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

August 2014

National Council for Prescription Drug Programs
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Final Rule As It Relates To The Pharmacy Industry
Version 9.0

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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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:

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.ncpdp.org) for information as it becomes available.

NCPDP offers information about HIPAA at http://www.ncpdp.org/Resources/HIPAA.

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

Please see important information under the November 2012 and August 2013 sections in Updates to this Document.
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**

<table>
<thead>
<tr>
<th>Transaction</th>
<th>Business/Service</th>
<th>Standard Named in January 16, 2009 Rule</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health claims and equivalent encounter information.</td>
<td>Retail pharmacy claims</td>
<td>NCPDP Telecommunication Standard Version D.0 and NCPDP Batch Standard Version 1.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Retail pharmacy supplies and professional services</td>
<td>NCPDP Telecommunication Standard Version D.0 and NCPDP Batch Standard Version 1.2 Or ASC X12N 837 Health Care Claim: Professional, Version 5010</td>
<td>See Note 1.</td>
</tr>
<tr>
<td></td>
<td>Dental claims</td>
<td>ASC X12N 837 Health Care Claim: Dental, Version 5010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Professional claims</td>
<td>ASC X12N 837 Health Care Claim: Professional, Version 5010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Institutional claims</td>
<td>ASC X12N 837 Health Care Claim: Institutional, Version 5010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enrollment and disenrollment in a health plan.</td>
<td>All named.</td>
<td>ASC X12N 834 Benefit Enrollment and Maintenance, Version 5010</td>
</tr>
<tr>
<td></td>
<td>Eligibility for a health plan.</td>
<td>Retail pharmacy eligibility.</td>
<td>NCPDP Telecommunication Standard Version D.0 and NCPDP Batch Standard 1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dental, professional, institutional</td>
<td>ASC X12N 270 Health Care Eligibility/Benefit Inquiry and ASC X12N 271 Health Care Eligibility/Benefit Response, Version 5010</td>
</tr>
<tr>
<td></td>
<td>Health care payment and remittance advice.</td>
<td>All named.</td>
<td>ASC X12N 835 Health Care Claim Payment/Advice, Version 5010</td>
</tr>
<tr>
<td></td>
<td>Health plan premium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Final Rule As It Relates To The Pharmacy Industry

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

### 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
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.

<table>
<thead>
<tr>
<th>Official Date of Final Rule:</th>
<th>January 16, 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date of Regulation:</td>
<td>March 17, 2009</td>
</tr>
<tr>
<td>Compliance Date:</td>
<td>October 1, 2013 original.</td>
</tr>
<tr>
<td></td>
<td>Final Rule CMS-0040-F changed Compliance Date to October 1, 2014.</td>
</tr>
<tr>
<td></td>
<td>Per April 1, 2014 – The Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets 12 as the standard for code sets.</td>
</tr>
<tr>
<td>New Compliance Date:</td>
<td>October 1, 2015</td>
</tr>
</tbody>
</table>

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
- AHIMA - ICD-10 Education
- 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.
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.ncpdp.org/](http://www.ncpdp.org/Members/Standards-Lookup)

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.ncpdp.org/Membership/Member-Benefits](http://www.ncpdp.org/Membership/Member-Benefits)

2. ASC X12


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.
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.0, in “Appendix A. History of Document Changes”, under “Version D.0” is a subsection “Editorial Corrections”. Updates will be made to this section as needed. (These editorial changes will be reflected in post Version D.0 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.ncpdp.org/Standards/Standards-Development-Process](http://www.ncpdp.org/Standards/Standards-Development-Process)

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.0 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.
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.ncpdp.org/Resources/Hipaa-Resources.aspx](http://www.ncpdp.org/Resources/Hipaa-Resources.aspx) and [http://www.ncpdp.org/Resources/HIPAA](http://www.ncpdp.org/Resources/HIPAA) for important notices, guidance documents, links, etc.

NCPDP implementation guides are included with membership and may be downloaded from the “Members Only”, “Standards Download” section of the website ([http://www.ncpdp.org/Members/Standards-Lookup](http://www.ncpdp.org/Members/Standards-Lookup)). The Standards Matrix provides documentation version information.

In the Telecommunication Version D.Ø document, there is a section of matrices to assist analysts/implmenters. 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.ncpdp.org/Resources/HIPAA

For general NCPDP information, see www.ncpdp.org

2. NCPDP PAYER TEMPLATES

The NCPDP SNIP Committee developed guidance to be used in filling out and creating payer sheets based on Version D.0 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.ncpdp.org/Resources/HIPAA under banner Telecommunication Version D.0.

3. 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.ncpdp.org/Resources/HIPAA Regulatory Timeline.

