

Modifications to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Electronic Transaction Standards

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

October 2010

National Council for Prescription Drug Programs
9240 East Raintree Drive
Scottsdale, AZ 85260



Phone: (480) 477-1000
Fax: (480) 767-1042

Final Rule As It Relates To The Pharmacy Industry **Version 4.0**

NCPDP recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

Published by:
National Council for Prescription Drug Programs

Publication History:
Version 3.0 February, 2009
Version 4.0 October 2010

Copyright © 2010

All rights reserved.
No part of this manual may be reproduced in any form
or by any means without permission in writing from:
National Council for Prescription Drug Programs
9240 East Raintree Drive
(480) 477-1000
Scottsdale, AZ 85260
ncdpd@ncdpd.org

Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.

TABLE OF CONTENTS

I. GENERAL INFORMATION	5
II. WHAT TRANSACTIONS WERE NAMED IN JANUARY 16, 2009 FINAL RULE? 6	
A. TRANSACTION CHART	6
B. NOTES	7
1. <i>Retail Pharmacy Supplies and Professional Services</i>	7
2. <i>Medicaid Subrogation</i>	7
C. GENERAL NOTES	7
III. WHO IS REQUIRED TO USE THE STANDARDS?.....	9
IV. CODE SETS NAMED IN THE FINAL RULE	10
A. ICD-10 AND THE PHARMACY INDUSTRY	10
V. WHERE TO FIND THE CODE SETS NAMED IN THE FINAL RULE	11
A. ICD-10-CM.....	11
B. ICD-10-PCS.....	11
C. ICD-10 GUIDANCE.....	11
D. NATIONAL DRUG CODES (NDC).....	11
E. CODE ON DENTAL PROCEDURES AND NOMENCLATURE (CDT-2).....	11
F. HCPCS.....	11
G. CPT-4	11
VI. OTHER CODE SET INFORMATION	12
A. REJECT/PAYMENT CODES	12
VII. FREQUENTLY ASKED QUESTIONS	13
A. HOW DO I OBTAIN THE STANDARDS?	13
1. <i>NCPDP</i>	13
2. <i>ASC X12</i>	13
B. DO I NEED TO IMPLEMENT ALL TRANSACTIONS IN TELECOMMUNICATION STANDARD VERSION D.Ø TO BE COMPLIANT WITH HIPAA REGULATIONS?	13
C. IMPLEMENTATION THOUGHTS	13
D. MINOR/EDITORIAL CHANGES TO THE NCPDP STANDARDS.....	14
E. HOW ARE ONGOING CHANGES (SUCH AS TELECOMMUNICATION STANDARD VERSION D.1 THROUGH CURRENT) AFFECTED?	14
F. IS THE ASC X12N 835 TRANSACTION SUBMITTED AS A RESPONSE TO THE NCPDP TELECOMMUNICATION STANDARD VERSION D.Ø (OR BATCH 1.2)?	15
G. WHAT NCPDP DOCUMENTS DO I NEED FOR HIPAA?	15
VIII. INDUSTRY INFORMATION	16
A. NCPDP.....	16
1. <i>HIPAA and Pharmacy Industry</i>	16
2. <i>NCPDP Transaction Guidance</i>	16
3. <i>NCPDP Payer Templates</i>	16
4. <i>NCPDP HIPAA Timelines</i>	16

B.	DSMO.....	16
C.	WEDI.....	16
D.	X12N.....	17
E.	HHS.....	17
F.	CMS.....	17
IX.	HIPAA TRANSACTIONS AND CODE SETS IMPLEMENTATION COMPLIANCE	
	18	
A.	CONTINGENCY PLANS.....	18
B.	TIMELINE FOR IMPLEMENTATION.....	18
C.	ENFORCEMENT INFORMATION.....	18
D.	NCPDP STANDARDS COMPLIANCE PROCESS.....	18
X.	UPDATES TO THIS DOCUMENT.....	20
A.	AUGUST 2009.....	20
B.	OCTOBER 2010.....	20

