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# Part II

# Department of Health and Human Services

## 45 CFR Part 162

## Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**45 CFR Part 162**

**[CMS–0009–P]**

**RIN 0938–AM50**

## Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This rule proposes to adopt updated versions of the standards for electronic transactions originally adopted in the regulations entitled, ''Health Insurance Reform: Standards for Electronic Transactions,'' published in the **Federal Register** on August 17, 2000, which implemented some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These standards were modified in our rule entitled, ''Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets,'' published in the **Federal Register** on February 20, 2003. This rule also proposes the adoption of a transaction standard for Medicaid Pharmacy Subrogation. In addition, this rule proposes to adopt two standards for billing retail pharmacy supplies and professional services, and to clarify who the ''senders'' and ''receivers'' are in the descriptions of certain transactions.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 21, 2008.

**ADDRESSES:** In commenting, please refer to file code CMS–0009–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0009–P, P.O. Box 8014, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0009–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

**FOR FURTHER INFORMATION CONTACT:**

Lorraine Doo (410) 786–6597.

Gladys Wheeler (410) 786–0273.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period will be available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951. *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you may view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The web site address is: *http://www.gpoaccess.gov/fr/index.html.*

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## I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Public Law 104–191, mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. In the August 17, 2000 final rule, the Secretary adopted standards for eight electronic health care transactions (65 FR 50312). The Secretary adopted modifications to some of those standards in a February 20, 2003 final rule (68 FR 8381). Since the standards compliance date of October 2003, a number of technical issues with the standards, including issues resulting from new business needs have been identified. Industry stakeholders submitted hundreds of change requests to the standards maintenance organizations, with recommendations for improvements to the standards. These requests were considered, and many were accepted, resulting in the development and approval of newer versions of the standards for electronic transactions. However, covered entities are not permitted to use the newer versions we are proposing herein until the Secretary of Health and Human Services (HHS) adopts them by regulation for covered transactions.

In addition to technical issues and business developments necessitating consideration of the new versions of the standards, there remain a number of unresolved issues that had been identified by the industry early in the implementation period for the first set of standards, and those issues were never addressed through regulation (for example, which is the correct standard to use for billing retail pharmacy supplies and professional services). This proposed rule addresses those outstanding issues.

*A. Legislative Background*

The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in HIPAA, which was enacted on August 21, 1996. HIPAA requires the adoption and use of standards to facilitate the electronic transmission of certain health information and the conduct of certain business transactions.

Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ''Administrative Simplification.'' Part C of title XI of the Act consists of sections 1171 through 1179. These sections define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the electronic transmission of health information.

Section 1171 of the Act establishes definitions for purposes of Part C of title XI for the following terms: code set, health care clearinghouse, health care provider, health information, health plan, individually identifiable health information, standard, and standard setting organization (SSO). Section 1172(a) of the Act makes any standard adopted under Part C applicable to: (1) Health plans; (2) health care clearinghouses; and (3) health care providers who transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard(s). Current standards are at 45 CFR part 162 subparts K through R.

Section 1172 of the Act requires any standard adopted by the Secretary under Part C of Title XI to be developed, adopted, or modified by a standard setting organization, except in the special cases where no standard for the transaction exists, as identified under section 1172(c)(2) of the Act. Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt standards. In the case of a standard that has been developed, adopted, or modified by an SSO, the SSO must consult with the following organizations in the course of the development, adoption, or modification of the standard: the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI) and the American Dental Association (ADA). Under section 1172(f) of the Act, the Secretary must also rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS) and shall also consult with appropriate Federal and State agencies and private organizations.

Section 1173(a) of the Act requires the Secretary to adopt transaction standards and data elements for such transactions, to enable the electronic exchange of health information for specific financial and administrative health care transactions and other financial and administrative transactions as determined appropriate by the Secretary. Under sections 1173(b) through (f) of the Act, the Secretary is also required to adopt standards for: specified unique health identifiers, code sets, security for health information, electronic signatures, and the transfer of certain information among health plans.

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications to the standards, including additions to the standards, as appropriate, but not more frequently than once every 12 months. Modifications must be completed in a manner that minimizes disruption and cost of compliance. The same section requires the Secretary to ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets. Moreover, if a code set is modified, the code set that is modified must include instructions on how data elements that were encoded before the modification may be converted or translated to preserve the information value of the data elements that existed before the modification.

Section 1175(b) of the Act provides for a compliance date not later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, which must comply not later than 36 months after such adoption. If the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than the 180th day following the date of the adoption of the modification. The Secretary must consider the time needed to comply due to the nature and extent of the modification when determining compliance dates, and may extend the time for compliance for small health plans, if the Secretary deems it appropriate.

*B. Regulatory History*

On August 17, 2000, we published a final rule entitled, ''Health Insurance Reform: Standards for Electronic Transactions'' in the **Federal Register** (65 FR 50312) (hereinafter referred to as the Transactions and Code Sets rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for eight electronic transactions and for code sets to be used in those transactions. Those transactions were: health care claims or equivalent encounter information; health care payment and remittance advice; coordination of benefits; eligibility for a health plan; health care claim status; enrollment and disenrollment in a health plan; referral certification and authorization; and health plan premium payments. We defined these transactions and specified the adopted standards at 45 CFR part 162, subparts I and K through R.

The standards that we adopted were developed by two American National Standards Institute (ANSI) accredited standard setting organizations (commonly and hereinafter referred to as Standards Developing Organizations (SDO)): the National Council for Prescription Drug Programs (NCPDP)

and the Accredited Standards Committee ASC X12, which will hereinafter be abbreviated and referred to as X12. In our regulations and guidance materials to date, we have always referred to ''X12N'' where the ''N'' indicates the particular subcommittee. However, we have been informed by the X12 committee that it no longer uses the ''N'' to indicate the subcommittee. Therefore, in keeping with the current practice of the X12, we will not continue to use the ''N'' either, and we will simply refer to the standards of that organization as ''X12'' standards. We adopted the NCPDP Telecommunication Standard version 5.1 (hereinafter referred to as NCPDP 5.1) and its equivalent batch standard for retail pharmacy drug claims under the health care claims or equivalent encounter transaction, as well as the eligibility for a health plan transaction for retail pharmacy drugs, the retail pharmacy drug claims remittance advice transaction, and the coordination of benefits information transaction for retail pharmacy drug claims. We adopted a number of X12 standards, all in Version 4010, for the remaining transactions (see § 162.1101 through 1802).

