

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Final Rule Information on Electronic Transactions As it relates to the Pharmacy Industry

October 2007

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I. GENERAL INFORMATION

On August 17, 2000, information was published in the *Federal Register* from the Department of Health and Human Services (HHS), the Office of the Secretary regarding: Health Insurance Reform: Standards for Electronic Transactions; Announcement of Designated Standard Maintenance Organizations; Final Rule and Notice

Official Date of Final Rule:	August 17, 2000
Effective Date of Compliance:	October 16, 2002
Effective Date of Compliance Small Health Plans:	October 16, 2003
Technical Corrections Published:	November 24, 2000
Date of Administration Simplification Compliance Act:	December 12, 2001
Presidential Signature:	December 27, 2001
First Deadline Date of HHS to have Compliance Request form completed:	March 31, 2002
Deadline for submission of Compliance Request forms:	October 16, 2002
Compliance Request implementers testing requirement:	April 16, 2003
Effective Date of Small Health Plans:	Remains October 16, 2003
Publication Date of Correction NPRMs:	May 31, 2002
Deadline for Public Comments to Correction NPRMS:	July 1, 2002
Publication Date of Final Rule:	February 20, 2003
Effective Date of Final Rule:	March 24, 2003
Effective Date of Compliance:	Remains October 16, 2003

More information from HHS, the final rule, and the technical corrections:

<http://www.cms.hhs.gov/hipaa/hipaa2/default.asp>

This site also offers answers to frequently asked questions, as well as all documentation. Note: NPRM is "Notice of Proposed Rule Making".

We strongly urge each business to review the documents available on the web site above, to evaluate how these changes will affect your business. Please see the NCPDP web site (<http://www.ncpdp.org>) for information as it becomes available.

NCPDP hosted a Version 5 Summit before the August 2000 Joint Technical Work Group meetings. On November 14, 2000 NCPDP hosted "HIPAA: Building Your HIPAA Gameplan" Forum before the November Work Group meetings. NCPDP also hosted a Track at the Annual Conference in February 2001 to discuss Version 5 of the Telecommunication Standard. In August 2001, a Version 5 Summit: "The Nuts and Bolts of HIPAA Transaction Standards" was held. In August 2002, a forum on "HIPAA Privacy

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and Confidentiality” was held. During the March 2003 NCPDP Annual Conference, numerous HIPAA tracks were held. Educational Forums have occurred or are planned for 2004, 2005. Please see the website (www.ncpdp.org) for more information on NCPDP activities.

II. WHAT TRANSACTIONS WERE NAMED IN AUGUST 17, 2000 FINAL RULE?

The following were named in the Final Rule. Please see the chart below and revision notes for current information.

1. ASC X12N 837 – Health Care Claim and Coordination of Benefits: Dental
2. ASC X12N 837 – Health Care Claim and Coordination of Benefits: Professional
3. ASC X12N 837 – Health Care Claim and Coordination of Benefits: Institutional
4. NCPDP Telecommunication Standard Version 5.1 and equivalent NCPDP Batch Standard Version 1.0 – Retail Pharmacy Drug Claims, Health Care Eligibility Benefit Inquiry and Response, Health Care Payment and Remittance Advice, and Coordination of Benefits
5. ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response: Dental, Professional, Institutional
6. ASC X12N 278 – Health Care Services Review: Referral Certification and Authorization - Dental, Professional, Institutional
7. ASC X12N 276/277 – Health Care Claim Status Request and Response
8. ASC X12N 834 – Benefit Enrollment and Maintenance
9. ASC X12N 835 – Health Care Claim Payment/Advice
10. ASC X12N 820 – Payroll Deducted and Other Group Premium Payment for Insurance Products

Refer to Subpart K – R. Note changes have been made to what was published and the changes will be incorporated into a re-released Final Rule.

2/20/2003 Update – The Final Rule makes a distinction between the standards that a covered entity should use during given timeframes, depending on whether a compliance plan was submitted (see section “[HIPAA Transactions And Code Sets Implementation Compliance](#)”). Note, corrections have also been made to the above list.

A. TRANSACTION CHART

Transaction	Business/Service	Standard Named in August 17, 2000 Rule (in effect if no Compliance Plan filed, in effect until October 15, 2003)	Modification Named in the February 20, 2003 Rule (Compliance Plan filed, in effect October 16, 2003 and beyond)	Notes
<i>Health claims and equivalent encounter information.</i>				
	Retail pharmacy claims	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.0	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.1.	Please see Note 1.
	Professional Pharmacy claims	ASC X12N 837 Health Care Claim: Professional, Version 4010, 004010X098	ASC X12N 837 Health Care Claim: Professional, Version 4010, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, 004010X098A1	Not specifically named, but noted here. Please see Note 2.
	Dental claims	ASC X12N 837 Health Care Claim: Dental, Version 4010, 004010X097	ASC X12N 837 Health Care Claim: Dental, Version 4010, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, 004010X097A1	
	Professional claims	ASC X12N 837 Health Care Claim: Professional, Version 4010, 004010X098	ASC X12N 837 Health Care Claim: Professional, Version 4010, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, 004010X098A1	
	Institutional claims	ASC X12N 837 Health Care Claim: Institutional, Version 4010, 004010X096	ASC X12N 837 Health Care Claim: Institutional, Version 4010, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, 003010X096A1	
<i>Enrollment and</i>				

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<i>disenrollment in a health plan.</i>				
	All named.	ASC X12N 834 Benefit Enrollment and Maintenance, Version 4010, 004010X095	ASC X12N 834 Benefit Enrollment and Maintenance, Version 4010, 004010X095, and Addenda to Benefit Enrollment and Maintenance, Version 4010, 004010X095A1	
<i>Eligibility for a health plan.</i>				
	Retail pharmacy eligibility.	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard 1.0	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.1.	Please see Notes 1., 4.
	All others named.	ASC X12N 270 Health Care Eligibility/Benefit Inquiry and ASC X12N 271 Health Care Eligibility/Benefit Response, Version 4010, 004010X092	ASC X12N 270 Health Care Eligibility/Benefit Inquiry and ASC X12N 271 Health Care Eligibility/Benefit Response, Version 4010, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, 004010X092A1	
<i>Health care payment and remittance advice.</i>				
	Retail pharmacy drug claims and remittance advice.	NCPDP Telecommunication Standard Version 5.1 and Batch Standard 1.0.	ASC X12N 835 Health Care Claim Payment/Advice, Version 4010, X004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, 004010X091A1	Please see Note 5.
	All others named.	ASC X12N 835 Health Care Claim Payment/Advice, Version 4010, X004010X091	ASC X12N 835 Health Care Claim Payment/Advice, Version 4010, X004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, 004010X091A1	
<i>Health plan premium</i>				

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<i>payments.</i>				
	All named.	ASC X12N 820 Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, 004010X061	ASC X12N 820 Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, 004010X061A1	
<i>Health claim status.</i>				
	All named.	ASC X12N 276/277 Health Care Claim Status Request and Response, Version 4010, 004010X093	ASC X12N 276/277 Health Care Claim Status Request and Response, Version 4010, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, 004010X093A1	
<i>Coordination of benefits.</i>				
	Retail pharmacy claims	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.0	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.1	Please see Note 3.
	Dental claims	ASC X12N 837 Health Care Claim: Dental, Version 4010, 004010X097	ASC X12N 837 Health Care Claim: Dental, Version 4010, 004010X097, and Addenda to Health Care Claim: Dental, Version 4010, 004010X097A1	
	Professional claims	ASC X12N 837 Health Care Claim: Professional, Version 4010, Volumes 1 and 2, 004010X098	ASC X12N 837 Health Care Claim: Professional, Version 4010, Volumes 1 and 2, 004010X098, and Addenda to Health Care Claim: Professional, Version 4010, Volumes 1 and 2, 004010X098A1	
	Institutional claims	ASC X12N 837 Health Care Claim: Institutional, Version 4010, Volumes 1 and 2, 004010X096	ASC X12N 837 Health Care Claim: Institutional, Version 4010, Volumes 1 and 2, 004010X096, and Addenda to	

