



Analysis of the Final Rule, January 16, 2009, Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards

On Friday, January 16, 2009, the Department of Health and Human Services (HHS) published its final rule for modifications to the HIPAA electronic transaction standards under rules, 45 CFR Part 162, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

An electronic copy of this Final Rule can be found on the electronic Web pages of the *Federal Register* at http://www.access.gpo.gov/su_docs/fedreg/a090116c.html, beginning on page 74FR3296. Go to the Health and Human Services Department category for the Final Rule which can be downloaded in either text or PDF format. In this same *Federal Register*, under the same heading of HHS, there is also published the Final Rule for Modifications to the Medical Data Code Set Standards in order to adopt ICD-10-CM and ICD-10-PCS.

The Final Rule for HIPAA-related transactions modifications was preceded by a proposed rule published in the *Federal Register* on Friday, August 22, 2008. An electronic copy of this proposed rule can also be found at the *Federal Register* Web site at www.access.gpo.gov/su_docs/fedreg/a080822c.html. AHIMA responded to this proposed rule and AHIMA's response can be found at the AHIMA ICD-10 website www.ahima.org/icd-10.

Key Highlights of the Final Rule

- Effective date for the HIPAA Transaction Rule is March 17, 2009, with the exception of Medicaid Pharmacy Subrogation section, which is effective January 1, 2010.
- HHS set compliance dates for Version 4010/4010a conversion to Version 5010 and technical reports type 3 and NCPCP Version 5.0 to Version D.0 for January 1, 2012, for all covered entities except Medicaid Pharmacy Subrogation Programs which have a January 1, 2013 compliance date. These dates are a change from the proposed rule.
- HHS has published a timeline for implementing the new versions following guidance from the NCVHS, and addressing the testing of the affected transaction standards.
- The HIPAA rule has been modified to preclude a health plan from requiring an earlier compliance date than those adopted.
- The definition of "standard transaction" has been revised in part to allow for the dual use of standards for the same function under certain conditions.
- A companion Final Rule related to the adoption and implementation of ICD-10-CM and ICD-10-PCS as replacements for ICD-9-CM extend the compliance date for those classifications until October 1, 2013.

The Final Rule for HIPAA-related transactions adopts updated versions of the standards for electronic transactions and also a transaction standard for Medicaid pharmacy subrogation. These modifications call for the adoption of the updated HIPAA transaction sets CMS-0009-P (RIN 0538-AN50) using Accredited Standards Committee X12 (X12) from standards Version 4010 to Version 5010 Technical

Reports Type 3 and National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Version 5.0 to Telecommunication Standard Implementation Guide Version D Release 0 (D.0).

Effective Dates

These regulations are effective March 17, 2009, except for the provisions of 45 CFR part 162 Subpart S – Medicaid Pharmacy Subrogation – which are effective January 1, 2010.

Compliance Dates

The compliance dates for most of the updated transactions is January 1, 2012. The exception, again for the Medicaid Pharmacy Subrogation program, has a compliance date of January 1, 2013. Within the Final Rule HHS has also placed some suggested timelines for implementing Versions 5010, D.0, and 3.0, but they do not serve as official compliance dates.

NOTICE: *This review of the Final Rule for Health Insurance Reform; Modifications to the HIPAA Electronic Transaction Standards is intended as an overview of the rule and not as a complete detailed analysis of the rule. Readers seeking to comply with this rule are encouraged to read the entire Final Rule and not rely on this or any other summary of the rule.*

I. Background (74FR3296)

The Final Rule provides background similar to that in the August 2008 proposed rule, citing previous legislation (HIPAA in 1996) and the regulations that have been proposed and finalized since then. Key to this Final Rule are references to the original proposed rule for the HIPAA transaction standards and subsequent rules:

- May 7, 1998 – initial proposed rule for transactions and standards (63FR25272)
 - No link available
- August 17, 2000 – initial final rule for transactions and standards (65FR50311)
 - http://www.access.gpo.gov/su_docs/fedreg/a000817c.html
- February 20, 2003 – modification to the transaction and standards (68FR8380)
 - http://www.access.gpo.gov/su_docs/fedreg/a030220c.html
- August 22, 2008 – proposed rule to further modify (update) transactions and standards (73FR49742)
 - http://www.access.gpo.gov/su_docs/fedreg/a080822c.html

The transactions involved are in the table below:

Standard	Transaction
ASC X12* 837 D	Health care claims – Dental
ASC X12 837 P	Health care claims -- Professional
ASC X12 837 I	Health care claims – Institutional
NCPDP* D.0	Health care claims – Retail pharmacy drug
ASC X12 837 P and NCPDP D.0	Health care claims – Retail pharmacy supplies and professional services
NCPDP D.0	Coordination of Benefits – Retail pharmacy drug

Standard	Transaction
ASC X12 837 D	Coordination of Benefits – Dental
ASC X12 837 P	Coordination of Benefits – Professional
ASC X12 837 I	Coordination of Benefits – Institutional
ASC X12 270/271	Eligibility for a health plan (request and response) – dental, prof., & instit.
NCPDP D.0	Eligibility for a health plan (request and response) – retail pharmacy drugs
ASC X12 276/277	Health care claim status (request and response)
ASC X12 834	Enrollment and disenrollment in a health plan
ASC X12 835	Health care payment and remittance advice
ASC X12 820	Health plan premium payment
ASC X12 278	Referral certification and authorization (request and response)
NCPDP D.0	Referral certification and authorization (request and response) – retail rx.
NCPDP 5/1 and NCPDP D.0	Retail pharmacy drug claims (telecommunication and batch standards)
NCPDP 3.0	Medicaid pharmacy subrogation (batch standards)
<p>* Accredited Standards Committee X12 (ASC X12 or X12)</p> <p>** National Council for Prescription Drug Programs (NCPDP)</p> <p>Both ASC X12 and NCPDP are American National Standards Institute (ANSI) accredited standards organizations.</p>	

II. Provisions of the Proposed Regulations and Responses to Comments (74FR3297)

Published final rules usually repeat a summary of the content of the proposed rule followed by summarized comments from those who chose to comment on the rule – some 192 comments in this case – followed by HHS’ responses to the comments. For detail behind the August 2008 proposed changes readers are referred to the August 22, 2008 proposed rule.

A. Adoption of X12 Version 5010 Technical Reports Type for HIPAA Transactions (74FR3297)

HHS proposed to adopt Version 5010 of the ASC X12 standards in August 2008. In some cases this Version was modified by Type 1 Errata which were also proposed. HHS noted: “In general, deficiencies inherent in the current standards continue to cause industry-wide difficulties to such a degree that much of the industry rely on ‘companion guides’ and proprietary ‘work-arounds.’ The four types of changes in Version 5010 are structural, front matter, technical improvements and data content changes.” HHS found that the proposed changes were “overwhelmingly” supported, and noted many believe the changes will help eliminate the proliferation of guides now experienced.

Among other responses, commenters also noted “the new claims transaction standard contained in Version 5010 significantly improves the reporting of clinical data, enabling the reporting of ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes and distinguishes between principal diagnosis, admitting diagnosis, external cause of injury and patient reason for visit codes.” The claims standard was also recognized as better handling the “Present on Admission” (POA) indicator for each diagnosis. Overall, it is believed the distinctions allowed will improve the understanding of clinical data and enable better monitoring of mortality rates for certain illnesses, outcomes for specific treatment options, and hospital length of stay for certain conditions, as well as the clinical reasons for why the patient sought hospital care.

After reviewing comments, HHS indicates it will move forward with implementing the proposal. HHS notes it will request the ASC X12 and the Designated Standards Maintenance Organization (DSMO)

produce a comprehensive list of changes made between the current Version 4010/4010A and the final Version 5010 for user convenience. HHS has also referred a number of technical issues carried in comments to the proposed rule to the ASC X12, and the X12 response will be posted at the CMS web site at www.cms.hhs.gov and the X12 site www.x12.org. HHS notes some comments were in fact requests for revisions to the standard and the Technical Reports Type 3, which have also been referred to the X12 for future revisions. X12 implementation potentially will be changed in the future. Similarly comments regarding external code sets for claims adjustments were referred to the Workgroup for Electronic Data Interchange (WEDI) special work group (SWG).