I. GENERAL INFORMATION

On January 16, 2009, 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: Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Final Rule (45 CFR Part 162)

Official Date of Final Rule:	January 16, 2009
Effective Date of Regulation (except Subrogation):	March 17, 2009
Effective Date of Regulation (Subrogation):	January 1, 2010
Compliance Date (5010, D.0 – all industry):	January 1, 2012
Compliance Date (Subrogation only – all appropriate except Small Health Plans):	January 1, 2012
Compliance Date for Small Health Plans (Subrogation only):	January 1, 2013

More information from HHS:

<http://www.cms.hhs.gov/TransactionCodeSetsStands/>

https://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=hALOhEoj

This site also offers answers to frequently asked questions submitted to CMS.

The final rule is available at:

http://www.access.gpo.gov/su_docs/fedreg/a090116c.html

under “Health and Human Services Department”.

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.ncdp.org>) for information as it becomes available.

NCPDP offers information about HIPAA at http://www.ncdp.org/news_hipaa.aspx. NCPDP hosted educational web casts which are available in archive form at http://www.ncdp.org/meeting_webinar_archive.aspx for a small fee. With the web cast, an overview of modifications document is provided to assist analysts.

NCPDP will offer educational sessions at the Annual Conference and other opportunities. Please see the website (www.ncdp.org) for more information on NCPDP activities.

II. WHAT TRANSACTIONS WERE NAMED IN JANUARY 16, 2009 FINAL RULE?

The following were named in the Final Rule (refer to Subpart K – R.)

A. TRANSACTION CHART

Transaction	Business/Service	Standard Named in January 16, 2009 Rule	Notes
<i>Health claims and equivalent encounter information.</i>			
	Retail pharmacy claims	NCPDP Telecommunication Standard Version D.Ø and NCPDP Batch Standard Version 1.2	
	Retail pharmacy supplies and professional services	NCPDP Telecommunication Standard Version D.Ø and NCPDP Batch Standard Version 1.2 Or ASC X12N 837 Health Care Claim: Professional, Version 5010	See Note 1.
	Medicaid Subrogation	NCPDP Batch Standard Medicaid Subrogation Implementation Guide Version 3.Ø	See Note 2.
	Dental claims	ASC X12N 837 Health Care Claim: Dental, Version 5010	
	Professional claims	ASC X12N 837 Health Care Claim: Professional, Version 5010	
	Institutional claims	ASC X12N 837 Health Care Claim: Institutional, Version 5010	
<i>Enrollment and disenrollment in a health plan.</i>			
	All named.	ASC X12N 834 Benefit Enrollment and Maintenance, Version 5010	
<i>Eligibility for a health plan.</i>			
	Retail pharmacy eligibility.	NCPDP Telecommunication Standard Version D.Ø and NCPDP Batch Standard 1.2	
	Dental, professional, institutional	ASC X12N 270 Health Care Eligibility/Benefit Inquiry and ASC X12N 271 Health Care Eligibility/Benefit Response, Version 5010	
<i>Health care payment and remittance advice.</i>			
	All named.	ASC X12N 835 Health Care Claim Payment/Advice, Version 5010	
<i>Health plan premium</i>			

Final Rule As It Relates To The Pharmacy Industry

<i>payments.</i>			
	All named.	ASC X12N 820 Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 5010	
<i>Health claim status.</i>			
	All named.	ASC X12N 276/277 Health Care Claim Status Request and Response, Version 5010	
<i>Coordination of benefits.</i>			
	Retail pharmacy claims	NCPDP Telecommunication Standard Version D.Ø and NCPDP Batch Standard Version 1.2	
	Dental claims	ASC X12N 837 Health Care Claim: Dental, Version 5010	
	Professional claims	ASC X12N 837 Health Care Claim: Professional, Version 5010	
	Institutional claims	ASC X12N 837 Health Care Claim: Institutional, Version 5010	
<i>Health Care Services: Referral Certification and Authorization</i>			
	Retail pharmacy	NCPDP Telecommunication Standard Version D.Ø and NCPDP Batch Standard Version 1.2	
	All others named.	ASC X12N 278 Health Care Services Review – Request for Review and Response, Version 5010	