On February 20, 2003, we published a final rule entitled, ''Health Insurance Reform: Modifications to Electronic Data Transaction Standards and Code Sets,'' in the **Federal Register** (68 FR 8381) (hereinafter referred to as the Modifications rule). In that rule, we adopted certain modifications to some of the standards for the eight electronic standard transactions. These modifications resulted in part from recommendations of the industry because the original versions of the X12 standards had certain requirements (for example, requiring information that is not available or not needed) that impeded implementation. Since the industry did not have extensive prior experience with the X12 standards, implementation problems were compounded. It is likely that this lack of expertise also contributed to limited input during the Version 4010 ballot process (to approve the ''original'' standards). For information about the ballot process for any particular SDO, interested parties should visit the individual Web sites for a full explanation of the process and how to participate. The result is that the standards were not thoroughly analyzed to identify problems before Version 4010 was adopted. The X12 agreed to create ''addenda'' to the original versions of the standards, called Version 4010A, in order to facilitate implementation for the industry, and the Secretary adopted those addenda into regulations in every instance where the Secretary had adopted Version 4010. (See 68 FR 8381). (Readers will note that we have removed the numeral ''1'' from the end of Version 4010/4010A1 for ease of reference. Since there is only one addendum, we did not feel the need to include the number ''1'' after each citation in this proposed rule.)

In Table 1 below, we summarize the full set of transaction standards adopted in the Transactions and Code Sets rule and as modified in the Modifications rule. The table uses abbreviations of the standards and the names by which the transactions are commonly referred, as a point of reference for the readers. The official nomenclature and titles of each standard and transaction are provided later in the narrative of this preamble.

TABLE 1—ADOPTED STANDARDS FOR HIPAA TRANSACTIONS

| 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. |
| ASC X12 837 | Health care claims—Coordination of Benefits. |
| ASC X12 270/271 | Eligibility for a health plan (request and response). |
| 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 5.1 | Retail pharmacy drug claims (telecommunication and batch standards). |

*C. Standards Adoption and Modification*

In addition to adopting the first set of transaction standards and code sets, the Transactions and Code Sets rule adopted procedures for the maintenance of existing standards and for adopting new standards and modifications to existing standards (see § 162.910).

1. Designated Standards Maintenance Organizations (DSMO)

Section 162.910 sets out the standards maintenance process and defines the role of SDOs and the DSMO. An SDO is an organization accredited by the ANSI that develops and maintains standards for information transactions or data elements. SDOs include the X12, the NCPDP, and Health Level Seven (HL7). In August 2000, the Secretary designated six organizations (see Health Insurance Reform: Announcement of Designated Standard Maintenance Organizations Notice (65 FR 50373)) to maintain the health care transaction standards adopted by the Secretary, and to process requests for modifying an adopted standard or for adopting a new standard. The six organizations include the three SDOs referenced above. The other three organizations are the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and the Dental Content Committee (DCC) of the American Dental Association. The DSMO operate through a coordinating committee. For additional information about the DSMO process and procedures, refer to the Web site at *http://www.hipaa-dsmo.org/Main.asp.*

2. Process for Adopting Modifications to Standards

In general, HIPAA requires the Secretary to adopt standards that have been developed by an SDO with certain exceptions. In addition to directing the Secretary to adopt standards, HIPAA, at section 1172(d) of the Act, also requires the Secretary to establish specifications for implementing each adopted standard.

The process for adopting a new standard or modifications to existing standards is described in the Transactions and Code Sets rule (65 FR 50312 at 50344) and implemented at § 162.910. Under § 162.910, the Secretary considers recommendations for proposed modifications to existing standards or a proposed new standard, only if the recommendations are

developed through a process that provides for—

- Open public access;
- Coordination with other SDOs;
- An appeals process for the requestor of the proposal or the DSMO that participated in the review and analysis if either of the preceding were dissatisfied with the decision on the request;
- An expedited process to address HIPAA content needs identified within the industry; and
- Submission of the recommendation to the NCVHS.

Any entity may submit change requests with a documented business case to support the recommendation to the DSMO. The role of the DSMO committee is to receive and manage those change requests. The DSMO review the request and notify the SDO of the recommendation for approval or rejection. If the changes are recommended for approval, the DSMO also notifies the NCVHS and suggest that a recommendation for adoption be made to the Secretary of HHS. Instructions for the DSMO process and access to the submission tools are available at *http://www.hipaa-dsmo.org.*

All of the modifications and the new transaction standard proposed in this rule were developed through a process that conforms with § 162.910. The suggested modifications and new standard recommended for approval by the DSMO were submitted to NCVHS for consideration. In 2007, the NCVHS conducted two days of hearings with health care providers, health plans, clearinghouses, vendors, and interested stakeholders on the adoption of the new ASC X12 Version 005010 Technical Reports Type 3 and the NCPDP Telecommunication Standard, Version D.0, to replace Versions 4010/4010A and the NCPDP Version 5.1. Testimony was also presented for the NCPDP Medicaid pharmacy subrogation standard (Version 3.0). A list of organizations that provided testimony to the NCVHS is available on the agenda for the July 2007 meetings, at *http://www.ncvhs.hhs.gov/070730ag.htm.* In addition to the standards organizations, other testifiers included Delaware Medicaid, MEDCO, Healthcare Billing and Management Association (HBMA), BlueCross BlueShield Association (BCBSA), Integra Professional Services, EDS, LabCorps, the American Dental Association, the American Hospital Association, the National Community Pharmacists Association (NCPA), the Medical Group Management Association (MGMA), the National Association of Chain Drug Stores (NACDS), the Workgroup for Electronic Data Interchange (WEDI) and Smith Premier. In a letter dated September 26, 2007 (available at *http://www.ncvhs.hhs.gov/070926lt.pdf* ), the NCVHS submitted to the Secretary its recommendations to adopt the updated versions of standards as well as the NCPDP Medicaid pharmacy subrogation standard.

As noted above, and as indicated in the letter from NCVHS, HHS consulted with other Federal and State agencies and private organizations to gain input for this proposed rule regarding the adoption and implementation of standards. We also worked with WEDI specifically to conduct industry-focused information forums on implementation of the modified standards proposed in this rule.

3. Implementation Specifications and Technical Reports Type 3

Each adopted standard has operating rules that are documented in an implementation specification or guide. These implementation specifications or guides comprise ''the specific instructions for implementing a standard'' (§ 162.103). In addition to ensuring that specific data are communicated in the same way among trading partners, and providing instructions to users for implementing standards, these implementation specifications dictate field size limits and provide guidance for the type of information to be included in a particular field. The specificity that results enables health information to be exchanged electronically between any two entities, using the same instructions for format and content without losing the integrity of the data.

In 2003, the X12 initiated the concept of the Technical Reports Type 3 to promote consistency and coherency among information processing systems which use X12 standards and encourage uniform standards implementation. X12 Technical Reports are in three formats: Type 1 reports are tutorials that describe the intent of the authoring subcommittee and provide guidance on usage of the standard; Type 2 reports provide models of business practices and data flows to assist users in the development of software systems that would use the EDI transmissions; and Type 3 reports are implementation guides that address a specific business purpose (for example, a claim), and provide comprehensive instructions for the use and content of a transaction. The Technical Reports Type 3 are the updated equivalents of the X12 Implementation Guides referenced in the current HIPAA regulations. We note that no format or function differences exist between previous implementation specifications and Technical Reports Type 3. We reference Technical Reports Type 3 in the proposed regulation text in accordance with the way in which the X12 now refers to its implementation guides. Documents called Type 1 Errata are used to supplement published Technical Reports Type 3 that solve significant problems that prevent achievement of the business purpose.