HHS also indicates that a few comments were received concerning the field size needed to accommodate ICD-10-CM and ICD-10-PCS codes. HHS responds that field size was never the issue with the ICD-10 codes rather, Version 4010 lacked a qualifier to indicate the code set name rather than the size of the field for the codes.

B. Adoption of NCPDP Telecommunication Standard Implementation Guide Version D Release 0 (D.0) and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (1.2) for Retail Pharmacy Transactions. (74FR3299)

As noted in the title, the NCPDP standards are proposed for retail pharmacies to use for pharmacy drug transactions including health care claims or equivalent encounter information; eligibility for a health plan, referral certification and authorization, and coordination of benefits. HHS notes commenters unanimously supported the proposal, and the Department is, therefore moving forward with the proposed revisions.

C. Adoption of a Standard for Medicaid Pharmacy Subrogation (74FR3300)

In August HHS proposed a new subpart S to 45CFR part 162 to adopt a standard for the subrogation of pharmacy claims paid by Medicaid. This proposal was accepted unanimously as well and several commenters suggested subrogation also be used for non-pharmacy claims. HHS responded that while it would consider such a move, since it was not in the August proposal, they would not move forward at this time. HHS did comment that nothing prohibited trading partners from using subrogation as long as both parties agreed. At the same time, HHS also clarified that when acting as a health plan Medicaid programs were required to accept standard electronic transactions.

D. Adoption of the NCPDP Telecommunications Standard Implementation Guide and X12 Technical Report Type 3 for Billing Retail Pharmacy Supplies and Services. (74FR3300)

HHS had proposed to adopt both Version D.0 and the X12 837 Health Care Claim: Professional ASC X12 Technical Report type 3 for billing retail pharmacy supplies and professional services. The use of either standard would be determined by trading partner agreements (see 73FR49752).

HHS notes in the Final Rule, that by adopting both standards for the one transaction, it is supporting current industry practices with respect to the use of these standards for billing supplies and services that are commonly dispensed or conducted via the retail pharmacy channel. The Department goes on to note, “we are also making a conforming change to the definition of ‘standard transaction... We indicate a “standard transaction” means a transaction that complies with ‘an’ applicable standard adopted under this part, rather than ‘the’ applicable standard adopted under this part.”

E. Modifications to the Descriptions of Transactions (74FR3301)

In the proposed rule HHS indicated its desire to revise the description of three covered transactions: Enrollment and Disenrollment in a Health Plan; Referral Certification and Authorization; and Health Care Claim Status. Given the relative few objections the Department will go forward with these changes. In response to comments asking for further modification of the transaction description beyond what HHS proposed, the Department responded that it did not think it is appropriate to revise the definition of enrollment and disenrollment in order to specify a “sponsor” type, especially when “it is not mandatory for a sponsor that is not otherwise a covered entity to use the transaction standards because, as a non-covered entity, HIPAA does not apply to it.”

F. Compliance and Effective Dates (74FR3301)

HHS reports it received considerable comment - most opposed - to the compliance dates proposed for the use of versions 5010 and D.0. Most commenters indicated they viewed the proposed rule as requiring extensive implementation, analysis, and reprogramming as well as significant functional changes. Commenters estimated approximately 850 changes will be required as a result of the delayed adoption of 5010 and that 22 version releases of NCPDP have occurred since Version 5.1 was adopted. Many commenters noted the “industry” was reluctant to develop software for any version that was not adopted under HIPAA.¹ As a result of reviewing these comments the following compliance dates have been established:

- Version 5010 and D.0 – January 1, 2012.
- Version 3.0 for all covered entities except small health plans – January 1, 2012.
- Version 3.0 for small health plans – January 1, 2013.