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			Health Care Claim: Institutional, Version 4010, Volumes 1 and 2, 004010X096A1	
<i>Health Care Services: Referral Certification and Authorization</i>				
	Retail pharmacy	ASC X12N 278 Health Care Services Review – Request for Review and Response, Version 4010, 004010X094	NCPDP Telecommunication Standard Version 5.1 and NCPDP Batch Standard Version 1.1.	Please see Note 6.
	All others named.	ASC X12N 278 Health Care Services Review – Request for Review and Response, Version 4010, 004010X094	ASC X12N 278 Health Care Services Review – Request for Review and Response, Version 4010, 004010X094, and Addenda to Health Care Services Review – Request for Request and Response, Version 4010, 004010X094A1	

B. NOTES

1. HEALTH CLAIMS AND EQUIVALENT ENCOUNTER INFORMATION – RETAIL PHARMACY CLAIMS AND ELIGIBILITY FOR A HEALTH PLAN – RETAIL PHARMACY

9/2000 Update - NCPDP Batch Standard Version 1.1 corresponds with Telecommunications Standard Version 5.1. However, the rule states Batch Standard Version 1.0. This correction was requested upon reading the published Final Rule. HHS was not creating corrections at that time. NCPDP and its members continued to work with HHS on this issue.

3/13/2001 Update – NCPDP posted the requested change to the DSMO (Designated Standards Maintenance Organization) Change Request System website (www.hipaa-dsmo.org). HHS has accepted the revision to support Batch Standard Version 1.1 for usage with Telecommunication Version 5.1. Preliminary approval was given. Published approval is expected during 2001. Once this is named, all references to NCPDP Batch 1.0 will stand as NCPDP Batch 1.1 for usage with Telecommunication Standard Version 5.1.

7/18/2001 Update – CRS # 113 and 361 were recommended by the DSMO for inclusion in the corrections. The corrected verbiage of NCPDP Batch Version 1.1 with NCPDP Version 5.1 as the Detail Data Record will be published in the NPRM addressing corrections, expected in 2001.

The term “encounter” has been clarified. HHS has stated that the transactions named are between a provider and a health plan. The term sometimes used in the industry as “encounter” described two health plans relaying information between themselves (plan, compliance, claim summary information) is not covered under the definition of encounter as HHS defined. Therefore, these types of reporting transactions are not defined under HIPAA regulations on transactions.

8/23/2001 Update – The final rule names the NCPDP Standards for the billing of drug claims. It states other claims will use the ASC X12N 837. NCPDP members asked HHS for clarification regarding the billing of supplies, currently done using NCPDP Standards. HHS responded to a Frequently Asked Question that said the drug would be billed via NCPDP Standards and the supply via ASC X12N. The rule does not specifically name a standard for billing of supplies, but HHS inferred the standard. The FAQ has not been posted yet, due to the pharmacy industry concerns about this clarification.

This clarification does not address supplies and drugs that co-exist (e.g. Epipen), or other supplies that are currently billed using NCPDP Standards. NCPDP WG9 Government Programs is creating a draft white paper that addresses recommendations for how supplies should be billed, as they affect the pharmacy industry. This white paper will be sent to HHS/CMS.

12/21/2001 Update – The white paper for billing of supplies was submitted to HHS/CMS on October 1, 2001. NCPDP members are continuing discussions with CMS (Center for Medicare and Medicaid Services) for the naming of NCPDP Standards for billing of supplies. In addition, member companies are

working with other healthcare associations, government representatives and political contacts to support the NCPDP Standards for billing of supplies. The paper can be viewed at http://www.ncdp.org/frame_members_government_hipaa.htm

2/4/2002 Update – The Designated Standards Maintenance Organizations (DSMO) have reviewed Change Request 492 (naming of code sets and NCPDP Standards for supplies) and will be discussing further within their organizations.

4/31/2002 Update – The DSMO have completed review of Change Request 492 (naming of code sets and NCPDP Standards for supplies) and have recommended:

“The billing of supplies from retail pharmacies should be permitted using the NCPDP Telecommunication Standard Version 5.1 or Batch Standard Version 1.1 under HIPAA. When supplies are billed by the dispensing retail pharmacy, HCPCS, NDC, UPC and HRI should be permitted code sets that can be used for the specific identification of supplies.”

Letters have been sent to the National Committee on Vital and Health Statistics (NCVHS) asking for further support the NCPDP Standards for current business practices. In addition, comments will be placed in the NCPDP response to the correction NPRMs.

7/15/2002 Update – The correction NPRM has proposed the modification to the “NCPDP Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 20000, supporting Telecommunication Version 5.1 for the NCPDP Data Records in the Detail Data Record”.

The billing of supplies was not addressed in the correction NPRM (it was not expected to), however the comments to the NPRM by the NCPDP membership included support of the NCPDP Standards for the billing of supplies, with the appropriate code sets of HCPCS, NDC, UPC, and HRI. The DSMO also sent in comments to the NPRM, and included their recommendation on the billing of supplies.

2/20/2003 Update – The Final Rule response to the billing of supplies is confused with the billing of professional services. The Rule incorrectly states that the DSMO are still evaluating a Change Request. The DSMO completed their recommendation on the supplies Change Request and recommended the support of NCPDP standards for supplies to NCVHS as well (see 4/31/2002 Update above). The Rule says that further guidance will be provided.

8/25/2003 Update – No official guidance on supplies or professional services has been issued yet. It may be published in a Spring 2004 NPRM that has been noted in the “Regulations Status”. CMS has stated in conferences, conference calls, and in Medicare Program Memorandum (B-03-057 http://www.cms.hhs.gov/manuals/memos/comm_date_dsc.asp) that supplies would be billed using the ASC X12N 837.

During the August work group meetings, NCPDP members discussed the issue of supply billing under the HIPAA Transactions and Code Sets regulation. Retail pharmacies would like to continue to use the HIPAA-named NCPDP standards for the payment of health care supply claims. The NCPDP standards used by retail pharmacies must be permitted under HIPAA for the billing of health care supplies. Since 2000, the industry has been trying to effect this change. Per the August discussion, the members discussed furthering this action with their governmental representatives. A draft letter, talking points, and historical documentation have been created by the task group. Please see http://www.ncdp.org/news/hipaa_trans.asp under "Supply Billing".

9/5/2003 Update - Industry representatives met on September 4, 2003 with Centers for Medicare and Medicaid (CMS) representatives. The topic was to discuss that retail pharmacy continue to be able to use NCPDP standards to bill supplies rather than the ASC X12 837 batch standard that CMS currently believes retail pharmacy must use after the October 16, 2003, HIPAA transaction implementation deadline.

Important Points:

- CMS said that they would open up the billing of supplies issue for public comment by publishing a proposed rule next spring.
- CMS said that retail pharmacy could continue to use NCPDP standards to bill supplies until CMS published a final ruling on this issue, but **only if** pharmacies and their business partner payors/PBMs and processors developed a contingency plan that described why continuing to use the NCPDP standards was in their best interest.
- CMS also will require that these business partners must be able to demonstrate good faith efforts in trying to comply with HIPAA standards... for example, communications that try to convince CMS to allow retail pharmacy to use NCPDP standards to bill supplies.
- CMS said they would publish a statement in the form of a Frequently Asked Question (FAQ) next week that will clarify the guidance CMS published on July 24, 2003 about the requirements of both the contingency plan and the good faith efforts.
- CMS plans to use the FAQ and the July 24 guidance in meetings with state Medicaid agencies so that Medicaid can continue to accept NCPDP standard supply claims.

9/25/2003 Update – The FAQs were posted by CMS during the week of September 8, 2003 on <http://www.cms.hhs.gov/hipaa/hipaa2/default.asp> under "FAQs". The questions are:

Q - What is an acceptable contingency plan?