NCPDP terminology has not changed since the adoption of the current HIPAA regulations. Therefore, the NCPDP standards continue to be referred to as implementation guides or specifications.

## II. Provisions of the Proposed Rule

### *A. Proposed Adoption of X12 Version 005010 Technical Reports Type 3 for HIPAA Transactions*

We propose to revise § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt the ASC X12 Technical Reports Type 3, Version 005010, hereinafter referred to as Version 5010, as a modification of the current X12 Version 4010 and 4010A1 standards, hereinafter referred to as Version 4010/4010A, for the HIPAA transactions listed below. In some cases, the Technical Reports Type 3 have been modified by Type 1 Errata, and these Errata are also included in our proposal. Covered entities conducting the following HIPAA standards would be required to use Version 5010:

- Health care claims or equivalent encounter information (§ 162.1101)
  - — Professional health care claims
  - — Institutional health care claims
  - — Dental health care claims
- Dental, professional, and institutional health care eligibility benefit inquiry and response (§ 162.1201)
- Dental, professional, and institutional referral certification and authorization (§ 162.1301)
- Health care claim status request and response (§ 162.1401)
- Enrollment and disenrollment in a health plan (§ 162.1501)
- Health care payment and remittance advice (§ 162.1601)
- Health plan premium payments (§ 162.1701)
- Coordination of Benefits (§ 162.1801)
  - — Dental health care claims
  - — Professional health care claims
  - — Institutional health care claims

Following is a brief description of the enhancements in the updated version of the standards and our rationale in support of its adoption.

Justification for Adopting Version 5010 TR3 Reports

Despite the changes made to Version 4010 that prompted the establishment of Version 4010A, which was adopted in the Modifications rule, operational and technical gaps still exist in Version 4010A. In addition, it has been more than 5 years since implementation of the original standards, and business needs have evolved during this time. While the implementation specifications continue to improve with each new version, deficiencies in the adopted versions continue to cause industry-wide issues. These deficiencies in the current implementation specifications have caused much of the industry to rely on ''companion guides'' created by health plans to address areas of Version 4010/4010A that are not specific enough or require work-around solutions to address business needs. These companion guides are unique, plan-specific implementation instructions for the situational use of certain fields and/or data elements that are needed to support current business operations. We believe that industry reliance on companion guides has minimized some of the potential benefits offered by the standards because each guide has a different set of requirements, making full standardization nearly impossible. Furthermore, as the industry worked with the standards and became more adept at using them, opportunities for improvement became apparent and were included in subsequent versions of the implementation specifications. It also became apparent that dependence on companion guides could be greatly reduced, if not eliminated, if proposed modifications were ultimately adopted for use by the industry.

As stated earlier, in the years following the compliance deadline, hundreds of requests to upgrade the standards have been submitted by the industry to the DSMO Steering committee. These requests have been made in accordance with the DSMO Change Request process, described in the Transactions and Code Sets rule. The DSMO Steering committee has evaluated approximately five hundred requests for changes to Version 4010/4010A. Version 5010 changes significantly improve the functionality of the transactions and correct problems encountered with Version 4010/4010A. Change Description Guides detailing the specific changes made to each new version are available at *http://www.wpc-edi.com.* The Medicare Fee-for-Service program is evaluating the impact of implementing Version 5010 in the future, and has completed a gap analysis of the standards. Medicare has prepared a comparison of the current X12 HIPAA EDI standards (Version 4010/4010A) with Version 5010 and the NCPDP EDI standards Version 5.1 to D.0, and has made these side-by-side comparisons available to other covered entities and their business associates on the CMS Web site: *http://www.cms.hhs.gov/ElectronicBillingEDITrans/18_5010D0.asp*.

The areas of improvement included in Version 5010 can be grouped into four main themes. Each theme is discussed in detail below:

*Front Matter/Education*—Information in the front matter (hereinafter referred to as the Front Matter section) of Version 5010 now provides clearer instructions. Ambiguous language has been eliminated and the rules for required and situational data elements are more clearly defined.

*Technical Improvements*—Technical improvements in Version 5010 include new guidelines that use the same data representation for the same purposes across all of the transactions for which Version 5010 is used. This reduces ambiguities and reduces the number of times that the same data could have multiple codes or qualifiers, or from appearing in different segments for the same purpose. Consistent data representation reduces ambiguities that result from the same data having multiple codes or qualifiers and from the same data appearing in different segments in different transactions. In other words, ambiguous language has been eliminated, the rules for required and situational data elements are more clearly defined, and instructions for many business processes have been clarified.

*Structural Changes*—Modifications to the physical components of the transaction have been made. New segments and new data elements have been added and data elements have been modified or removed to make the data elements longer, shorter, or of a different data type to add functionality and improve consistency. In some cases, new ''composites,'' defined as a collection of related data elements, have been added in order to ensure that related data is reported and received in the same section of the transaction instead of spread out in different areas. This increases the accuracy of processing because programming can be consistent for each transaction.

*Data Content*—Redundant and unnecessary data content requirements have been removed to eliminate confusion for implementers. Additional requirements have been added where needed to clarify existing data content requirements.

The following section includes a brief summary of changes for each of the versions of the implementation guides. We note that some of the implementation guides had significant modifications while others were changed only moderately. In the following discussions for each transaction, we use short-hand for referring to the current and modified versions of the standard. Instead of writing out the full name of the standard in each case, we refer to ''Version 4010/4010A'' and ''Version 5010.'' The Version 4010/4010A and Version 5010 short-hand refers to the particular transaction standard discussed in each section below. For example, in the first section below, we address the Health Care Claims or Equivalent Encounter Information transaction for institutional health care claims. Rather than refer to the ASC X12 837I, Version 4010/4010A and the X12 837 Version 5010 Technical Report Type 3 for the Health Care Claims or Equivalent Encounter Information transaction for institutional claims, we refer to Version 4010/4010A and Version 5010, respectively, with the understanding that we are referring to those versions in the context of the health care claims or equivalent encounter information transactions for institutional claims. This is true also for our discussion of the NCPDP transaction standards. Finally, the standards are presented in the order we believe best represents the level of utilization within the industry; in other words, the transactions which are used most often by the industry, such as claims and eligibility verification, are listed before lesser used transactions, such as enrollment and premium billing. In the section below, the order of the transactions does not follow the order of the regulation text. However, in the regulation text section of this proposed rule, the standards are represented in the same order in which they have been published in each of the earlier regulations.

Health Care Claims or Equivalent Encounter Information Transaction (837)

Institutional Health Care Claims (837I)

We propose to revise § 162.1102 by adding a new paragraph (c)(4) that would replace the ASC X12N 837I Version 4010/4010A with the Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and Type 1 Errata to Health Care Claim: Institutional for the Health Care Claims

or Equivalent Encounter Information Transaction for institutional claims.