In commenting on the implementation process HHS states: “We believe that it is crucial for covered entities to meet certain milestones during the compliance period in order to ensure full, successful, and timely compliance. The NCVHS² recommended a framework for compliance that we believe will be very effective for these purposes.” HHS expects covered entities to adhere to the recommendations and schedule proposed by the NCVHS.

The NCVHS recommendations suggested establishing two different levels of compliance for the implementation of Version 5010. Level 1 compliance means that the HIPAA covered entity can demonstrate that it can create and receive Version 5010 compliant transactions. Level 2 compliance is interpreted to mean HIPAA covered entities have completed end-to-end testing with all of their partners and are ready to move into full production with the new version.

In the Final Rule comments, HHS notes its expectations are as follows: “The Level 1 testing period is the period during which covered entities perform all of their internal readiness activities in preparation for testing the new versions of the standard with their trading partners” – meaning a covered entity can

¹ For over four years, AHIMA has been advocating for more concurrent updating of HIPAA standards, similar to other industries’ updates to standards. AHIMA intends to continue this advocacy effort so the healthcare industry does not find itself so far behind as the industry is now experiencing with 5010 and D.0.

² National Committee on Vital and Health Statistics letter to Secretary of HHS, September 26, 2007, <http://www.ncvhs.hhs.gov>

demonstrably create and receive compliant transactions, resulting from the completion of all design/build activities and internal testing and is not ready for external testing of the new versions, in a test or production environment, pursuant to its standard protocols for testing and implementing new software or data exchanges.

Level 2 testing is interpreted by HHS as the period during which covered entities are preparing to reach full production readiness with all trading partners. Level 2 compliance is reached when the entity has completed end-to-end testing with each of its trading partners, and is able to operate in production mode with the new versions of the standards. During the Level 1 and Level 2 testing periods, either version of the standards may be used in production mode³ as agreed to by trading partners.

HHS suggests covered entities should be prepared to meet Level 1 compliance by December 31, 2010, and Level 2 compliance by December 31, 2011. After December 31, 2011, covered entities cannot use Versions 4010/4010A and 5.1. On January 1, 2012 all covered entities will have reached Level 2 compliance, and must be fully compliant in using Versions 5010 and D.0 exclusively. HHS “anticipates” that since there was support for a phased-in schedule health plans and clearinghouses will make every effort to be fully compliant on January 1, 2012.

HHS urges covered entities to “begin preparations now, to incorporate effective planning, collaboration, and testing in their implementation strategies, and to identify and mitigate any barriers long before the deadline.” HHS goes on to state: “While we have authorized contingency plans in the past, we do not intend to do so in this case, as such an action would likely adversely impact ICD-10 implementation activities.”

Compliance Date for Version 3.0 (74FR3303)

HHS proposed in the August NPRM that for implementation of Version 3.0 for the Medicaid pharmacy subrogation transactions a compliance date would be set 24 months after the effective date of the final rule for all covered entities except for small health plans, which would have 36 months. HHS at the same time proposed language requirements in the rule to address situations where transactions require the participation of two covered entities where one entity is under a different set of compliance requirements. Responding to concerns that Version 3.0 had to be implemented either at the same time as Version D.0 or after due to data issues, HHS has decided to make the effective date for the portion of the rule concerning the adoption of Version 3.0 January 1, 2010, meaning covered entities except small health plans must be in compliance with Version 3.0 no later than January 1, 2012. In the rule (74FR3303 – column 3) HHS provides additional direction for Medicaid and other entities involved in pharmacy subrogation transactions.

Timeline (74FR3303)

HHS published a revised timeline for implementing Versions 5010/D.0 and Version 3.0, and included the ICD-10-CM and ICD-10-PCS dates from the Final Rule also issued as part of the rule.

³ HHS defines “production mode” to mean that covered entities can successfully exchange (accept and/or send) standard transactions and as appropriate, be able to process them successfully.