B. NOTES

1. RETAIL PHARMACY SUPPLIES AND PROFESSIONAL SERVICES

Based on industry response, the regulations continue the current industry practice to allow the use of either the X12 or the NCPDP standard for billing retail pharmacy supplies and professional services, based on trading partner agreements. The regulation does not dictate the terms of trading partner agreements.

2. MEDICAID SUBROGATION

From the Final Rule, HHS clarifies that “...*Medicaid agencies could continue to bill on paper as long as both parties to the transaction agree to conduct the paper transaction. However, Medicaid agencies will still be required to have the capacity to transmit and receive the Medicaid pharmacy subrogation transaction electronically, in standard format...*” (p 3300) See also section 162.923.

C. GENERAL NOTES

Final Rule As It Relates To The Pharmacy Industry

1. HHS revised section 162.925 by adding a new paragraph (a)(6) regarding health plans:
“(6) During the period from March 17, 2009 through December 31, 2011, a health plan may not delay or reject a standard transaction, or attempt to adversely affect the other entity or the transaction, on the basis that it does not comply with another adopted standard for the same period.”
2. HHS *“...strongly discourage health plans from having companion guides unless they are focused significantly on the basics for connectivity, trading partner arrangements, and use of situational data elements” and “if companion guides contradict the implementation guides, the transaction will not be compliant”.*
3. On page 3308, there is discussion of “ignore, don’t reject”.
“Another commenter said that HHS should encourage an “ignore, don’t reject” approach to implementation, which would mean that, if a transaction is submitted conforming to the standard, but it contains more information than is necessary for an entity to process that transaction, the additional information should be ignored by the receiver, and the transaction not rejected.

Regarding the commenter’s suggestion of an “ignore, don’t reject” policy, we point out that § 162.925(a)(3) provides that a health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan. Finally, we do have an enforcement program through which covered entities may file complaints, and we continue to encourage the industry to utilize this program when faced with conflicts about the compliance of a transaction.”

III. 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 Telecommunication Standard Version D.Ø or the Batch Standard Version 1.2. 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 Telecommunication Standard Version D.Ø or the Batch Standard Version 1.2. 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.

IV. CODE SETS NAMED IN THE FINAL RULE

On January 16, 2009, information was published in the *Federal Register* from the Department of Health and Human Services (HHS), the Office of the Secretary regarding: HIPAA Administrative Simplification: Modifications to the Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS (45 CFR Part 162)

1. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (i) Diseases. (ii) Injuries. (iii) Impairments. (iv) Other health problems and their manifestations. (v) Causes of injury, disease, impairment, or other health problems.
2. International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) (including The Official ICD-10-PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: (i) Prevention. (ii) Diagnosis. (iii) Treatment. (iv) Management.

Official Date of Final Rule:	January 16, 2009
Effective Date of Regulation:	March 17, 2009
Compliance Date:	October 1, 2013

The other code sets named in the original HIPAA final rule were not changed:

1. National Drug Codes (NDC)
2. Code on Dental Procedures and Nomenclature (CDT-2)
3. HCPCS
4. CPT-4

A. ICD-10 AND THE PHARMACY INDUSTRY

The NCPDP Telecommunication Standard (used for claims, reporting) and the SCRIPT Standard (used in electronic prescribing) supports the exchange of diagnosis information using the ICD-9 or ICD-10.

What was not gleaned during pharmacy industry input to the HIPAA rule making process was the impact of the use of diagnosis codes in other aspects of pharmacy processing. For example, pharmacy benefit managers use ICD for disease management reporting, for client reporting, benchmarking, and patient stratification. For accurate alignment of historical medical information to current information, if a one to one mapping cannot occur systematically, manual research will need to be done to obtain the appropriate ICD-10 from the source.