Version 4010/4010A does not provide a means for identifying an ICD–10 procedure or diagnosis code on an institutional claim. Version 5010 anticipates the eventual use of ICD–10 procedure and diagnosis codes and adds a qualifier as well as the space needed to report the number of characters that would permit reporting of ICD–10 procedure and diagnosis codes on institutional health care claims.

Other significant changes include the following:

• Version 5010 separates diagnosis code reporting by principal diagnosis, admitting diagnosis, external cause of injury and reason for visit, allowing the capture of detailed information (for example, mortality rates for certain illnesses, the success of specific treatment options, length of hospital stay for certain conditions, and reasons for hospital admissions).

• Version 4010/4010A does not allow for the identification of a ''Present on Admission'' indicator (POA) on the institutional claim. Present on Admission means the condition or diagnosis that is present at the time the order for inpatient admission occurs—conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are considered as present on admission. This information is being captured through a workaround in Version 4010/4010A by placing this information in an unassigned segment. This has created confusion for hospitals and has limited access to information that is critical to identifying hospital acquired conditions and the ability to track utilization of the POA indicator and treatment outcomes as specified by section 5001 of the Deficit Reduction Act. Version 5010 allows the POA indicator to be associated with each individual diagnosis code allowing the capture of detailed information (for example, mortality rates for certain illnesses, length of hospital stay for certain conditions and reasons for hospital admissions).

• Version 5010 includes clear and precise rules that clarify how and when the NPI is to be reported. Instructions require submitters to report the same organizational type NPI in the same position for all payers. This improves the accuracy of information that is needed to conduct coordination of benefits by ensuring that the NPI information that is submitted to a secondary or tertiary payer reflects the NPI information that was processed by the primary payer. Version 4010/4010A does not have clear rules about how an NPI should be reported for subparts, or how to identify atypical providers (for example, taxi services, home and vehicle modifications services, and respite services that are not required to obtain an NPI), resulting in confusion among providers about who needs an NPI and when an NPI for a subpart or an individual provider should be reported.

• Version 5010 provides clear definitions and precise rules with instructions for consistently reporting provider information in the same position and with the same meaning throughout the transaction. Version 4010/4010A lacks a clear definition for the various types of providers (other than attending and operating) who participate in providing health care and who could be named in the claim transaction (for example, ordering provider and referring provider).

Version 5010 makes programming more efficient because it uses the same structure for all data elements across the transactions for which 5010 is used. Therefore, the structure for patient information in the institutional health care claims transaction would be the same as that for eligibility for a health plan transaction. Version 4010/4010A does not structure certain data (for example, patient information) consistently with the standards for other transactions, such as the eligibility for a health plan transaction.

• Professional health care claims (837P).

We propose to revise § 162.1102 by adding a new paragraph (c)(3) that would replace the ASC X12N 837P Version 4010/4010A with the 837 Health Care Claim: Professional ASC X12 Technical Report Type 3 for the Health Care Claims or Equivalent Encounter Information Transaction for professional claims.

Like the institutional health care claim transaction, Version 4010/4010A does not provide a means for identifying an ICD–10 diagnosis code on a professional claim. Version 5010 anticipates the eventual use of ICD–10 diagnosis codes and adds a qualifier as well as the space needed to report the number of characters that would permit reporting of ICD–10 diagnosis codes on professional claims.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 only allows the reporting of minutes for anesthesia time, ensuring consistency and clarity across transactions. Version 4010/4010A lacks consistency in allowing for the reporting of anesthesia time, in either units or minutes. This inconsistency creates confusion among providers and plans, and frequently requires electronic or manual conversions of units to minutes or vice versa, depending on a health plan's requirement, and is especially complicated when conducting COB transactions with varying requirements among secondary or tertiary payers.

• Version 5010 allows ambulance providers to report pick-up information for ambulance transport electronically and makes it a requirement on all ambulance claims. Version 4010/4010A does not allow ambulance providers to report pick-up information for ambulance transport. Plans that need this information to adjudicate an ambulance claim must request this information after the claim is received. This means that providers are required to submit the information separately or on paper, which complicates the claim submission substantially. Version 5010 includes an implementation note that states that the provider specialty information applies to the entire claim unless there are individual services where the provider specialty information differs. This feature eliminates redundant reporting. Version 4010/4010A contains redundant requirements for reporting a referring provider's medical specialty when a claim contains more than one service, and the referring provider specialty information differs for at least one of the services.

• Dental health care claims (837D).

We propose to revise § 162.1102 by adding a new paragraph (c)(2) that would replace the ASC X12N 837D Version 4010/4010A with the 837 Health Care Claim: Dental ASC X12 Technical Report Type 3 and Type 1 Errata for Health Care Claims or Equivalent Encounter Information for dental claims.

Certain services performed by dentists are considered to be medical services and are covered as medical benefits by insurance plans. In Version 4010/4010A, a dental claim cannot be processed as a medical claim because not all the required or situational information for a medical claim is included in the dental claim. In Version 5010 for dental claims, data requirements are closely aligned with the data requirements for medical claims, which supports coordinating benefits between dental and medical health plans.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 includes a designated location for treatment start and stop

dates for dental crowns or bridges, which health plans need to appropriately administer their dental benefits. Version 4010/4010A does not allow for this information to be reported.

• Version 5010 supports the reporting of specific tooth numbers with the International Tooth Numbering System (ITNS) code. Version 4010/4010A does not support this reporting, which makes submitting claims for dental services that may be covered under a medical plan complicated and burdensome. The services typically relate to wisdom teeth extraction and traumatic dental injuries, and are generally provided by oral and maxillofacial surgeons. Since these services often are covered by a medical benefit, they are reported on the 837 professional claim. Without support for the ITNS on the 837 professional claim, providers face denials, claim re-works and the manual submission of paper documentation to provide the tooth number information that is needed by plans to properly adjudicate claims and electronically conduct coordination of benefits. Version 5010 eliminates these cumbersome processes by providing a standardized field for reporting the ITNS code on claims that may be required to report certain dental services on an 837 professional claim, rather than the dental version.

• Version 5010 includes an enhancement that supports the reporting of an address for the place of treatment for dental claims. Version 4010/4010A does not support the recording of this information. The place of treatment is typically the dentist's address and it is needed by health plans for claims adjudication. The support for this information is available in Version 4010/4010A but only for institutional and professional claims.

• Version 5010 requires a first name only when the entity is a person, whereas Version 4010/4010A requires a first name even in instances when the entity is not a person. The deficiency in Version 4010/4010A means that, even if an organization or company is the subscriber for a workers' compensation claim, in which case there would be no first name, the submitter is still required to provide a first name.

Health Care Payment and Remittance Advice Transaction (835)—For All Claim Types

We propose to revise § 162.1602 by adding a new paragraph (c) that would replace the ASC X12N 835 Version 4010/4010A with the 835 Health Care Claim Payment/Advice ASC X12 Technical Report Type 3 for the Health Care Payment and Remittance Advice transaction. This would apply to all claim types, including retail pharmacy claims.