Dates	Version 5010/D.0 and Version 3.0	ICD-10-CM /ICD-10-PCS
01/2009	<ul style="list-style-type: none"> Publish Final Rule. Begin Level I testing period activities (gap analysis, design, development, internal testing) for Versions 5010 and D.0. 	<ul style="list-style-type: none"> Publish Final Rule.
01/2009	<ul style="list-style-type: none"> Begin internal testing for Versions 5010 and D.0 	
12/2010	<ul style="list-style-type: none"> Achieve Level 1 compliance (Covered entities have completed internal testing and can send and receive compliant transactions for Versions 5010 and D.0. 	
01/2011	<ul style="list-style-type: none"> Begin Level 2 testing period activities (external testing with trading partners and move into production; dual process mode) for Versions 5010 and D.0. 	<ul style="list-style-type: none"> Begin initial compliance activities (gap analysis, design, development, internal testing).
01/2012	<ul style="list-style-type: none"> Achieve Level 2 compliance; Compliance date for all covered entities. This is also the compliance date for Version 3.0 for all covered entities except small health plans*. 	
01/2013	<ul style="list-style-type: none"> Compliance date for Version 2.0 for small health plans. 	
10/1/2013		<ul style="list-style-type: none"> Compliance date for all covered entities subject to the final compliance date in any rule published for the adoption of ICD-10-related classifications.

* Note: Level 1 and Level 2 compliance requirement only apply to Versions 5010 and D.0.

In the Final Rule HHS addresses several comments concerning the timetable originally proposed. Some of the comments opposed to the proposed rule and responses addressed include:

- Concerns for **Medicaid agencies** being able to comply with the published deadlines – HHS acknowledged the need to work with States to coordinate their budget requests and implementation activities. HHS noted however that no waivers will be given to accommodate Medicaid legacy systems.
- A variety of comments related to suggestions for **staggered compliance** – HHS noted that different compliance dates for different types of covered entities or transactions could significantly complicate trading partner implementation and testing.
- Concerns were raised regarding health **plans that might require early compliance** – HHS agreed with the concerns raised and noted it was adopting a revision to §162.925 by adding a new paragraph, (a) (6), to specify a health plan is not permitted to delay, reject, or attempt to adversely affect the other entity or the transaction on the basis that the transaction does not comply with another adopted standard during the period from the effective date [in this case March 17, 2009] of the Final Rule until the compliance date.
- Many comments were made regarding the significant **importance of testing and the coordination of testing** – HHS agreed testing is absolutely crucial and must be dealt with early and effectively. HHS responds it revised the regulation text identifying the adopted standard for each transaction, in every instance to highlight the testing that must occur during the period from the effective date of

the Final Rule until the compliance date for Versions 5010 and D.0. The revised regulations permit the dual use of standards during the identified timeframe. HHS notes the **adoption of two standards for one transaction** during the period prior to compliance does not mean covered entities must use both standards, but rather, the use of either standard is permitted.

- Concerns were raised on the **role of vendors and their approach to revising the standards and testing** – HHS noted it could not control vendors since they are not covered entities, but by adopting a later compliance date HHS hopes to ensure that software development vendors have sufficient time to conduct the appropriate internal and external testing.

G. Miscellaneous/General Other Comments (74FR3306)

The Final Rule includes HHS responses to several other miscellaneous comments including the following implementation pertinent topics.