A - An acceptable contingency plan is whatever is appropriate for the individual plan's situation in order to ensure the smooth flow of payments. Health plans will need to make their own determinations regarding

contingency plans based on their unique business environments. A contingency plan could include, for example, maintaining legacy systems, flexibility on data content or interim payments. Other more specific contingency plans may also be appropriate. For example, a plan may decide to continue to receive and process claims for supplies related to drugs using the NCPDP format rather than the 837 format currently specified in the regulations. The appropriateness of a particular contingency or the basis for deploying the contingency will not be subject to review.

Q - Is it acceptable for a health plan to announce its contingency now?

A - Yes. Health plans should announce their contingency plans as soon as possible to allow their trading partners enough time to make any needed adaptations to their business operations to ensure minimal disruptions. In deciding whether to deploy a contingency plan, organizations would have to make an assessment of their outreach and testing efforts to assure they made a "good faith" effort.

Q - How does a covered entity demonstrate good faith?

A - Covered entities should keep track of the efforts they have made - both before and after the October 16 compliance date - to become compliant. For a provider, that could include your efforts to work with vendors, clearinghouses and submitters to schedule testing with plans, and the results of those tests. For a plan, it could include keeping track of outreach activities (letters, conferences, phone calls, etc.) encouraging providers/submitters to schedule testing, testing schedules, and statistics showing increased testing results.

Q - Will Medicare be ready on October 16, 2003?

A - Yes. Medicare already accepts HIPAA-compliant transactions.

Q - Who will determine whether I made a good faith effort?

A - The Office of HIPAA Standards within the Centers for Medicare & Medicaid Services (CMS) is responsible for enforcing the electronic transactions and code sets provisions of the law. When OHS receives a complaint about a covered entity, it would ask the entity to demonstrate their reasonable and diligent efforts to become compliant and, in the case of health plans, to facilitate the compliance of their trading partners. Strong emphasis will be placed on sustained actions and demonstrable progress in determining a covered entity's good faith effort.

Q- What will Medicare's contingency plan be?

A - Medicare's contingency would be to continue to accept and send transactions in legacy formats - in addition to HIPAA compliant transactions - while trading partners work through issues related to implementing the HIPAA standards. The contingency plan will be the same for all Medicare's fee-for-service contractors. A decision on whether to deploy a contingency will be made by September 25, 2003. Medicare will continue its active outreach and testing efforts to bring its trading partner community into compliance with the HIPAA standards.

Q - How will Medicare decide whether to implement its contingency plan?

A - CMS is currently assessing the readiness of our trading partner community including the number of Medicare submitters who are testing and in production with our contractors. The results of these indicators will determine whether CMS will deploy its contingency.

Q - What kind of activities is Medicare doing to demonstrate good faith efforts?

A - CMS has directed the Medicare contractors to intensify all HIPAA outreach and testing efforts with their respective provider and submitter communities and trading partners. Contractors are communicating HIPAA information via individual provider contacts, published provider bulletins, websites, and many other mechanisms. CMS also provides HIPAA information via webcasts, videos, advertising in industry publications, and audioconferences.

11/21/2003 Update – HHS will issue a Notice of Proposed Rule Making in August (?) 2004 that will possibly ask for comments on the definition of “retail pharmacy”, possibly “drug claims”, the issue of supplies, professional pharmacy services, possibly home infusion processing, possibly a process whereby standards modifications may be made without the federal rule making process, and other items.

03/31/2004 Update – On 3/31/2004, industry representatives provided testimony to the National Committee on Vital and Health Statistics (NCVHS) on the Designated Standards Maintenance Organization Change Request 492, which was for the billing of supplies. For full information, the transcript will be available on the NCVHS website <http://www.ncvhs.hhs.gov/>. See also http://www.ncdp.org/news_hipaa_trans.asp

Based on the testimony, representation present from community pharmacy, chain pharmacy, health plans and PBMs agreed with the testimony, which reflects current industry practice. The recommendation statement that tried to succinctly define the request for the billing of supplies is:

"It is requested that the billing of supplies that are consumed or used during, or as a consequence of, the administration of a drug therapy, or commonly dispensed via a retail pharmacy use the NCPDP standards."

It was also noted that the Medicare Part D plan will be paying for some supplies and that since Part D was ambulatory/outpatient, the patients would be serviced by retail pharmacy and therefore using NCPDP standards. In addition, NCVHS asked about a demarcation of "for pharmacy benefit" versus "medical benefit". It was noted that NCPDP had attempted to incorporate this language in the past with CMS and it was not accepted. However, if NCVHS wishes to pursue this recommendation further, NCPDP would be glad to assist with drafting the language.

The NCVHS Subcommittee will begin a draft letter stating the verbiage above as the recommendation to HHS. In May, they will hold hearings that will include the use of the code sets. Lynne Gilbertson will be working with the Staff Liaison to see what that will all entail. After the May testimony, the NCVHS Subcommittee plans to complete the letter, hopefully approving it in

June, and send to HHS. The importance of the relationship of the code sets to the standards for billing, and the current usage was stressed, but NCVHS wishes to hear testimony regarding the codes since these code sets are not all named in HIPAA.

Concern was expressed regarding the timing of the recommendation to HHS so that the recommendations would be included in the NPRM. The "modifications" rule may not come out until late summer/early fall (a lengthy time since the 2003 rule said guidance would be issued on supplies). With the hearings, the letter completion, the NPRM approval process, the publication, there is the possibility of even further delay. The NCVHS Chair said they would address the concern.

06/17/2004 Update – NCVHS posted the letter of recommendation to HHS. The letter can be viewed at <http://www.ncvhs.hhs.gov/> under "Hot Topics", "Letters to Secretary Thompson".

"NCVHS recommends the continued use of the NCPDP Telecommunication Standards for billing of supplies that are consumed or used during, or as a consequence of, the administration of a drug therapy or commonly dispensed via a retail pharmacy channel. We also recommend that the Department investigate this issue further, especially as it relates to possible overlaps in the use of NCPDP and X12 standards for the billing of certain supplies by pharmacies."

They also addressed the use of NDC, HRI, UPC.

9/16/2004 Update – No official guidance on supplies or professional services has been issued yet. It may be published in a Spring 2005 NPRM that has been noted in the "Regulations Status".

7/24/2005 Update – No official guidance on supplies or professional services has been issued yet. Other items have been added to CMS' list of what might be included in an NPRM and the date has been pushed out. It may be published in a Spring 2006 NPRM that has been noted in the "Regulations Status".

03/09/2006 Update – No official guidance; perhaps Summer 2006. OESS did clarify a question on eligibility between health plans and coordination of benefits between health plans.

"The eligibility exchange between plans is a HIPAA covered transaction (not referenced as an encounter). See 162.1201. Also COB exchanges between plans are HIPAA covered transactions (162.1801)."

2. HEALTH CLAIMS AND EQUIVALENT ENCOUNTER INFORMATION – PROFESSIONAL PHARMACY CLAIMS

9/2000 Update - The final rule incorrectly stated that NCPDP Telecommunication Standard Version 5.1 could not support the billing of professional pharmacy services since it did not support HCPCS J-codes to identify the pharmacy procedure or service. However in another section, it listed qualities of the NCPDP Telecommunication Standard, which included professional pharmacy services.

The NCPDP Telecommunication Standard Version 5.1 clearly supports HCPCS J-codes as a qualifier. The rule named the ASC X12N 837 Health Care Claim: Professional, Version 4010 transaction. The correction was requested. NCPDP members are working to have Telecommunication V5.1 and Batch 1.0 (revised 1.1) added for retail pharmacy professional services. This document has been modified to indicate the HHS decision.

3/13/2001 Update – HHS has asked for assistance in defining professional pharmacy services. NCPDP's Work Group 10 Professional Pharmacy Services is creating a task group to assist in this definition.