Many of the enhancements in Version 5010 involve the Front Matter section of the Technical Report Type 3, which contains expanded instructions for accurately processing a compliant 835 transaction. Version 5010 provides refined terminology for using a standard, and enhances the data content to promote clarity. The benefits of these refinements could include more accurate use of the standard, reduction of manual intervention and could motivate vendors and billing services to provide a more cost-effective solution for the submission and receipt of electronic remittance advice transactions.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 makes improvements to permit better use of remittance advice by tightening business rules and reducing the number of available code value options. Version 4010/4010A for remittance advice lacks standard definitions and procedures for translating remittance information and payments from various health plans to a provider which makes automatic remittance posting difficult.

• Version 5010 provides instructions for certain business situations where none had existed before. For example, Version 5010 instructs providers on how to negate a payment that may be incorrect and post a correction.

• Version 5010 for the 835 transaction does not affect the processing of Version 4010/4010A claim transactions. This compatibility with the earlier standard would permit implementers to begin testing Version 5010 for the 835 transaction before the compliance date, and, at the same time, continue to process 837 claims using Version 4010/4010A. This flexibility is important because there may be a transition period with claims for services rendered before the compliance date that will be in the older version of the standard because data elements required in Version 5010 might not have been captured at the time services were rendered.

• Version 5010 includes a new Medical Policy segment that provides more up-to-date information on payer policies and helps in detail management, appeals, and reduces telephone and written inquiries to payers. The new segment helps providers locate related published medical policies that are used to determine benefits by virtue of the addition of a segment for a payer's URL for easy access to a plan's medical policies. Version 4010/4010A does not provide the ability to include information or resources for policy-related payment reductions or omissions.

• Version 5010 eliminates codes marked ''Not Advised,'' but leaves the code representing ''debit'' as situational, with instructions on how and when to use the code. Version 4010/4010A contains codes marked ''Not Advised,'' which means that the guide recommends against using it, but does not prohibit its use. For example, in Version 4010/4010A, there are codes to indicate whether a payment is a debit or a credit, and the debit code is marked ''Not Advised'' because the transaction is a payment, and a credit code is expected instead. There is no use for the debit code, so the instruction ''Not Advised'' appears for that field.

• Version 5010 provides clear instructions for use of the claim status indicator codes. Version 4010/4010A includes status codes that indicate a primary, secondary, or tertiary claim, but no instructions for the use of these codes. This creates confusion when a claim is partially processed, or when a claim is processed but there is no payment.

Enrollment and Disenrollment in a Health Plan (834)

We propose to revise § 162.1502 by adding a new paragraph (c) that would replace the ASC X12N 834 Version 4010/4010A with the 834 Benefit Enrollment and Maintenance ASC X12 Technical Report Type 3 for the Enrollment and Disenrollment in a health plan transaction.

The most significant differences between Version 4010/4010A and Version 5010 for the enrollment and disenrollment in a health plan transaction is the addition of functionality in Version 5010 that did not exist in Version 4010/4010A. For example, Version 5010 can use ICD–10 diagnosis codes for reporting pre-existing conditions and additional ICD–10 disease classifications. This functionality was added in anticipation of the adoption of the ICD–10 code sets.

Other changes in Version 5010 that were added in response to requests for improvements to Version 4010/4010A include:

• Version 5010 adds the ability to designate certain information as confidential and restrict access to member information. This new function provides privacy protection by safeguarding confidential information.

• Version 5010 adds maintenance reason codes to explain coverage

changes. The new codes reflect changes in student status, age limitations, additional coverage information, life partner changes, termination due to non-payment, and other changes. This information is important for establishing coverage patterns and recording accurate information on coverage status.

• Version 5010 provides the ability to report enrollment subtotals by employees and dependents or grand totals, unlike Version 4010/4010A; although not a critical change, this is a feature of Version 5010 that facilitates use of the 834 transaction.

• Version 5010 eliminates date range confusion by adding fields for a ''start'' date and an ''end'' date. Version 4010/4010A lacks definitions and instructions for reporting date ranges that indicate coverage ''to'' a certain date, versus coverage ''through'' a certain date, and instructions as to when to send the dates of effectiveness for coverage changes. Without accurate coverage effectiveness and coverage change information, the administration of enrollment and disenrollment in a health plan becomes inefficient and cumbersome and frequently requires manual intervention, negating the benefits of electronic data interchange (EDI).

Health Plan Premium Payments (820).

We propose to revise § 162.1702 by adding a new paragraph (c) that would replace the ASC X12N 820 Version 4010/4010A with the 820 Payroll Deducted and Other Group Premium Payment for Insurance Products, ASC X12 Technical Report Type 3 for the Health Plan Premium Payments Transaction.

A deficiency in Version 4010/4010A is the inability for health plan sponsors to report additional deductions from payments. The addition of this data element is an important improvement in Version 5010 because it helps reduce confusion for health plans when payments are not the amount expected. Version 4010/4010A does not have a way to indicate the method used to deliver the remittance. Version 5010 includes an indicator for the delivery method, and options include file transfer, mail, and online. This permits trading partners to select and indicate the method that best meets their business needs.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 permits a health plan sponsor to adjust an entire transaction for a previous payment without tying it to an individual member record. Version 4010/4010A requires a health plan sponsor to link a transaction payment adjustment for a previous payment to an individual member record, creating extra work and additional administrative tasks.

• To eliminate confusion, Version 5010 changes the premium remittance detail information from ''situational'' to ''required,'' so that all entities must provide the specific data regarding premiums. In Version 4010/4010A, premium remittance detail information is situational and only required for HIPAA transactions. Plan sponsors always use the transaction for premium payments to health plans so the transaction is always a HIPAA transaction and, therefore, premium remittance detail information is always required.

Eligibility for a Health Plan (270/271).

We propose to revise § 162.1202 by adding a new paragraph (c)(2) that would replace the ASC X12N 270/271 Version 4010/4010A with the 270/271 Health Care Eligibility/Benefit Inquiry and Information Response ASC X12 Technical Report Type 3 for the Eligibility for a Health Plan Transaction. This transaction is used to determine eligibility for institutional, professional and dental services, and for eligibility and benefit inquiries between prescribers and Part D Plan Sponsors. (It is not used between pharmacies and health plans for a pharmacy's eligibility inquiries—that standard is an NCPDP standard, and its use is discussed in the section on Version D.0 later in this preamble.)

Version 4010/4010A does not require health plans to report relevant coverage information, for example, coverage effectiveness dates—health plans are only required to provide a response that coverage does exist. Version 5010 corrects this deficiency by requiring the payer to report specific coverage information (for example, the name of plan coverage, beginning effective date, benefit effective dates, and primary care provider (if available)). This additional information significantly improves the value of the transaction to the provider community.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• Version 5010 adds nine categories of benefits that must be reported if they are available to the patient. Some examples of those categories are pharmacy, vision, and mental health. Version 4010/4010A contains no requirement to report categories of benefits.