For pharmacies, a percentage of claims submitted require a diagnosis code. For a refill that crosses the compliance date, if the system cannot map one to one from the ICD-9 to ICD-10, the pharmacy will need to obtain the ICD-10 from the source (the prescriber) prior to the claim being processed successfully. Education and collaboration from the industry participants will be key to servicing the patient timely.

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

A. ICD-10-CM

The ICD–10–CM code set is also available free of charge on the NCHS Web site at <http://www.cdc.gov/nchs/icd/icd10cm.htm>

The final rule is available at:

http://www.access.gpo.gov/su_docs/fedreg/a090116c.html under “Health and Human Services Department” and offers websites of activities for mapping documents, educational information, etc.

B. ICD-10-PCS

The ICD–10–PCS code set is available at no charge on the CMS Web site at <http://www.cdc.gov/nchs/icd/icd10cm.htm>

The final rule is available at:

http://www.access.gpo.gov/su_docs/fedreg/a090116c.html under “Health and Human Services Department”. This link also offers websites of activities for mapping documents, educational information, etc.

C. ICD-10 GUIDANCE

- NCHS – Basic ICD-10-CM information
 - <http://www.cdc.gov/nchs/icd/icd10cm.htm>
- CMS – ICD-10-PCS information
 - <http://www.cms.gov/ICD10/>
- AHIMA - ICD-10 Education
 - <http://www.ahima.org/ICD10/default.aspx>
- WEDI – ICD-10 Implementation
 - www.wedi.org

D. 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/Drugs/InformationOnDrugs/ucm142438.htm>

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

Available via the American Dental Association.

<http://www.ada.org/3827.aspx>

F. HCPCS

<http://www.cms.hhs.gov/MedHCPCSGenInfo/>

G. CPT-4

Available via the American Medical Association.

<http://www.ama-assn.org/ama/pub/category/3113.html>

VI. OTHER CODE SET INFORMATION

A. REJECT/PAYMENT CODES

The final rule notes that Reject/Payment Codes are available through NCPDP, and are contained in the NCPDP *External Code List* documents, available with membership.

VII. FREQUENTLY ASKED QUESTIONS

A. HOW DO I OBTAIN THE STANDARDS?

1. NCPDP

If already a member of NCPDP, all the standard implementation guides, data dictionaries, and external code lists of NCPDP are available via the “Standards Download” section of the website http://www.ncdp.org/members/members_download.aspx?

If not a member of NCPDP, sign up to become a member. With membership, you receive the documents NCPDP publishes, as well as other versions published http://www.ncdp.org/member_benefits.aspx

2. ASC X12

ASC X12 documents are available at <http://www.disa.org/bookstore/public/index.cfm> or through Washington Publishing at <http://www.wpc-edi.com/>

B. DO I NEED TO IMPLEMENT ALL TRANSACTIONS IN TELECOMMUNICATION STANDARD VERSION D.Ø TO BE COMPLIANT WITH HIPAA REGULATIONS?

No.

The business entities named in the rule must implement the functionality of Telecommunication Standard Version D.Ø that is named in the Final Rule (eligibility, claims/encounters, prior authorizations, COB, and supplies and services) 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.

For example, some of the transactions in Version D.Ø 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.

C. IMPLEMENTATION THOUGHTS

In order to support current business needs in Telecommunication Version 5.1 (which could not be updated due to HIPAA), there were a number of “kludges/use of free text/etc” that were determined by the industry to exchange information. Implementers

are reminded to remove the kludges in favor of the Telecommunication Version D.Ø solutions.