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 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 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

<table>
<thead>
<tr>
<th>TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.Ø, VERSION 3.Ø AND ICD–10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version 5010/D.Ø and Version 3.Ø</strong></td>
</tr>
<tr>
<td>01/09: Publish final rule</td>
</tr>
<tr>
<td>01/09: Begin Level 1 testing period activities (gap analysis, design, development, internal testing) for Versions 5010 and D.Ø.</td>
</tr>
<tr>
<td>01/10: Begin internal testing for Versions 5010 and D.Ø.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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 *.</td>
</tr>
<tr>
<td>01/13: Compliance date for Version 3.Ø for small health plans.</td>
</tr>
</tbody>
</table>

* 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/Resources/HIPAA Transition](http://www.ncpdp.org/Resources/HIPAA Transition) - Standards Transition.

ICD-10 white paper for the pharmacy industry - [http://www.ncpdp.org/Resources/HIPAA](http://www.ncpdp.org/Resources/HIPAA) under ICD-10 banner

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/](https://htct.hhs.gov/).
D. **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.ncpdp.org/Resources/Hipaa-Compliance.aspx](http://www.ncpdp.org/Resources/Hipaa-Compliance.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](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](https://fedreg.gov) 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.ncpdp.org/news_hipaa_trans_current.aspx#ImpGuiCorr](http://www.ncpdp.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](http://www.x12.org/newsletters/tr/index.cfm)


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

**C. AUGUST 2012**

On August 24, 2012, regarding the ICD-10 - Final Rule CMS-0040-F changed Compliance Date to October 1, 2014.

**D. NOVEMBER 2012**

Enhancement of Telecommunication Standard Implementation Guide Version D.Ø

November 2012 - Quantity Prescribed (46Ø-ET)

NCPDP has published an enhancement of the Telecommunication Standard Implementation Guide Version D.Ø. The enhanced guide contains a publication date of “November 2012”. In the guide in section “Appendix A. History of Document Changes”, “Version D.Ø”, “November 2012 Enhancement”, the following entry appears:

Quantity Prescribed (46Ø-ET) for claim billings was changed from “not used” to “situational” for Schedule II dispensing under the following situational circumstance “Required for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only.” (This modification was made to Claim Billing/Encounter, Claim Rebill, Prior Authorization Request And Billing (Claim)).
11/2012 NCPDP provided a request to the Office of e-Health Standards and Services to publish regulatory notice about the implementation guide enhancement. NCPDP also submitted Designated Standards Maintenance Organizations (DSMO) change request 1182 (http://www.hipaa-dsmo.org/ViewRequests.asp). As of 12/2012 we are waiting on word from OESS. See http://www.ncpdp.org/Hipaa.aspx under Implementation Guide Corrections Banner for updates to this action.

E. AUGUST 2013


In early summer of 2013, NCPDP was notified that OESS would not be able to publish a Federal Register notice only; that they were seeking approval to publish an Interim Final Rule (IFC). In later summer of 2013, NCPDP was notified that the use of the IFC was in question by the Office of the General Counsel who did not interpret the ACA that IFC could be used for HIPAA transactions not named in ACA. This would mean the naming of the November 2012 Telecommunication Standard Version D.0 would have to go through a Notice of Proposed Rule Making (NPRM) then a Final Rule process. This impacts the January 2014 implementation date the industry had sought in 2012.

NCPDP is seeking another interpretation of the ACA and whether naming of the Telecom D.0 November 2012 would need to go through the full rulemaking process, or the IFC as it was believed was intended for administrative simplification. As such, the industry is notified that the January 1, 2014 expected implementation date is not expected to be completed due to the HIPAA regulatory process. The industry is strongly requested to NOT implement the Quantity Prescribed new processing until the federal processes have been completed. As of now, processes should be status quo until further information is received from OESS and then the industry can appropriately plan a new timeframe.

F. APRIL 2014

Links were updated.

Quantity Prescribed (460-ET) - See http://www.ncpdp.org/Resources/HIPAA under Implementation Guide Corrections Banner for updates to this action.

The Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 14 162.1002 of title 45, Code of Federal Regulations.

G. AUGUST 2014

Quantity Prescribed (460-ET) - See http://www.ncpdp.org/Resources/HIPAA under Implementation Guide Corrections Banner for updates to this action.

July 31, 2014 CMS released a notice - Deadline for ICD-10 allows health care industry ample time to prepare for change - Deadline set for October 1, 2015
The U.S. Department of Health and Human Services (HHS) issued a rule today finalizing Oct. 1, 2015 as the new compliance date for health care providers, health plans, and health care clearinghouses to transition to ICD-10, the tenth revision of the International Classification of Diseases. This deadline allows providers, insurance companies and others in the health care industry time to ramp up their operations to ensure their systems and business processes are ready to go on Oct. 1, 2015. See http://www.cms.gov/Medicare/Coding/ICD10/index.html