7/28/2001 Update – NCPDP Work Group 10 Professional Pharmacy Services has created a draft White Paper on the usage of the NCPDP transactions and the ASC X12N 837, as appropriate for billing of professional services. The recommendation is that NCPDP Telecommunication Standard Version 5,1, Batch 1.1, and ASC X12N 837 Health Care Claim: Professional, Version 4010 are all appropriate transactions for billing professional services, for different business practices.

The term “encounter” has been clarified. HHS has stated that the transactions named are between a provider and a health plan. The term sometimes used in the industry as “encounter” described two health plans relaying information between themselves (plan, compliance, claim summary information) is not covered under the definition of encounter as HHS defined. Therefore, these types of reporting transactions are not defined under HIPAA regulations on transactions.

12/21/2001 Update – The white paper on billing of professional pharmacy services was submitted to HHS/CMS on October 1, 2001. NCPDP members are continuing discussions with CMS (Center for Medicaid and Medicare Services) for the naming of NCPDP Standards for billing of professional pharmacy services. In addition, member companies are working with other healthcare associations, government representatives and political contacts to support the NCPDP Standards for billing of professional pharmacy services. The paper can be viewed at http://www.ncpdp.org/frame_members_government_hipaa.htm

2/4/2002 Update – The white paper has been shared with DSMO for discussion within their organizations.

2/14/2002 Update – Change Request #574 has been added to the DSMO Change Request System to request support for the NCPDP Standards for the billing of professional pharmacy claims.

4/31/2002 Update – Change Request #574 is being adjudicated by the DSMO. Letters of support and letters of disapproval have been received by HHS and the DSMO. Discussions are taking place as the DSMO adjudicate the request. In addition, support of the NCPDP Standards for use in professional pharmacy services when part of the pharmacy benefit, will be included in the NCPDP response to the correction NPRM.

7/15/2002 Update – Change Request #574 will be published with the DSMO categorization of “No Change” and the recommendation of:

“The DSMO recommend that these types of claims should continue to be submitted as they are currently being submitted.”

2/20/2003 Update – The Final Rule incorrectly states that the DSMO are still evaluating a Change Request on the billing of professional pharmacy services. The DSMO completed their recommendation on the Change Request (see 7/15/2002 Update above). The Rule says that further guidance will be provided.

8/25/2003 Update – No official guidance on supplies or professional services has been issued yet. It may be published in a Spring 2004 NPRM that has been noted in the “Regulations Status”.

9/16/2004 Update – No official guidance on supplies or professional services has been issued yet. It may be published in a Spring 2005 NPRM that has been noted in the “Regulations Status”.

7/24/2005 Update – No official guidance on supplies or professional services has been issued yet. Other items have been added to CMS’ list of what might be included in an NPRM and the date has been pushed out. It may be published in a Spring 2006 NPRM that has been noted in the “Regulations Status”. With the advent of Medicare Part D providing medication therapy management, the item is under discussion at NCPDP’s Work Group 10 Professional Pharmacy Services.

10/13/2006 Update – CMS published an FAQ and guidance on 10/4/2006. There are supporters of this in the industry, and those who do not agree.

CMS FAQ 7943

Feedback

When a Provider submits a claim to a Part D sponsor for a clinical service provided as part of a Medication Therapy Management Program (MTMP), should they submit the claim using the NCPDP 5.1 transaction standard or must they use the (ASC) X12N 837P Version 4010/4010A1 transaction standard?

Answer

The American Standards Committee (ASC) X12N 837P Version 4010/4010A1. We articulated in our January 28, 2005 Final Rule on the Medicare Prescription Drug Benefit that we viewed Medication Therapy Management (MTM) as a clinical service (70 FR 4194, 4231). Therefore, claims for MTM would be considered professional health care claims rather than retail pharmacy drug claims. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, HHS adopted, in the August 17, 2000 Transactions and Code Sets Final Rule, the ASC X12N 837P Version 4010/4010A1 as the transaction standard for professional health care claims. Therefore, similar to physician clinical services, if MTM providers bill Part D sponsors electronically for MTM services, such billing claims must be transmitted using the ASC X12N 837 P Version 4010/40010A1. Part D Sponsors are not precluded from using the NCPDP 5.1 system edits as a method to identify targeted beneficiaries, or provide applicable information at the point of service to pharmacists or other MTM providers responsible for providing the MTMP services, but the health care claim must be transmitted using the ASC X12N 837P.

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For more information on HIPAA, Plans should refer to the following website for detailed information: <http://www.cms.hhs.gov/HIPAAGenInfo/>

10/23/2007 Update – CMS published an updated FAQ on 10/23/2007.

Question:

When a Provider submits an electronic claim for MTMP services, to a health plan, including a Part D drug plan, should they use the NCPDP 5.1 standard or must they use the X12N 837P standard, under HIPAA?

Feedback:

Please note that this FAQ has been revised to include a HIPAA enforcement addendum as of October 22, 2007.

When a Provider submits a claim to a health plan including a drug plan for a clinical service provided as part of a Medication Therapy Management Program (MTMP), should the provider submit the claim using the NCPDP 5.1 transaction standard or must he/she use the X12N 837P Version 4010/4010A1 transaction standard?

Please note that this FAQ has been revised to include a HIPAA enforcement addendum as of October 22, 2007.

Answer:

To bill MTM services, covered entities should use the American Standards Committee (ASC) X12N 837P Version 4010/4010A1. We articulated in our January 28, 2005 Final Rule on the Medicare Prescription Drug Benefit that we viewed Medication Therapy Management (MTM) as a clinical service (70 FR 4194, 4231). Therefore, claims for MTM would be considered professional health care claims rather than retail pharmacy drug claims. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the ASC X12N 837P was adopted as the transaction standard for professional health care claims. Therefore, similar to physician clinical services, if MTM providers bill Part D sponsors electronically for MTM services, such billing claims must be transmitted using the ASC X12N 837 P Version 4010/4010A1. Part D Sponsors are not precluded from using the NCPDP 5.1 system edits as a method to identify targeted beneficiaries, or provide applicable information at the point of service to pharmacists or other MTM providers responsible for providing the MTM services, but the health care claim must be transmitted using the ASC X12N 837P.

Enforcement Addendum-10/22/07

While CMS adheres to its foregoing interpretation of the regulations requiring that MTM retail pharmacy services be reported using the X12N 837P standard, we recognize that a reasonable argument could be advanced in response to the Department seeking to enforce this regulation, contending that the regulations could be read to instead direct the use of the NCPDP, Version 5.1 standard for such services. We further realize that notice and comment rulemaking, which the Department anticipates initiating in the near future, will very likely resolve the apparent ambiguity of these regulatory provisions. In light of the foregoing planned rulemaking and the uncertain outcome of any enforcement action, CMS elects not to take enforcement action against those covered entities that continue to use the NCPDP, Version 5.1 standard for this transaction.

3. COORDINATION OF BENEFITS – RETAIL PHARMACY

9/2000 Update - The final rule actually states Version 3.2, but in a further comment the rule notes the verbiage will be changed to Version 5.1.

4. ELIGIBILITY FOR A HEALTH PLAN – RETAIL PHARMACY

9/2000 Update - Comment vi. in the Eligibility section cites the change to Version 5.1 and Batch Standard for retail pharmacy.

4/31/2002 Update – The technical corrections published 11/24/2000 correct this statement.

5. HEALTH CARE PAYMENT AND REMITTANCE ADVICE

9/2000 Update - In the final rule, NCPDP Telecommunications Standard Version 5.1 was named for pharmacy remittance advice transactions. The Telecommunications Standard does not handle remittance advice information such as check number and amount. HCFA will correct the final rule in the preamble and the section on remittance advice.

See "[Updates To This Document](#)" section in this document. NCPDP's Work Group 5 Payment Reconciliation is developing a crosswalk document from the Payment Reconciliation Standard Version 3.0 to the ASC X12N 835 Implementation Guide. The crosswalk should assist in the transition from the NCPDP Standard to the ASC X12N Standard.