- **Claims attachments:** Several commenters urged HHS not to adopt a final rule related to a standard for electronic health care claims attachments during the implementation of the HIPAA transactions in this Final Rule or the ICD-10-CM and ICD-10-PCS implementations. These comments suggested that another implementation would be more than the industry could handle. HHS notes it will consider these concerns.
- **Standards Adoption and Modification:** A number of comments address concerns that the current process for adoption and modification under HIPAA is not keeping pace with the industry's needs. The lapse of time between 4010 and 5010 was cited as an example. A variety of suggestions on how this could be fixed were submitted by commenters. HHS acknowledges the issue and indicates it had evaluated alternatives and hoped to work with the industry for some process changes.
- **Education and Training:** A variety of comments were made highlighting the need for education and training throughout all sectors in the healthcare industry. Commenters also noted national associations could be involved in this training, but there was a need for a consistent message and materials. HHS agreed with the importance of consistent and accurate messages and /or materials by authoritative sources and promised to work closely with the industry to put together a comprehensive diverse plan that addresses Medicare specific policies as well as industry-wide policies and implementation issues. HHS cited its HIPAA website at <http://www.cms.hhs.gov> as a source of information. HHA also indicated it would work with State Medicaid agencies to “support their development of communication and outreach initiatives as [it] developed the overarching implementation strategy for education.”
- **Companion Guides:** In the proposed rule HHS noted its concern with the proliferation of companion guides being used or required in conjunction with 4010. HHS went on to suggest that given the proposed rule and upgrade to 5010, it hoped that “companion guides could potentially be eliminated if the updated versions of the standards were adopted. A wide variety of comments were received, which agreed and disagreed with this hope and how standardization could be accomplished. In the Final Rule HHS responded by stating: “We acknowledge the issues presented by companion guides, but note that we do not have the authority to expressly prohibit the use of these guides...based on our review of many such documents, and the ongoing efforts of the industry to collaborate, we strongly discourage health plans from having companion guides unless they are focused significantly on the basics for connectivity, trading partner arrangement, and use of situational data elements, so that the minimum number of fields remain situational. If companion guides contradict the implementation guides, the transaction will not be compliant.”

- **Standardization of Data Content:** Several comments recommended HHS support the work of groups such as the Coalition for Affordable and Quality Healthcare (CAQH) who are attempting to standardize the use of data content to maximize the benefits of transaction standards. HHS notes it supports such work but cannot mandate participation or adherence to their requirements.
- **Acknowledgement:** Concern was raised that HHS did not propose or adopt a new acknowledgement standard. Version 5010 accommodates the X12 acknowledgement transaction for the data receiver to communicate any errors or transmission problems back to the sender. HHS notes users are not prohibited from using such standards even though it has not adopted such a standard under HIPAA. HHS further notes it will consider the adoption of a standard for the acknowledgment transaction at the time it receives a recommendation from the NCVHS.
- **Real-Time Eligibility:** Similar concerns for a HIPAA standard for real-time eligibility were raised and again HHS notes that today such a transaction has not been vetted through the current standards adoption process.
- **HHS Funding the Purchase of TR3 Reports:** A few commenters raised concerns at the price of copies of the Version 5010, and the cost of the X12 TR3s. HHS notes it is not uncommon for such a charge and even though it underwrote the cost of the 4010/4010a guides it does not see it is beneficial to do so now. HHS goes on to say vendors, rather than small entities will most likely purchase these guides and spread the cost across many users rather than the entities each purchasing these guides.
- **Certification:** Several commenters suggested HHS consider petitioning the Certification Commission for Healthcare Information Technology (CCHIT) to include Versions 5010 or D.0 in all products that would be expected to carry the upgraded standards in order to facilitate compliance with the final rules. HHS suggests CCHIT does not certify products for administrative transactions and therefore will not pursue this avenue. HHS goes on to indicate it “does not recognize certification of any systems or software for purposed of HIPAA compliance.”

H. Comments Considered Out of Scope (74FR3310)

The Final Rule acknowledges comments considered by HHS as out of scope for the rule. These comments include issues related to: The Family Educational Rights and Privacy Act (FERPA); the number of diagnosis codes accepted by HHS on claims; need for a definition of real-time adjudication; and health plan incentives for using direct data entry (DDE).

III. Provision of the Final Rule (74FR3310)

This section is a list of what is incorporated into the Final Rule identified by the sections of HIPAA regulation. We repeat this section in its entirety for those needing this identification:

III. Provisions of the Final Rule

This Final Rule incorporates the provisions of the proposed rule, with the following exceptions and changes:

- HHS proposed to adopt a compliance date for Versions 5010 and D.0 of April 1, 2010 for all covered entities.
- In this Final Rule, HHS adopts a compliance date of January 1, 2012 for Versions 5010 and D.0 for all covered entities.