• Version 5010 adds 38 additional patient service type codes to the ones that are available in Version 4010/4010A. This expands the use of patient service type codes available to submit in an eligibility inquiry. The use of a more specific patient services type code enriches the data that is returned in the eligibility response, matching the information in the eligibility response to that in the eligibility inquiry.

• Version 5010 provides clearer instructions for describing subscriber and dependent relationships. Health plan subscriber and dependent relationships are unclear in Version 4010/4010A, creating ambiguity and confusion about when to use ''subscriber'' and when to use ''dependent'' when one of them is also the patient.

Referral Certification and Authorization (278).

We propose to revise § 162.1302 by adding a new paragraph (c)(2) that would replace the ASC X12N 278 Version 4010/4010A with the 278 Health Care Services Request for Review and Response ASC X12 Technical Report Type 3 and Type 1 Errata for the Referral Certification and Authorization transaction.

This transaction is not commonly used in the industry today because of the many implementation constraints of Version 4010/4010A. These constraints include the inability to report specific information on patient conditions (for example, mental status), functional limitations of the patient (for example, handicapped), and the specialty certifications of a provider. Version 4010/4010A also does not provide a way for the requestor to limit the number of occurrences of a service within a defined time frame (for example, limiting the number of visits to three within a ninety-day period). Version 5010 corrects these deficiencies.

Version 5010 includes the following additional improvements over Version 4010/4010A:

• Version 5010 includes rules and separate implementation segments for key patient conditions, including: ambulance certification information; chiropractic certification; durable medical equipment information; oxygen therapy certification information; patient functional limitation information; activities currently permitted for the patient information; and patient mental status information. Version 4010/4010A lacks differentiating rules for various conditions, making the standard cumbersome to use for both providers and health plans.

• Version 5010 supports or expands support for, a variety of business cases deemed important by the industry, including: Medical services reservations (permitting requesters to reserve a certain number of service visits within a defined period of time, for example, number of physical therapy visits); dental service detail (for tooth numbering and other dental related services); and ambulance transport requests to capture multiple address locations for multiple trips.

• Version 5010 supports or expands authorization exchanges, including requests for drug authorization procedure code modifiers and patient state of residence, which may be important from a coverage determination standpoint. Version 4010/4010A does not support authorizations for drugs and certain pharmaceuticals, and a number of other common authorization exchanges between covered entities.

Health Care Claim Status (276/277)

We propose to revise § 162.1402 by adding a new paragraph (c) that would replace the ASC X12N 276/277 Version 4010/4010A with the Health Care Claim Status Request and Response ASC X12 Technical Report Type 3 and Type 1 Errata for the Health Care Claim Status Transaction, for institutional, professional and dental claims.

One of the deficiencies of the Version 4010/4010A 276 inquiry is that it does not identify prescription numbers and the associated 277 response cannot identify which prescription numbers are paid or not paid at the claim level of the transaction. The ability to identify a prescription by the prescription number is important for pharmacy providers when identifying claims data in their systems. Version 5010 includes new functionality that allows for identification of prescription numbers and the associated response allows for identification of which prescription numbers are paid or not paid at the claim level.

Other changes in Version 5010 that were added in response to requests for improvements to Version 4010/4010A include:

• Version 5010 eliminates a number of requirements to report certain data elements which are considered sensitive personal information specific to a patient, and which are not necessary to process the transaction. The Version 4010/4010A requirements for the collection and reporting of sensitive patient health information have raised concerns about privacy and minimum necessary issues. For example, the Version 4010/4010A standard requires the subscriber's date of birth and insurance policy number, which often is a social security number. This information is not needed to identify the subscriber because the policy number recorded for the patient already uniquely identifies the subscriber.

• To reduce reliance on companion guides, and ensure consistency in the use of the Implementation Guides, situational rules that were ambiguous in Version 4010/4010A are clarified in Version 5010. For example, Version 4010/4010A contains a number of situational rules that are unclear and open to different interpretations. Based on industry requests for changes, the DSMO reviewed all of the 4010/4010A situational rules and revised each standard as appropriate to reduce multiple interpretations. For example, Version 5010 clarifies the relationships between dependents and subscribers, and makes a clear distinction between the term ''covered status'' (whether the particular service is covered under the benefit package) and ''covered beneficiary'' (the individual who is eligible for services). Since Version 4010/4010A does not provide clear rules for the interpretation of these terms, industry use of the fields is inconsistent, and subject to entity-specific determinations. An additional example of a clarification is the creation of a new section in the Version 5010 Referral Certification and Authorization transaction, where a separate segment was created to allow for the entry of information to clearly indicate that a patient's medical condition met certification requirements for ambulance or oxygen therapy. The creation of a specific section to capture such information eliminates the need to request or send that information later.

• Version 5010 implements consistent rules across all TR3s regarding the requirement to include both patient and subscriber information in the transaction. Some current implementation guides (Version 4010/4010A) require that subscriber information be sent even when the patient is a dependent of the subscriber and can be uniquely identified with an individual identification number, whereas other transactions (for example, eligibility for a health plan inquiry (270) and referral certification and authorization request (278)) permit sending only the patient dependent information if the patient has a unique member ID. These standards do not require the subscriber ID. The requirement to include the subscriber information with the dependent member information for a uniquely identifiable dependent is an administrative burden for the provider.

• Version 5010 provides clear instructions for users on how to use the transaction in either batch or real time mode. Version 4010/4010A does not provide any such guidance, which is needed by the industry.

Coordination of Benefits (COB)—(837)

We propose to revise § 162.1802 by adding new paragraphs (c)(2), (c)(3), and (c)(4) that would replace the ASC X12N 837 Version 4010/4010A implementation guides for the Coordination of Benefits (COB) Transaction, with Version 005010 Technical Report Type 3 and Type 1 Errata for institutional, professional and dental claims. COB is a claim function included in each of the individual named claim Type 3 Technical Reports (837I, 837P and 837D).

There are a number of deficiencies with Version 4010/4010A, including the lack of clear instructions for several important scenarios, including how to create a COB claim when the prior payer's remittance information came to the provider in a paper format and how a receiver can calculate a prior payer's allowed amount. Additional deficiencies that have made coordination of benefits transactions among payers difficult is the presence of statements such as ''if needed by a payer for adjudication'' and similar statements that have allowed for varying interpretations within the health care industry. These obstacles to successfully completing an electronic compliant COB transaction using Version 4010/4010A, and accepting and adjudicating COB transactions among a variety of payers, have been removed or significantly mitigated in Version 5010.

Other changes in Version 5010 that were added in response to industry requests for improvements to Version 4010/4010A include:

• A number of sections have been added or modified in Version 5010 to provide the broad-based instructions necessary to ensure a standard implementation of COB transactions, including instructions for balancing dollar amounts on a claim.

• The Front Matter section of Version 5010 includes an explanation of the destination payer's specific information (for example, claims data and provider identifiers that are needed for conducting COB).

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

We propose to revise § 162.1102, § 162.1202, § 162.1302, and § 162.1802 by adding new paragraphs (c)(1) to each of those sections to adopt the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) (hereinafter collectively referred to as Version D.0) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (hereinafter collectively referred to as Version 5.1), for the following retail pharmacy drug transactions: Health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits.