7/18/2001 Update – Change Request # 228 on the Designated Standards Maintenance Organizations website (www.hipaa-dsmo.org) was recommended for inclusion in the NPRM addressing corrections, expected in 2001

12/21/2001 Update – NCPDP WG5 Payment Reconciliation continues work on mapping documents to assist conversions from the NCPDP reconciliation file formats to ASC X12N 835. Change Requests were submitted to the DSMO site upon discovery of pharmacy needs.

4/31/2002 Update – The correction NPRM is addressing this modification. Please review for more information.

07/15/2002 Update – The correction NPRM has addressed and recommended this modification. Please review the NPRM for more information.

02/20/2003 Update – The Final Rule has been corrected to the ASC X12N 835.

6. HEALTH CARE SERVICES: REFERRAL CERTIFICATION AND AUTHORIZATION – RETAIL PHARMACY

9/2000 Update - The Final rule, in the Eligibility section and page 50364 discusses prior authorization transactions using ASC X12N 278. After further discussion with HCFA, NCPDP Telecommunications Standard Version 5.1 and Batch Standard 1.0 will be named in the corrected version. See "[Updates To This Document](#)" section in this document.

11/24/2000 Update – HCFA published a revision to the final rule that named the NCPDP Standards for Referral Certification and Authorization. See "[Updates To This Document](#)" section.

03/13/2001 Update – Page 50371 section M of the Final Rule does not note NCPDP Telecommunication Standard Version 5.1 or Batch Standard 1.0. This appears to be an oversight. The Technical Corrections noted in

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11/24/2000 do update the usage of these standards, but it appears this section was not corrected.

4/31/2002 Update – The correction NPRM is addressing this modification. Please review for more information.

7/15/2002 Update – The correction NPRM has addressed and recommended this modification. Please review the NPRM for more information.

02/20/2003 Update – The Final Rule has been corrected to the NCPDP Standards for retail pharmacy.

08/25/2003 Update – In the packet of information on supplies (see section “*Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy*”, subsection “[8/25/2003 Update](#)” above), the talking points document notes that the NCPDP Standards for prior authorizations on supplies is to be used as well.

III. NOTICE OF PROPOSED RULE MAKING (NPRM)

In response to corrections or Change Requests made through the Designated Standards Maintenance Organization (DSMO) HIPAA website, HHS has published correction Notices of Proposed Rule Making (NPRM). Only requests that were deemed to be “necessary for compliance” were included. The Rule allows the Secretary to publish corrections. The NPRMs address:

- X12N Changes necessary for compliance
- Usage of NDC versus HCPCS
- Corrections to NCPDP standards (the naming of Batch 1.1, Prior Authorization, correction of naming NCPDP Telecommunication Standards for payment reconciliation, etc)

Each of the X12N Implementation Guides originally published May 2000 and adopted for use under HIPAA have had addenda created for them. Since these guides were named for use under HIPAA, these Draft Addenda will go through the NPRM process, just as the original Implementation Guides did, before becoming final addenda to the guides published by X12N. Only the modifications noted in this Draft Addenda will be considered in the NPRM. For more information and to download the Addenda: <http://www.wpc-edi.com/hipaa/addenda>

The correction NPRM process comment period ended on July 1, 2002. The correction NPRMs are available at <http://www.cms.hhs.gov/hipaa/hipaa2/default.asp>

Please Note the Following: Since there is an extension to October 2003 for compliance, the official HIPAA guidelines are still the named implementation guides without the NCPDP changes and X12N addenda. The NCPDP changes and X12N addenda will become effective 6 months after publication of the final rule, which will probably go past the October 2002 time frame.

Covered entities should evaluate this information carefully for their business and implementation plans. The correction NPRMs are not expected to be final by October 16, 2002, therefore the original final rule of August 2000 is the rule in effect for October 2002.

Covered entities, who desire to implement in October 2002 for compliance as of October 2002, would need to implement under the transactions and code sets named in the August 2000 final rule, with known errors (the incorrect naming of Telecommunication Standard Version 5.1 for remittance advice, of which it was not intended; use of Batch 1.0 (instead of Batch 1.1); use of NDC code in all drug claims (pharmacy or medical); X12N addenda corrections not available for usage, etc...). There may be some covered entities that are not affected by the corrections in the NPRMs; however, it is thought that most entities are affected by the corrections.

If a covered entity proceeds with implementation October 16, 2002 using the August 2000 rule, when the NPRMs eventually become finalized, the entity would need to make the necessary changes to their system to be in compliance with the corrected final rule and its deadline.

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If a covered entity decides to wait until the NPRMs are published as a final rule and this is projected to be after October 16, 2002, the entity will need to file a Compliance Form.

This information is not intended to confuse the reader; but is intended to offer some level of information so the covered entity can then make decisions applicable to their company.

4/31/2002 Update – above section updated to reflect the correction NPRMs were published.

2/20/2003 Update – The Final Rules were published with which standards to implement based on which dates and whether a compliance plan was filed.

IV. HIPAA TRANSACTIONS AND CODE SETS IMPLEMENTATION COMPLIANCE

In December 2001, the House of Representatives and the Senate passed H.R. 3323, "To ensure that covered entities comply with the standards for electronic health care transactions and code sets adopted under part C of title XI of the Social Security Act, and for other purposes." It is also referred to as the "Administrative Simplification Compliance Act". There may be additional language that accompanies the bill. As of this publication, the President still needed to sign the bill, but that was expected to happen.

This bill allows covered entities (excluding small health plans) to seek an extension for compliance of the HIPAA Transactions and Code Sets implementation by October 16, 2003 (instead of October 16, 2002). This does not affect the timeframes of the Privacy regulations. The bill also includes a section amending the Social Security Act requiring electronic submission of Medicare claims. It is reported that the House staff and the Senate staff are working on "legislative history / report language" that may accompany the bill.

The Department of Health and Human Services will be creating the compliance plan form, with incentives for them to complete the form by March 31, 2001. For business entities that wish to seek an extension of the deadline for Transactions and Code Sets implementation, the plan form will request 1) an analysis reflecting the extent and reasons why the business entity will not be in compliance with the October 16, 2002 date. 2) A budget, schedule, work plan, and implementation strategy for achieving compliance. 3) Whether the entity will use a contractor or vendor to achieve compliance. 4) A timeframe for testing that begins no later than April 16, 2003. The completed compliance plan must be submitted by the covered entity to the Secretary of Health and Human Services before October 16, 2002. In the language of the bill, there are no "next steps" outlined after the submission of the compliance plan; no steps for approval of the submitted plan.

The Secretary will submit a sample of plans submitted to the National Committee on Vital and Health Statistics (NCVHS) for analysis. NCVHS will publish reports containing effective general solutions to compliance problems identified in the submitted plans. The Secretary will ensure that submitted compliance plans will not disclose confidential or private information in the plans.

As a note, companies should not look on this bill as a "one year extension". Based on the current timelines and the timelines outlined above, at most, this is a few months extension, since testing must begin no later than April 16, 2003.

Please see http://www.ncdp.org/news_hipaa_trans.asp for the final bill.

Please see the previous section "[Notice for Proposed Rule Making \(NPRM\)](#)" for an important note.

A. ENFORCEMENT INFORMATION

In July 2003, CMS issued "Guidance on Compliance with HIPAA Transactions and Code Sets After the October 16, 2003, Implementation Deadline". The document urges

covered entities to make best efforts to test, test, test, and to document their steps and their outreach.

11/21/2003 Update – CMS will be publishing a Notice of Proposed Rule Making (NPRM) in 2004 that contains procedural and substantive requirements for the Enforcement Regulations.

CMS website for posting suspected complaints is <https://htct.hhs.gov/>.