- HHS revises § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 accordingly.
- HHS proposed a compliance date of 24 months after the effective date of the Final Rule for the Medicaid pharmacy subrogation standard (Version 3.0) with an additional 12 months for small health plans. In this Final Rule, HHS indicates an effective date of January 1, 2010 for the provisions of 45 CFR Subpart S. This means covered entities other than small health plans must be in compliance on January 1, 2012, while small health plans, which have an additional 12 months, must be in compliance on January 1, 2013.
- In § 162.925, HHS adds paragraph (a)(6) that precludes health plans from requiring an earlier compliance date than those adopted.
- Use of Versions 5010 and D.0 in advance of the mandatory compliance date is permissible, based upon mutual agreement by trading partners.
- HHS adopts revisions to § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to enable covered entities to engage in Level 2 testing by allowing for the use of both the old standard and the updated standard.
- HHS allows covered entities to use either Version 4010/4010A, 5010, 5.1 or D.0 for billing retail pharmacy supplies and services, and reflect that policy in revisions to § 162.1102. HHS also revises the definition of “standard transaction” in accordance with our policy to allow for the dual use of standards, by replacing “the applicable standard” with “an applicable standard” at §162.103
- HHS proposed to clarify the descriptions for three standards: Enrollment and disenrollment, referral certification and authorization, and health care claims status and request. In the Final Rule it does so, by specifying the senders and receivers of those transactions in § 62.1301, § 162.1401 and § 162.1501.
- In the proposed rule, at § 162.900, HHS stated that ASC X12N implementation specifications and the ASCX12 Standard for Electronic Data interchange Technical Report Type 3 were available from the Washington Publishing Company. In the Final Rule, HHS provides the correct address and Web site for obtaining the Version 5010 guides, from X12. Version 4010/4010A specifications may still be obtained from the Washington Publishing Company.

IV. Collection of Information Requirements (74FR3310)

HHS acknowledges its obligations to provide a 30-day notice to solicit comments on changes in data collection. HHS notes the publishing of its NPRM on August 22, 2008 and a 60 day notice on the revisions published in the *Federal Register* on October 10, 2008 (73FR60296), which received no comments.

V. Regulatory Impact Analysis (74FR3311)

This section covers:

- A. Overall Impact (74FR3311)
- B. Regulatory Flexibility Analysis (74FR3311)
 - 1. Number of Small Entities (74FR3311)
 - 2. Cost for Small Entities (74FR3312)
 - 3. Alternatives Considered (74FR3313)
 - 4. Conclusion (74FR3313)

C. Anticipated Effects (74FR3313)

- Assumptions for Version 5010 Impact Analysis (74FR3314)
- Explanation of Cost Calculations (74FR3315)
- Explanation of Benefits and Savings Calculations (74FR3316)
 - Hospitals
 - Physician and Other Providers
 - Dentists
 - Pharmacies
 - Health Plans
 - Government Plans
 - Clearinghouses and Vendors
- Other Comments Pertaining to Cost Estimates (74FR3318)
- Version D.0 (and Version 5010 for pharmacies) (74FR3319)
- Costs (74FR3319)
 - Chain Pharmacies
 - Independent Pharmacies
 - Health Plans and PBMs
 - Vendors
- Benefits (74FR3320)
 - Pharmacies
 - Health Plans and PBMs
- Version 3.0 (Medicaid Pharmacy Subrogation) (74FR3320)
 - Impact on States That Use a Contingency Fee Contractor
 - Impact on States Converting From Paper
 - Impact on States That Bill Electronically (Without a Contractor)
- Summary of Costs and Benefits for This Final Rule (74FR3322)

For the most part there were either no comments on what HHS had provided in the NPRM or the comments while challenging HHS estimates and assumptions provided no alternative assumptions or estimates to use. HHS acknowledges several assumptions where there was enough detail and made changes in the original estimates published in August 2008. In spite of these changes and revision to the original costs and benefits HHS saw no reason for the proposed rule to be made final and the implementation of the HIPAA transaction standards to be upgraded in line with the original proposed rule and the changes noted elsewhere.

