

# **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**

February 2009

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 3.0**

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.

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**National Council for Prescription Drug Programs**  
**9240 East Raintree Drive**  
**(480) 477-1000**  
**Scottsdale, AZ 85260**  
**ncdpd@ncdpd.org**

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## 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)

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

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](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](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.ncpdp.org>) for information as it becomes available.***

NCPDP offers information about HIPAA at [http://www.ncpdp.org/news\\_hipaa.asp](http://www.ncpdp.org/news_hipaa.asp). NCPDP hosted educational web casts which are available in archive form at [http://www.ncpdp.org/news\\_outreach.asp#webcasts](http://www.ncpdp.org/news_outreach.asp#webcasts) 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 2009 Annual Conference and other opportunities. Please see the website ([www.ncpdp.org](http://www.ncpdp.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>			

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<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**

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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.

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

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/about/otheract/icd9/icd10cm.htm>

The final rule is available at:

[http://www.access.gpo.gov/su\\_docs/fedreg/a090116c.html](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.cms.hhs.gov/ICD10/02\\_ICD-10-PCS.asp#TopOfPage](http://www.cms.hhs.gov/ICD10/02_ICD-10-PCS.asp#TopOfPage)

The final rule is available at:

[http://www.access.gpo.gov/su\\_docs/fedreg/a090116c.html](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/about/otheract/icd9/abtcd10.htm>
- CMS – ICD-10-PCS information
  - [http://www.cms.hhs.gov/ICD10/02\\_ICD-10-PCS.asp](http://www.cms.hhs.gov/ICD10/02_ICD-10-PCS.asp)
- AHIMA - ICD-10 Education
  - <http://www.ahima.org/icd10/index.asp>
- WEDI – ICD-10 Implementation
  - [www.wedi.org](http://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/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>

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

Available via the American Dental Association.

[https://siebel.ada.org/ecustomer\\_enu/start.swe?SWECmd=Start&SWEHo=siebel.ada.org](https://siebel.ada.org/ecustomer_enu/start.swe?SWECmd=Start&SWEHo=siebel.ada.org)

### **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.asp](http://www.ncdp.org/members/members_download.asp)?

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/about\\_benefits.asp](http://www.ncdp.org/about_benefits.asp)

#### **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.ncdp.org/pdf/HIPAA\\_2.ppt](http://www.ncdp.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.ncdp.org/standards\\_derf.asp](http://www.ncdp.org/standards_derf.asp)

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](http://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.asp#SSHP](http://www.ncdp.org/news_hipaa_trans_current.asp#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.asp](http://www.ncdp.org/news_hipaa_trans_current.asp) and [http://www.ncdp.org/members/members\\_government\\_hipaa\\_current.asp](http://www.ncdp.org/members/members_government_hipaa_current.asp) 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](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.asp](http://www.ncdp.org/members/members_download.asp)) The Standards Matrix provides documentation version information <http://www.ncdp.org/pdf/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.asp](http://www.ncdp.org/news_hipaa_trans_current.asp)

For information on the NCPDP Strategic National Implementation Process (SNIP)

Liaison Special Committee, see [http://www.ncdp.org/news\\_hipaa\\_snip.asp](http://www.ncdp.org/news_hipaa_snip.asp)

For general NCPDP information, see [www.ncdp.org](http://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](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.asp#PayerST](http://www.ncdp.org/news_hipaa_snip.asp#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.asp](http://www.ncdp.org/news_hipaa_snip.asp)

### **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](http://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 <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.ncdp.org/news\\_hipaa\\_snip.asp](http://www.ncdp.org/news_hipaa_snip.asp)

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.asp](http://www.ncdp.org/standards_info.asp) for the process requirements and the form.

**X. UPDATES TO THIS DOCUMENT**

**A. xx**