B. CONTINGENCY PLANS

CMS published at <http://www.cms.hhs.gov/hipaa/> information about *Basic Contingency Planning Guidelines*. See also the 9/25/2003 update in section “[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)”. CMS has stated in public forums that covered entities are only allowed to have contingency plans if they are already compliant and waiting on trading partners. Contingency plans are not viable for covered entities that have not begun compliance (e.g. not begun coding yet, not working on HIPAA, ignoring HIPAA, etc).

C. NCPDP STANDARDS COMPLIANCE PROCESS

NCPDP members have established a process that identifies the steps that should be followed when there is a suspected misapplication of an NCPDP standard(s). Misapplication of a standard might be the incorrect use of a field, format, value, or a stated standard use. Trading partners are highly encouraged to work together to resolve issues, but when further steps are required, the Standards Compliance Process can be followed. Please see http://www.ncdp.org/standards_info.asp for the process requirements and the form.

V. WHO IS REQUIRED TO USE THE STANDARDS?

1. Private sector health plans
2. Government health plans
3. Healthcare clearinghouses
4. Healthcare providers who submit or receive electronically the above transactions.

If the current business function is named above as a transaction, regardless of electronic, on paper, via phone, et cetera), the entity must be able to support the electronic standard for that transaction. The entity may perform this business directly or through a healthcare clearinghouse. Please note that healthcare providers have the option to not perform the function electronically.

For example, if a current business function is Coordination of Benefits, and this is currently done on paper, for the retail pharmacy industry, this business function must support the electronic pharmacy standard for COB, namely the Telecommunications Standard V5.1 or the Batch Standard V1.0 (revised V1.1). Like rules apply for the other healthcare industries and the appropriate ASC X12N standard.

If a current business function is supporting eligibility checking or prior authorization via telephone, for the retail pharmacy industry, these business functions must support the electronic pharmacy standard for eligibility or prior authorization, namely the Telecommunications Standard V5.1 or the Batch Standard V1.0 (revised V1.1). Like rules apply for the other healthcare industries and the appropriate ASC X12N standard.

The statutory definition of a health plan does not specifically include workers' compensation programs, property and casualty programs, or disability insurance programs, and consequently, those programs are not required to comply with the standards.

VI. CODE SETS NAMED IN THE FINAL RULE

1. ICD-9-CM Volumes 1 and 2
2. ICD-9-CM Volume 3 Procedures
3. National Drug Codes (NDC)
4. Code on Dental Procedures and Nomenclature (CDT-2)
5. HCPCS
6. CPT-4

3/13/2001 Update – There has been much healthcare industry discussion concerning the use of NDC codes on professional and institutional claims. The NCVHS (National Committee on Vital and Health Statistics) will be recommending to the Secretary of HHS that HCPCS J-codes should be allowed to be used as well as NDCs and HCPCS until a more robust coding system is developed. This is important to the ASC X12N 837 professional and institutional guides, since possible situations need to be written to explain usage.

7/18/2001 Update – NCPDP has recommended to HHS that NDC be used as the exclusive identifier for drugs and biologics. The NCPDP letter sent to HHS and the response from HHS are available on the NCPDP website http://www.ncdp.org/frame_members_government_hipaa.htm

National Committee on Vital and Health Statistics (NCVHS), after public hearings, has recommended to HHS that the Secretary retract the adoption of NDCs on standard transactions other than retail pharmacy. The Secretary's response is also available on the NCPDP website http://www.ncdp.org/frame_members_government_hipaa.htm

8/23/2001 Update – UPC AND HRI - NCPDP is creating a Change Request that will be posted to the Designated Standards Maintenance Organization (DSMO) website. The Change Request will be evaluated by the organizations and a recommendation for action will be given. The request is for HHS to recognize UPC and HRI codes, in addition to NDCs as valid identifiers for drug supply billing transactions. These codes should be permitted via the NCPDP Telecommunication Standard Version 5.1 and Batch Standard Version 1.1 for the billing of drug supplies.

12/21/2001 Update – The Change Request #492 on UPC and HRI was submitted to the DSMO website. It is going through the DSMO processing.

The National Committee on Vital and Health Statistics (NCVHS) will be hearing testimony throughout 2002 on code set issues. More information is available at their website <http://www.ncvhs.hhs.gov/>

4/31/2002 Update – The DSMO have completed review of Change Request 492 (naming of code sets and NCPDP Standards for supplies) and have recommended:

“The billing of supplies from retail pharmacies should be permitted using the NCPDP Telecommunication Standard Version 5.1 or Batch Standard Version 1.1 under HIPAA. When supplies are billed by the dispensing retail pharmacy, HCPCS, NDC, UPC and HRI should be permitted code sets that can be used for the specific identification of supplies.”

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Letters have been sent to the National Committee on Vital and Health Statistics (NCVHS) asking for further support the NCPDP Standards for current business practices. In addition, comments will be placed in the NCPDP response to the correction NPRMs.

The correction NPRM addresses the retraction of the use of NDCs for other than retail pharmacy claims. Please see the NPRM for more information.

02/20/2003 Update – The Final Rule preamble (page 35) states that there is “no identified standard medical data code set in place for reporting drugs and biologics on non-retail pharmacy transactions. The absence of a code set would not preclude the use of NDC for reporting drugs and biologics by covered entities on standard transactions. Covered entities could continue to report drugs and biologics as they prefer and agree upon with their trading partners.”

The final rule in §162.1002 Medical data code sets notes

(b) For the period on and after October 16, 2003:

- (1) The code sets specified in paragraphs (a)(1), (a)(2),(a)(4), and (a)(5) of this section.
- (2) National Drug Codes (NDC), as maintained and distributed by HHS, for reporting the following by retail pharmacies:
 - (i) Drugs.
 - (ii) Biologics.
- (3) The Healthcare Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:
 - (i) Medical supplies.
 - (ii) Orthotic and prosthetic devices.
 - (iii) Durable medical equipment.

07/15/2004 Update - In June 2004, NCVHS posted their letter of recommendation to Secretary Thompson concerning the billing of supplies. Please see section “[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)” for an update dated 6/17/2004.

VII. WHERE TO FIND THE CODE SETS NAMED IN THE FINAL RULE

A. ICD-9-CM VOLUMES 1 AND 2

For information on changes and updates to the diagnosis part of ICD–9–CM (Volumes 1 & 2) see the following Internet site:

<http://www.cdc.gov/nchswww/about/otheract/icd9/maint/maint.htm>

B. ICD-9-CM VOLUME 3 PROCEDURES

For information on changes and updates to the procedure part of ICD–9–CM (Volume 3) see the following Internet site: <http://www.hcfa.gov/medicare/icd9cm.htm>

C. NATIONAL DRUG CODES (NDC)

Website: <http://www.fda.gov/cder>.

For the list of codes found in the National Drug Codes, see the following Internet site: <http://www.fda.gov/cder/ndc/index.htm>

For information about submitting a request to modify the National Drug Codes, see the following Internet site: <http://www.fda.gov/cder>

D. CODE ON DENTAL PROCEDURES AND NOMENCLATURE (CDT-2)

<http://www.ada.org/P&S/benefits/cdtguide.html>

E. HCPCS

An email link is available for questions and comments related to the HCPCS process. The Internet site is <http://www.hcfa.gov/medicare/hcpcs.htm>

F. CPT-4

Write:

American Medical Association,
Department of Coding and Nomenclature
515 North State Street
Chicago, Illinois, 60610.

The Internet site for the American Medical Association is <http://www.ama-assn.org>

VIII. OTHER CODE SET INFORMATION

A. REJECT/PAYMENT CODES

The final rule notes that Reject/Payment Codes are available through NCPDP. The final rule notes “A listing of NCPDPs payment and reject reason codes, the explanation of the code, and the field number in error (if rejected).”

NCPDP has a list of the values available for the field Reject Code (511-FB); we do not have a code list for Payment Codes. The Reject Codes are not a separate code list from NCPDP; they are part of the Data Dictionary available with membership.