NCPDP has created a presentation to provide summary information of the transactions requested in the next round of HIPAA. This document also provides important information needed for analysis and planning, and resource links. http://www.ncdpd.org/pdf/HIPAA_2.ppt

D. MINOR/EDITORIAL CHANGES TO THE NCPDP STANDARDS

On occasion, a typographical or minor editorial change is found in the NCPDP standards named in HIPAA. In the appendix of changes of each guide, there will be an editorial section that lists the changes made. For example, in NCPDP Telecommunication Standard Version D.Ø, in “Appendix A. History of Document Changes”, under “Version D.Ø” is a subsection “Editorial Corrections”. Updates will be made to this section as needed. (These editorial changes will be reflected in post Version D.Ø versions as well.)

E. HOW ARE ONGOING CHANGES (SUCH AS TELECOMMUNICATION STANDARD VERSION D.1 THROUGH CURRENT) AFFECTED?

The NCPDP membership will continue to bring forth and approve changes to the Standard. Most of the NCPDP standards related modifications are brought through the Data Element Request Form (DERF) process. See http://www.ncdpd.org/standard_changes.aspx

Another avenue for requesting changes is the DSMO. 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. See www.hipaa-dsmo.org Changes to the named standards must go through requests either to the standards organization (NCPDP or ASC X12), or to the DSMO. 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 D.Ø Standard, and via the process, make recommendations for the next version/release to be adopted for a transaction.

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

NCPDP, ASC X12, and HL7 jointly created a streamline document to propose a predictable and timely process modification to the federal rule making process. This document was presented to the National Committee on Vital and Health Statistics (NCVHS) and HHS/CMS.

See http://www.ncdp.org/news_hipaa_trans_current.aspx#SSHP

F. IS THE ASC X12N 835 TRANSACTION SUBMITTED AS A RESPONSE TO THE NCPDP TELECOMMUNICATION STANDARD VERSION D.Ø (OR BATCH 1.2)?

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

No. The NCPDP Telecommunication Standard Version D.Ø 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 1.2 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.

G. WHAT NCPDP DOCUMENTS DO I NEED FOR HIPAA?

Please see http://www.ncdp.org/news_hipaa_trans_current.aspx and http://www.ncdp.org/members/members_government_hipaa_current.aspx for important notices, guidance documents, links, etc.

NCPDP has created a presentation to provide summary information of the transactions requested in the next round of HIPAA. This document also provides important information needed for analysis and planning, and resource links. http://www.ncdp.org/pdf/HIPAA_2.ppt

NCPDP implementation guides are included with membership and may be downloaded from the "Members Only", "Standards Download" section of the website (http://www.ncdp.org/members/members_download.aspx) The Standards Matrix provides documentation version information http://www.ncdp.org/pdf/Standards_matrix.pdf

In the Telecommunication Version D.Ø document, there is a section of matrices to assist analysts/implementers. The matrices have text in different fonts to let the reader know about changes. There is also information about changes and matrices in the appendix of changes that list modifications.

VIII. INDUSTRY INFORMATION

A. NCPDP

1. HIPAA AND PHARMACY INDUSTRY

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

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

For general NCPDP information, see www.ncdp.org

2. NCPDP TRANSACTION GUIDANCE

NCPDP has created a presentation to provide summary information of the transactions requested in the next round of HIPAA. This document also provides important information needed for analysis and planning, and resource links. http://www.ncdp.org/pdf/HIPAA_2.ppt

3. NCPDP PAYER TEMPLATES

The NCPDP SNIP Committee developed guidance to be used in filling out and creating payer sheets based on Version D.Ø and above. Payer Sheets may be used in addition to provider manuals or included in provider manuals. Payers may take the request and response template sections within the guidance document, fill out the template per their usage, and send to their trading partners. The guidance also provides instructional sections to assist the payers in completing their payer sheets http://www.ncdp.org/news_hipaa_snip.aspx#PayerST

4. NCPDP HIPAA TIMELINES

The NCPDP SNIP (Strategic National Implementation Process) Liaison Special Committee created a white paper for implementation timelines and expectations that is in greater detail for the pharmacy industry. It highlights industry preparedness earlier than the latest dates named in HIPAA, to lessen patient and processing impacts. See http://www.ncdp.org/news_hipaa_snip.aspx

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,

Final Rule As It Relates To The Pharmacy Industry

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 <http://www.x12.org/>

E. HHS

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

F. CMS

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

IX. HIPAA TRANSACTIONS AND CODE SETS IMPLEMENTATION COMPLIANCE

A. CONTINGENCY PLANS

There is no expectation of a contingency plan.