Part 162 – Administrative Requirements (74FR3324)

This is the actual Final Rule section that revises or adds to the HIPAA regulations at Part 162.

- Part 162’s authority citation is revised.
- Subpart A §162.103 has a revised definition – “Standard transaction” to mean “a transaction that complies with an applicable standard adopted under this part.”
- Subpart I – **General Provisions for Transaction** has several minor changes, important among them are:
 - Several sections in §162.900 are removed or revised.

- § 169.920 – **Availability of implementation specifications** [repeated here verbatim so readers may have knowledge of the resources listed]:

A person or an organization may directly request copies of the implementation specifications and the Technical Reports Type 3 described in subparts I through S of this part from the publishers listed in this section. The Director of the Federal Register approves the implementation specifications, which include the Technical Reports Type 3 described in this section, for incorporation by reference in subparts I through S of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications and Technical Reports Type 3 described in this section are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786-6597. The implementation specifications and Technical Reports Type 3 are also available at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Implementation specifications are available for the following transactions.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3*. The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970-4480; and FAX (703) 970-4488. They are also available through the internet at <http://www.X12.org>. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

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(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/ 005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/ N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/ 005010X223A1, as referenced in § 162.1102 and § 62.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/ 005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008,

ASC X12N/005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in § 162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477-1000; FAX (480) 767-1042. They are also available through the Internet at <http://www.ncpdp.org>. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

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(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

○ § 169.923 – **Requirements for covered entities** – add the following:

(2) *General Rule.* Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

- Subpart K – **Health Care Claims or Equivalent Encounter Information:** this subpart identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates. §162.1102 is specifically changed to include provider claims for billing of: retail pharmacy drugs, dental health care, professional health care, institutional health care, and retail pharmacy supplies and professional services.
- Subpart L – **Eligibility for a Health Plan:** this subpart identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates. §162.1202 is specially modified to apply new detail for retail pharmacies and dental, professional, and institutional health care eligibility benefit inquiry and response.
- Subpart M – **Referral Certification and Authorization:** this subpart identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates. §162.1301 is changed to identify which transmissions are covered. §162.1302 is modified to apply

new detail for retail pharmacies and dental, professional, and institutional requests for review and response.

- Subpart N – **Health care Claim Status**: this subpart identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates.
- Subpart O – **Enrollment and Disenrollment**:
 - §161.1501 **Enrollment and disenrollment in a health plan transaction** is changed to note: The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage benefits, or policy, to a health plan to establish or terminate insurance coverage.
 - §162.1502 **Standard for enrollment and disenrollment in a health plan transaction**: this section identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates.
- Subpart P – **Health Care Payment and Remittance Advice**: this subpart identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates in §162.1602.
- Subpart Q – **Health Plan Premium Payments**: again this subpart, specifically §162.1702 identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates.
- Subpart R – **Coordination of Benefits**: this subpart has some minor revisions as well as changes to §162.1802 **Standards for coordination of benefits information transaction** – which identifies the conversion to the new standards as they apply to over the period between now and the final compliance dates.
- Subpart S – **Medicaid Pharmacy Subrogation**: this subpart as noted is new and has two sections:
 - § 162.1901 **Medicaid pharmacy subrogation transaction** which states: “The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.”
 - § 162.1902 **Standard for Medicaid pharmacy subrogation transaction** which describes the adoption of Version 3.0 and its intended compliance dates.

AHIMA is the premier association of health information management (HIM) professionals. AHIMA’s 53,000 members are dedicated to the effective management of personal health information needed to deliver quality healthcare to the public. Founded in 1928 to improve the quality of medical records, AHIMA is committed to advancing the HIM profession in an increasingly electronic and global environment through leadership in advocacy, education, certification, and lifelong learning. To learn more about the association, go to www.ahima.org.