IX. FREQUENTLY ASKED QUESTIONS

A. HOW DO I OBTAIN THE CODE SETS OR THE ASC X12N DOCUMENTS?

The addresses for the organizations maintaining the code sets is available from the HHS web site, in the document entitled "Frequently Asked Questions About Code Set Standards Adopted Under HIPAA".

In each of the transaction sections of the final rule, an identification number is given for the document from the Washington Publishing Company (for example, the Referral Certification and Authorization document is 004010X094). Section 162.920 on page 50368 lists the address.

B. WHAT ACTION MIGHT BE TAKEN TO CORRECT SOME OF THE INCONSISTENCIES NOTED ABOVE?

HHS has stated that Notice of Proposed Rule Making (NPRM)s will be issued in 2002 for the following:

- 1) DSMO Change Requests that were deemed necessary to comply
- 2) Clarification on the use of NDC versus HCPCS
- 3) Corrections to name the NCPDP Standards for appropriate usage (Prior Authorization, Batch 1.1, etc...)

C. DO I NEED TO IMPLEMENT ALL TRANSACTIONS IN TELECOMMUNICATION STANDARD VERSION 5.1 TO BE COMPLIANT WITH HIPAA REGULATIONS?

No.

The business entities named in the rule must implement the functionality of Telecommunication Standard Version 5.1 that is named in the Final Rule (eligibility, claims/encounters, prior authorizations, COB, and PPS) if it is part of their business today. Business entities need to evaluate if they must implement a given functionality. If a business function is performed today, and that functionality is named in the rule, the business entity needs to comply with the rule. However, if the business entity does not perform a function today, they are not required to support it under HIPAA.

For example, a business entity does not support eligibility verification by any method currently. In this case, the business entity would not have to implement the eligibility functionality.

Some of the new transactions introduced in Version 5.1 are not named in HIPAA. Business entities do not have to implement under HIPAA the Controlled Substance Reporting and Information Reporting functionality unless trading partners determine a business need. These transactions were not named in HIPAA.

A provider may choose to submit paper or electronic transactions under the final rule. A health plan must accept the named electronic standards in their business if a provider wishes to submit an electronic transaction. A health plan may use a clearinghouse to perform some of this functionality. Covered entities should consult the final rule and evaluate according to their company.

D. HOW ARE ONGOING CHANGES (SUCH AS TELECOMMUNICATION STANDARDS VERSION 5.2 THROUGH CURRENT) AFFECTED?

The NCPDP membership will continue to bring forth and approve changes to the Standard.

The Secretary has designated six organizations that have agreed to serve as Designated Standards Maintenance Organizations (DSMOs). These are:

1. Accredited Standards Committee X12
2. The Dental Content Committee
3. Health Level Seven
4. National Council for Prescription Drug Programs
5. National Uniform Billing Committee
6. National Uniform Claim Committee

Together, these organizations will review and evaluate requests for changes and then suggest changes to the Secretary. A change request process will be available on the web. The web site url is www.hipaa-dsmo.org Once the final rule is effective (October 16, 2000), all changes to the Telecommunication Standard or the Batch Standard must go through this process. Please refer to the web site or page 50368, Section 162.910 for further information. The Secretary may modify a standard or its implementation guide one year after the standard or implementation guide has been adopted, but no more than once every twelve months. If approved for modification, the implementation of the change may be no earlier than 180 days from the adoption. These modifications will be published as regulations in the Federal Register.

NCPDP members will be evaluating the changes that have progressed since the naming of the Version 5.1 Standard, and via the process, make recommendations for the next version/release to be adopted for a transaction.

In addition, the final rule does allow for entities to apply for an exception to test a new standard. Please see the final rule for guidelines.

8/25/2003 Update – NCPDP members are building a white paper discussing a predictable process for naming new transactions and code sets, and a predictable process for new version/releases to already named transactions and code sets. Participation has been extended to representatives from SDOs on this white paper. If interested in participating, contact Lynne Gilbertson (lgilbertson@ncpdp.org).

7/25/2005 Update – After reviewing different options in the white paper, it was difficult to create a predictable and timely process in the federal rule making processes. The DSMO are working with the Office of E-Health Standards and Services (OESS, formerly OHS) on a predictable and timely process.

E. WHICH STANDARDS SHOULD BE USED FOR PRIOR AUTHORIZATION TRANSACTIONS?

For Prior Authorization transactions submitted by a pharmacy, the NCPDP Telecommunication Standard Version 5.1 or the Batch 1.0 Standard (revised V1.1) should be used.

For Prior Authorization transaction submitted by a physician, the ASC X12N 278 Health Care Services Review: Referral Certification and Authorization – Dental, Professional, Institutional (with Addenda) should be used.

F. WHAT IS THE NCPDP “EDITORIAL DOCUMENT”?

NCPDP has created a document called “Telecommunication Version 5 Questions, Answers, and Editorial Updates” (the “Editorial” document). This document includes frequently asked questions about the standards, offers clarification for prior authorization, compounds, and other items, lists typographical errors found, and contains general information. This document is important for implementers of the standards for further understanding of business cases and for the editorial changes.

This document is available on the public and members only sections of NCPDP website at http://www.ncdp.org/news_hipaa.htm or at http://www.ncdp.org/members/members_download.htm The document is also included in the packet of the Standards and Implementation Guides provided with membership.

G. IS THE ASC X12N 835 TRANSACTION SUBMITTED AS A RESPONSE TO THE NCPDP TELECOMMUNICATION STANDARD VERSION 5.1 (OR BATCH 1.1)?

If the pharmacy submits an NCPDP request, does the health plan respond with the 835?

No. The NCPDP Telecommunication Standard Version 5.1 is an online, real-time conversation of a request from the pharmacy to the health plan AND a response from the health plan to the pharmacy. The NCPDP Batch Standard Version 1.1 works in the same manner as a request and response, but is submitted via batch means instead on real-time. The ASC X12N 835 is used for reconciliation. It is not used as the response to a NCPDP Standard for claim billing in the pharmacy environment.

The pharmacy submits the NCPDP Standard for the billing of a claim and receives the NCPDP Standard response from the health plan. Some time later, the health plan submits the 835 to the pharmacy for reconciliation. The pharmacy then applies the 835 information to their accounting system.

H. WHAT NCPDP DOCUMENTS DO I NEED FOR HIPAA?

Please see http://www.ncdp.org/news_hipaa_trans.asp and http://www.ncdp.org/members/members_government_hipaa.asp for the document “Implementation of the Telecommunication or Batch Standard”.

NCPDP documents are free to members and may be downloaded from the “Members Only”, “Standards Download” section of the website.

X. HHS CONTACT PERSONS

Pat Brooks	(410) 786-5318	Medical diagnosis, procedure, and clinical code sets
Joy Glass	(410) 786-6125	For the following transactions: Health claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; and health claim status.
Gladys Wheeler	(410) 786-0273	Ms Wheeler is the contact for the final rule (2/20/2003).

XI. INDUSTRY INFORMATION

A. NCPDP

For information on HIPAA as it affects the pharmacy industry, see http://www.ncdp.org/news_hipaa_trans.asp

For information on the NCPDP SNIP (Strategic National Implementation Process) Liaison Special Committee, see www.ncdp.org

For general NCPDP information, see www.ncdp.org

B. DSMO

For information on the Designated Standards Maintenance Organization (DSMO) website, see <http://www.hipaa-dsmo.org/>

C. WEDI

For information on the Workgroup for Electronic Data Interchange, see www.wedi.org

WEDI SNIP

WEDI's work group for Strategic National Implementation Process (<http://snip.wedi.org/>). WEDI SNIP offers several white papers, documentation, list serves on Security, Transactions, HIPAA Issues, etc. Discussions underway include questions about paper processing, direct data entry devices, Medicaid post pay recovery, and other topics.

D. X12N

For information on ASC X12N, see www.wpc-edi.com Click on "HIPAA" for more information.

