCPD data record in the detail record by October 16, 2003. The NCPDP standard will be accepted for retail pharmacy drugs only. Claims for supplies and services must be billed using version 4010 of the ANSI ASC X12N 837 and must be submitted in a separate transmission from the NCPDP retail drug claims. Although Medicare will accept the NCPDP formats, the Medicare retail drug payment policies have not been changed. Very few categories of self-administered drugs are ever covered by Medicare;

2. A pharmacy that elects to use a clearinghouse for translation services is liable for those costs;

3. Individuals who want to review the NCPDP standard implementation guides can obtain them at www.ncpdp.org for a fee of $450.00;

4. Pharmacies, agents, and clearinghouses planning to exchange retail pharmacy drug claims data with Medicare electronically by October 16, 2003 must schedule testing with their DMERC by April 1, 2003. There is no Medicare charge for this system testing; and

5. Although Medicare will furnish pharmacies with basic information on the HIPAA standard transaction requirements to make them aware of the changes to be made, Medicare will not furnish in-depth training on the use of the standards implementation guides.

DMERCs must be pro-active to assure that:

1. Pharmacies, agents, and clearinghouses are furnished information for them to understand the impact of the HIPAA Administrative Simplification requirements;

2. Appropriate information regarding this implementation is included in regularly scheduled provider bulletins/newsletters, in other provider educational publications, and as part of education and outreach programs to enable pharmacies to make informed decisions about implementing the HIPAA standards;

3. Successful testing can be completed with pharmacies, agents, and clearinghouses before October 16, 2003 when CMS must discontinue support of retail drug transactions in any other electronic format or version;

4. Pharmacies, agents, and clearinghouses schedule testing by April 1, 2003;

5. Retail pharmacy drug paper and electronic claim submitters (suppliers, clearinghouses) and other payers with whom they interact for COB for retail pharmacy drug claims are notified of these HIPAA requirements in a regularly scheduled paper or electronic bulletin/newsletter. Any current electronic billers must receive advance notice prior to October 16, 2003 of the change in policy as a result of HIPAA. Users of the NCPDP formats must be given advance notice of any subsequent changes in our programming that may affect them. The initial notice must include the approximate date when testing will begin and when/whom/how to contact you to schedule a testing appointment; and

6. Providers are aware that we are not implementing the NCPDP standard for eligibility at this time. Nor do we expect to begin to prior authorize retail drugs.

Cost Issues

The last bullet of the Carrier HIPAA EDI Transactions Productivity Investments section of the FY Budget and Performance Requirements (BPRs) required DMERCs to "include an estimate in your BR [budget request] of the Productivity Investment funds that you will need to implement and operate the NCPDP transaction in FY 2003 using Miscellaneous Code 17004/07. This Program Memorandum (PM) contains more detail than previously shared about the actual CMS requirements for this transaction. As result, DMERCs must submit a supplemental budget request (SBR) to CMS through normal channels by October 15, 2002. The SBR must include the following separately itemized costs incremental to those that otherwise would have been incurred to receive and process retail drug claims pre-implementation of the NCPDP format:

- Any necessary hardware costs;
- Any necessary software costs;
- Release testing costs;
- Submitter testing costs;
- Anticipated number of submitters;
- Share of data center costs;
- Staff training costs;
- Any subcontracting costs and identify the activity being subcontracted; and
- Other costs not previously included in one of the above estimates. Identify the costs and the associated amount of each reported as "other;" and
- Total funding requested.

Do not include provider outreach costs in these estimates. Limit these estimates to direct costs for implementation of the NCPDP transaction as discussed in this PM. Provider costs included in these estimates must be limited to those incurred for testing with individual providers, agents and clearinghouses.

In preparation of any HIPAA-related funding requests, it must be noted that HIPAA established requirements binding on all health care payers, not only on Medicare. The HIPAA did not provide funding for implementation of the administrative simplification transaction standards requirements by each health payer. As with other system and program changes that impact a Medicare contractor's parent company's private/commercial lines of business as well as their Medicare processing activities, direct and indirect costs related to such changes must be proportionately shared by the impacted lines and cost centers, and not charged to Medicare in total. Programming, transition, and operational costs related to a corporate clearinghouse operated by a Medicare contractor's parent company, or any other profit or non-profit line of business of the parent company not required to support Medicare processing under the terms of their Medicare contract, may not be charged in total or in part to the Medicare program.

Manualization of this Information and DMERC Contract Modification

The Medicare Carriers Manual sections dealing with the professional claim transaction will be updated to include changes detailed in this and other HIPAA PMs. The CMS plans to combine and manualize all of the HIPAA transactions information at the same time, following release of individual PMs for the various transactions. The DMERC contracts are also being updated to correspond to these changes.

The *effective date* for this PM is July 31, 2002.

There are multiple *implementation dates* for this PM:

- **VMS maintainer must complete the NCPDP-flat file translator by October 1, 2002.**
- **Incoming NCPDP claim changes must be in the January, 2003 VMS release.**
- **Outbound COB changes must be in the Aril, 2003 VMS release.**

See the section titled "Cost Issues" for detailed information on SBR submissions for costs related to implementation of requirements in this PM.

This PM may be discarded after January 6, 2004.

If you have any questions, contact Marilyn Abramovitz, 410-786-5939 or e-mail mabramovitz1@cms.hhs.gov