Since the adoption of Version 5.1 as a transaction standard in the Transactions and Code Sets rule, the industry has submitted requests to NCPDP for modifications to Version 5.1. These modification requests were for similar reasons as those for the X12 standards—changing business needs, many necessitated by the requirements of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

In NCVHS hearings held in July 2007, industry stakeholders cited business needs that would be addressed by the increased functionality in Version D.0 to include:

- *Enhanced guidance for Coordination of Benefits (COB).* In Version D.0, extensive clarification is made to the implementation guide for coordination of benefits processing. New data elements, for example, patient responsibility and benefit stage were added, along with a refined use of the Other Coverage Code field.
- *Processing of Medicare Part D claims.* Changes in Version D.0 include the addition of three new data elements and rejection codes.
- *Enhanced eligibility checking.* Version D.0 provides more complete eligibility information for Medicare Part D and other insurances.
- *Specific COB for Medicare Part D.* Version D.0 includes identification of patient responsibility, benefit stage, and coverage gaps on secondary claims.
- *Streamlined claims processing for compounded drugs.* In Version D.0, the compound segment has been modified to allow for the billing of multiple ingredients. To standardize this process, the two alternative ways of billing compounded claims have been removed.

As a result of the hearings, the NCVHS Subcommittee on Standards and Security determined that the business needs identified by the industry would be met by Version D.0. The NCVHS expressed its support for Version D.0, and recommended that it be proposed for adoption as a HIPAA transaction standard through rulemaking. Based on the comments from industry stakeholders (as discussed above), the NCVHS specifically referenced several of the improvements in Version D.0, including: The modified field and segment defined situations; resolution of the situational versus optional data requirements to accommodate the HIPAA privacy regulations; and segment usage matrices that clarify which segments and fields are sent for each transaction type, and segments and fields within each transaction type. It also cited the enhancements made to accommodate Medicare Part D, which include the addition of a ''facilitator'' entity and eligibility transaction to provide coded patient eligibility information for Medicare Part D and enhancements to identify and process Medicare Part D long term care claims. Enhancements with respect to Medicare Part B claims include additional segments for processing Medicare certificates of medical necessity, new data elements for processing those transactions, and assistance in the crossover of claims from Medicare to Medicaid. Finally, the NCVHS stated that Version D.0 also supports the following: COB and collection of rebates for compounded claims; clarification for pricing guidelines; the addition of new data elements that give more specificity to the COB process; a new section on prior authorization added to the implementation guide; a prescription/service reference number increase to 12 digits; and transaction codes for service billings.

Because we believe Version D.0 would better support the business needs of the industry, for the reasons cited by the NCVHS, we propose to adopt Version D.0. We solicit comments regarding the proposed adoption of Version D.0 as the HIPAA standard, set forth in proposed revisions to § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

*C. Proposed Adoption of a Standard for Medicaid Pharmacy Subrogation: NCPDP Medicaid Subrogation Implementation Guide, Version 3.0 for Pharmacy Claims*

We propose to add a new subpart S to 45 CFR part 162 to adopt a standard for the subrogation of pharmacy claims paid by Medicaid. The transaction would be the Medicaid Pharmacy Subrogation transaction, defined at proposed § 162.1901, and the new standard would be the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007 (hereinafter referred to as Version 3.0) at proposed § 162.1902. The standard would be applicable to Medicaid agencies in their role as health plans, but not to providers or health care clearinghouses because this transaction is not utilized by them. As a condition of Medicaid eligibility, an individual must assign to the State Medicaid agency his or her rights to payments for medical services from other liable third parties. This allows the Medicaid agency the right to stand in the place of the Medicaid recipient for the purpose of collecting reimbursement from liable third parties wherever the Medicaid agency has paid claims on behalf of a Medicaid recipient. This is referred to as ''Medicaid subrogation.''

Federal law requires, with some exceptions, that Medicaid be the payer of last resort. Health plans that are legally required to pay for health care services received by Medicaid recipients are to pay for services primary to Medicaid. However, Medicaid agencies sometimes pay claims for which a third party may be legally responsible. This can occur when the Medicaid agency is not aware of the existence of other coverage. There are also specific circumstances for which States are required by Federal law to pay claims and then seek reimbursement afterward. Whenever Medicaid pays claims for which another party is legally responsible, the State is required to seek recovery.

For the purpose of adopting a HIPAA standard, we propose to define a Medicaid pharmacy subrogation transaction as 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.

A majority of health plans use a pharmacy benefit manager (PBM) to manage prescription drug coverage and handle claims processing. Some health

plans administer the prescription coverage in-house, but contract with a claims processor to handle claims adjudication. A few of the large health plans perform their own claims processing. When PBMs process claims on behalf of health plans, they are considered to be business associates of the health plans. Section 162.923(c) requires a covered entity that chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, to require the business associate to comply with all applicable requirements of the HIPAA regulations. Therefore, while entities such as PBMs and claims processors do not necessarily have ultimate financial liability, to the extent they are required by contract or otherwise to process claims on behalf of health plans, they will need to be able to receive the Medicaid pharmacy subrogation transaction in the standard format.

There are many different formats utilized for submitting Medicaid pharmacy subrogation claims. To meet the many different requirements of the third party payers, States must maintain and utilize a variety of pharmacy billing formats. This is because different third party payers require different pieces of information. According to a study conducted by the Office of the Inspector General (OIG) entitled, *''Medicaid Recovery of Pharmacy Payments from Liable Third Parties''* (OEI–3–00–00030, August 2001, available at *http://oig.hhs.gov/oei/reports/oei-03-00-00030.pdf*), 29 States indicated that the lack of universal formatting and data elements on pharmacy claims leads to the denial of Medicaid claims, contributing to millions of dollars of lost revenue to Medicaid. States have had to work through numerous changes and challenges to submit claims that are correctly formatted for various health plans. When States' claims are denied for formatting or missing data, and have to be reworked and resubmitted; there is additional administrative and financial burden on States and third parties. According to the OIG study, some PBMs have reimbursed claims at a lower rate as a penalty for the claim being in the wrong format. In order to recover Medicaid funds, some States have found it necessary to recoup from the pharmacies and it is left up to the pharmacies to seek reimbursement from the third party payers.

In 1999, representatives from CMS and the Medicaid agencies began working closely with NCPDP to develop a standard electronic format that could be used to facilitate electronic transmission of pharmacy subrogation claims from Medicaid agencies to other payers. The standard combines a subset of elements from the NCPDP Version 5.1 drug claim standard with additional elements that Medicaid specifically needs to conduct subrogation, such as the Medicaid paid amount and the Medicaid agency identification number. The additional Medicaid-specific elements had to be placed in other NCPDP fields that were not discretely defined in Version 5.1. In June 2000, as a result of these collaborative efforts, NCPDP issued the Medicaid Subrogation Implementation Guide Version 2.0 for the Batch Standard.