E. HHS

For information from the Department of Health and Human Services, see <http://aspe.hhs.gov/admsimp/>

F. CMS

For information on the Centers for Medicare and Medicaid Services, see <http://www.cms.hhs.gov/hipaa/>

For information on pharmacy, Medicare, and HIPAA, see <http://www.cms.hhs.gov/hipaa/> menu "Publications", "Program Manuals", search on NCPDP or other key words.

1. CMS GUIDANCE

For information on industry roundtable conference calls, town hall meetings, guidance documents, and other information, please see <http://www.cms.hhs.gov/hipaa/hipaa2/default.asp>.

XII. UPDATES TO THIS DOCUMENT

A. OCTOBER, 2000

Section 162.1305 of the Final Rule has been amended to require implementation of the NCPDP Telecommunications Standard version 5.1 and batch equivalent version 1.0 for retail pharmacy referral certification and authorization.

The NCPDP Telecommunication Standard and batch equivalent do not support the remittance advice information. Section 162.1302 has been amended to require the implementation of the ASC X12 835 Health Care Payment and Remittance Advice version 4010 implementation guide for retail pharmacies.

Professional Pharmacy Claims - The final rule incorrectly stated that NCPDP Telecommunication Standard Version 5.1 could not support the billing of professional pharmacy services since it did not support HCPCS J-codes to identify the pharmacy procedure or service. This is incorrect, since V5.1 clearly supports HCPCS J-codes as a qualifier. The rule named the ASC X12N 837 Health Care Claim: Professional, Version 4010 transaction. The correction was requested. This document has been modified to indicate the HHS decision.

B. NOVEMBER, 2000

Question “Do I Need To Implement All Transactions In Telecommunication Standard Version 5.1 To Be Compliant With HIPAA Regulations?” with answer was added.

C. DECEMBER, 2000

On Friday, November 24, 2000 technical corrections to the final rule for transactions and code sets. In the final rule revision, changes were made to page 50361, section “N. Transaction Standards”. NCPDP Telecommunication Standard Version 5.1 and Batch Standard Version 1.0 were specified for health care claim and equivalent encounter information, eligibility for a health plan, referral certification and authorization, and coordination of benefit transactions for the retail pharmacy sector.

The section “[What Transactions Are Named?](#)” has been updated with this information, of which “Referral Certification and Authorization” was added to the list of transactions under NCPDP Telecommunication Standard, item 4 on the list.

The section “[Transaction Chart](#)” has also been updated with the changes for “Health Care Services: Referral Certification and Authorization” Note 6.

D. MARCH 2001

A new section has been added “[Industry Information](#)”. This section provides information about where other information may be obtained about HIPAA related topics. This list is not exhaustive, but rather shows active sites that may be of interest to the reader.

Final Rule As It Relates To The Pharmacy Industry

The section "[What Transactions Are Named?](#)" has been updated with current information dated 3/13/2001 in Note 1, 2, and 6.

A comment was added to the section "[Code Sets Named In The Final Rule](#)" regarding NDC and HCPCS J-codes.

The question "[Which Standards Should Be Used For Prior Authorization Transactions?](#)" has been added to a new section "[Frequently Asked Questions](#)". Other questions were moved to this section.

E. JULY 2001

Throughout the document, "7/18/2001 Update" sections have been added to relay updated information on the transactions and code sets.

F. AUGUST 2001

Notations of "8/23/2001 Update" exist in the document to relay updates at that time. See "[Notes](#)" section and "[Code Sets...](#)" sections. Please note section "[Health Claims and Equivalent Encounter Information...](#)" for information about supply billing.

FAQ "[What Action Might Be Taken To Correct Some Of The Inconsistencies Noted Above?](#)" has been modified with updated information.

G. DECEMBER 2001

Opening information and a section were added to this document on the recent passing of H.R. 3323, the Administrative Simplification Compliance Act. In addition, a section on the NPRMs has been added. Updates of 12/21/2001 occur throughout the document as appropriate. A question on the Editorial document has been added.

H. JANUARY 2002

The Frequently Asked Question "Is the ASC X12N 835 transaction submitted as a response to the NCPDP Telecommunication Standard Version 5.1 (or Batch 1.1)? If the pharmacy submits an NCPDP request, does the health plan respond with the 835?" was added.

I. FEBRUARY 2002

In the section "[Notice of Proposed Rule Making \(NPRM\)](#)", the "Please note" has been added. Other updates dated "2/4/2002 Update" have been added in the document.

Additional information has been added to the "[Notice of Proposed Rule Making \(NPRM\)](#)" section regarding the Administration Simplification Compliance Act and how the projected dates might affect covered entities. References to H.R. 3323 have been changed to refer to the Administration Simplification Compliance Act, rather than the House rule.

Final Rule As It Relates To The Pharmacy Industry

Information has been added to identify where to obtain more information on the code sets named in the Final Rule. In addition, a note dated "02/14/2002 Update" has been added to Note 2 regarding the filing of a Change Request on the DSMO system.

J. MAY 2002

The sections of "*General Information*", "*What Transactions Are Named in the August 17, 2002 Final Rule*", "[Notice of Proposed Rule Making](#)", and "[Code Sets Named in the Final Rule](#)" have been updated with information noted 4/31/2002.

K. JULY 2002

The section "[Other Code Set Information](#)" has been added. NCPDP web pages have been updated. General updates to the document are noted with date 7/15/2002.

L. AUGUST 2002

The "[Industry Information](#)" section has been updated with CMS website and a link for Medicare information.

M. JANUARY 2003

The question "[What NCPDP Documents Do I Need For HIPAA](#)" has been added to the "*Frequently Asked Questions*" section.

N. FEBRUARY 2003

The document has been updated throughout with information on the Final Rule of 02/20/2003. In particular, sections "[Transaction Chart](#)" and "[Code Sets Named In The Final Rule](#)" were updated.

O. AUGUST 2003

In July 2003, enforcement guidance was issued by CMS. See section "[Enforcement Information](#)" under "*HIPAA Transactions And Code Sets Implementation Compliance*". CMS is also offering educational documents, conference calls, etc. See new section on "[CMS Guidance](#)" under "*Industry Information*", "*CMS*". In August, NCPDP members created a packet of information on supply billing to be used with their government representatives and as background guidance. See the document for updates dated 8/25/2003.

P. SEPTEMBER 2003

In August and September, industry representatives met with CMS to discuss the billing of supplies. Please see section "[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)" for an update dated 9/5/2003. This section was also updated on 9/25/2003.

Q. NOVEMBER 2003

“[Enforcement Information](#)” section was updated 11/21/2003. Under “*HIPAA Transactions And Code Sets Implementation Compliance*” section, a new section was added “[Contingency Plans](#)”. A new section was also added for “[NCPDP Standards Compliance Process](#)”. Section “[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)” was updated 11/21/2003 with information about a NPRM in 2004.

R. APRIL 2004

In March 2004, industry representatives testified to NCVHS on the billing of supplies. Please see section “[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)” for an update dated 3/31/2004.

S. SEPTEMBER 2004

In June 2004, NCVHS posted their letter of recommendation to Secretary Thompson concerning the billing of supplies. Please see section “[Health Claims and Equivalent Encounter Information – Retail Pharmacy Claims and Eligibility for a Health Plan – Retail Pharmacy](#)” for an update dated 6/17/2004.

The possible NPRM to propose definitions to retail pharmacy, for the billing of supplies and professional pharmacy services and other items have been pushed to Spring 2005.

T. JULY 2005

Updates of 7/25/2005 were added on the billing of supplies and services. Other updates noted with “7/25/2005 Update” were added.

U. MARCH 2006

An update of 3/9/2006 was added on eligibility and billing of claims.

V. OCTOBER 2006

An update of 10/13/2006 was added to the billing of professional pharmacy services.

W. OCTOBER 2007

An update of 10/23/2007 was added to the billing of professional pharmacy services.