B. TIMELINE FOR IMPLEMENTATION

In the Final Rule, HHS presents a timeline for implementation of the transactions and ICD-10, using industry input and NCVHS recommendations. See page 3303. They recommend

TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.Ø, VERSION 3.Ø AND ICD-10

Version 5010/D.Ø and Version 3.Ø	ICD-10
01/09: Publish final rule	01/09: Publish Final Rule
01/09: Begin Level 1 testing period activities (gap analysis, design, development, internal testing) for Versions 5010 and D.Ø.	
01/10: Begin internal testing for Versions 5010 and D.Ø.	
12/10: Achieve Level 1 compliance (Covered entities have completed internal testing and can send and receive compliant transactions) for Versions 5010 and D.Ø.	
01/11: Begin Level 2 testing period activities (external testing with trading partners and move into production; dual processing mode) for Versions 5010 and D.Ø.	01/11: Begin initial compliance activities (gap analysis, design, development, internal testing).
01/12: Achieve Level 2 compliance; Compliance date for all covered entities. This is also the compliance date for Version 3.Ø for all covered entities except small health plans*.	
01/13: Compliance date for Version 3.Ø for small health plans.	10/13: Compliance date for all covered entities (subject to the final compliance date in any rule published for the adoption of ICD-10).

* Note: Level 1 and Level 2 compliance requirements only apply to Versions 5010 and D.Ø

The NCPDP SNIP (Strategic National Implementation Process) Liaison Special Committee created a white paper for implementation timelines and expectations for the transactions that is in greater detail for the pharmacy industry. It highlights industry preparedness earlier than the latest dates named in HIPAA, to lessen patient and processing impacts. See http://www.ncpdp.org/news_hipaa_snip.aspx

They plan on creating a white paper for the ICD-10 for the pharmacy industry.

C. ENFORCEMENT INFORMATION

The compliance process currently underway with HIPAA is still in place. Page 3310 of the Final Rule notes that HHS plans to expand their compliance review process to include random reviews of compliance.

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

D. NCPDP STANDARDS COMPLIANCE PROCESS

Final Rule As It Relates To The Pharmacy Industry

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.aspx for the process requirements and the form.

X. UPDATES TO THIS DOCUMENT

A. AUGUST 2009

NCPDP and ASC X12 have sought a process from OESS for corrections to the implementation guide(s) named in HIPAA that are more than just clarifications handled by the Version D Editorial document. The Department of Health and Human Services expects to publish a Correction Notice in the Federal Register. ASC X12N also has a correction which is being made to the 834 Benefit Enrollment and Maintenance Technical Report 3. <http://www.x12.org/newsletters/tr/index.cfm>

The correction to this guide is expected to be completed in September 2009. The HHS [Federal Register](#) notice would likely not appear until after this. HHS has suggested that NCPDP can proceed in the republication, distribution, and notification of this change in advance of the Correction Notice in order to assure that the industry has this information to continue with implementation activities. See http://www.ncdp.org/news_hipaa_trans_current.aspx#ImpGuiCorr for specifics of the republished Telecommunication Implementation Guide version D.Ø.

B. OCTOBER 2010

X12 submitted other corrections since August 2009 (errata) which can be found at <http://www.x12.org/newsletters/tr/index.cfm>

NCPDP has submitted a correction for Medicare Part D plans processing multi-ingredient compounds. See http://www.ncdp.org/news_hipaa_trans_current.aspx#ImpGuiCorr for specifics of the republished Telecommunication Implementation Guide version D.Ø.

On Wednesday, October 13, 2010, HHS published a correction notice citing the modified implementation specifications.