At least two-thirds of the States utilize Version 2.0 voluntarily, many through the use of a business associate that bills pharmacy claims on the State's behalf. The States, or their business associates, use the NCPDP format with some modifications to accommodate the various other health plan requirements. There are at least ten major third party payers that have entered into an agreement with States and/or their business associates to accept the NCPDP format. However, the absence of full standardization now presents challenges for States, which must continue to maintain and use many billing formats.

We did not adopt a standard for Medicaid pharmacy subrogation at the time the first set of HIPAA transaction standards were adopted because it was not one of the specified transactions mandated in the law. However, we believe that, in light of the challenges noted above, deriving from the lack of full standardization, it is now appropriate to propose a standard for the Medicaid pharmacy subrogation transaction. Section 1173(a)(1)(B) of the Act authorizes the Secretary to adopt standards for any other financial and administrative transactions as deemed appropriate, consistent with the goals of improving the operation of the health care system and reducing administrative costs. We believe that adopting a standard for Medicaid pharmacy subrogation would facilitate electronic data interchange; thereby reducing administrative costs and improving the operations of the health care system by eliminating multiple formats and methods of performing this transaction.

We solicit comments regarding the proposed adoption of the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0 as the HIPAA standard for the Medicaid pharmacy subrogation transaction, and the proposed dates for compliance with the standard addressed in proposed § 162.1902.

*D. Proposed adoption of the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard D.0 and the Health Care Claim: Professional ASC X12 Technical Report Type 3 for Billing Retail Pharmacy Supplies and Services*

We propose to revise § 162.1102 to adopt both Version D.0 and the 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.

The Transactions and Code Sets rule adopted two transaction standards relating to the billing of retail pharmacy claims. Version 5.1 is required for the transmission of retail pharmacy drug claims, and the X12 837 for professional services and supplies. (§ 162.1102). The final rule, however, does not define what or who constitutes ''retail pharmacies'' and further, what a ''retail pharmacy drug claim'' is in the context of the NCPDP, Version 5.1 standard. The regulations also do not specify, define, or describe the items or services that are to be billed on the X12N 837P standard, only that the services are ''health care services.'' As a result, different interpretations of the regulations exist as to whether a ''retail pharmacy drug claim,'' which is to be billed using Version 5.1, includes claims only for drug products, for drug products and associated pharmacy services and supplies, or for drug products and any retail pharmacy services or supplies. CMS has interpreted the regulation as requiring that Version 5.1 be used only for drug products and that the X12N 837P be used for retail pharmacy services and supplies other than drug products.

Since publication of the Transactions and Code Sets rule, there has been ongoing debate in the industry about which is the appropriate standard for billing retail pharmacy supplies and professional services. Retail pharmacy supplies and professional services include syringes, applicators, inhalers and nebulizers, and home infusion IV supplies. These are often tied to a retail pharmacy claim for a prescription, such as insulin, ointments, and inhaler solutions. For example, a patient could get a prescription and/or refill for insulin and the syringes. Under the current rule, pharmacies are expected to submit the insulin claim in real-time, using the NCPDP standard, and get immediate benefit coverage and co-pay insurance information. However, they must bill the prescription for the syringes with the X12 standard, which

is typically a batch billing process so the pharmacist would not get immediate notification of coverage and co-pay insurance information. The transaction could be further complicated if the patient is prescribed consultation or Medication Therapy Management (MTM) services for the use and dosage of the insulin with the syringes. The issue of MTM is discussed later in this section.

At the time the Transactions and Code Sets rule was published, HHS' opinion that the NCPDP standard should be used for retail pharmacy and the X12 standard should be used for professional pharmacy claims was based on the inability of NCPDP to accommodate HCPCS codes that could be used to identify pharmacy procedures and services. The code set has since expanded, and Version 5.1 is now capable of accommodating the National Drug Codes (NDC) and the HCPCS codes to identify pharmacy procedures and services more accurately. In the Modifications rule (68 FR 8387), there was additional discussion regarding the complications of not allowing the use of NCPDP for pharmacy supplies and services, and there is significant discussion in that rule that supports the industry need to be able to use the NCPDP standard in place of the Version 4010 standard for these claims. Since publication of the Transactions and Code Sets rule and the Modifications rule, we have responded to substantial correspondence and provided guidance in a Frequently Asked Question (FAQ) clarifying that the NCPDP standard is to be used for billing retail pharmacy drug claims and that the X12 837 standard is to be used for billing retail pharmacy supplies and professional services. Nonetheless, there continues to be a lack of consensus in the industry regarding which standard to use for billing retail pharmacy supplies and professional services because of the disagreement as to what is a retail pharmacy drug claim. Some segments of the pharmacy industry interpret a retail pharmacy drug claim as one that could include pharmacy supplies and professional services, and therefore would permit the use of the NCPDP standard. Others believe that retail pharmacy drug claims do not include retail pharmacy supplies and professional services and, therefore, permit the X12 standard to be used. There are also entities that believe it is appropriate to use one or the other standard depending on whether the insurance benefit is medical, in which case X12 is used for retail pharmacy supplies and professional services, or whether it is a pharmacy benefit, in which case the NCPDP standard should be used. Whether the benefit is covered under medical or pharmacy is typically determined by the design of an employer's or health plan's benefit package. We also continue to receive input from the industry that it is common practice for pharmacies to use the NCPDP standard instead of the X12 standard because of the convenience and accuracy NCPDP provides for these services and claim types.

In 2006, the debate escalated due to implementation of the Medicare Part D Program under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). The MMA provides coverage for certain professional pharmacy services, referred to as Medication Therapy Management (MTM) services. MTM services are a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product. MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. Some pharmacies believe it is appropriate to use the NCPDP standard for MTM services because the service is part of a prescription. Other segments, notably the small independent pharmacies, believe it is appropriate to use the X12 standard because they interpret ''professional services'' to mean that a ''professional'' (837P) claim is required and their vendor software offers that capability.

The industry acknowledges advantages and disadvantages for use of both standards, and has provided evidence that both standards should be considered compliant and that the use of either would be appropriate under HIPAA. In August 2007, a national organization sent a letter to CMS in support of using the NCPDP for both retail pharmacy service and supply type claims. The letter explained that chain drug stores feel strongly that they should be able to bill using NCPDP 5.1. Entities supporting the use of NCPDP 5.1 make the argument that NCPDP 5.1 offers real-time adjudication of claims, whereas the X12 837P is a batch process. According to the National Association of Chain Drug Stores, pharmacies are not coding for the X12 837 transaction because it is too cumbersome. Instead, when forced to use this transaction, pharmacies must use an outside vendor or clearinghouse, even though it is an added expense because they already have the capability to exchange the same information in real time with NCPDP 5.1. On the other side of the discussion, the independent pharmacies argue that X12 837 is the appropriate standard for ''supplies and professional services'' as evidenced by the fact that they have purchased software from their national association to accommodate this standard. Further, they believe that the X12 837 is more robust in its support of the data elements needed to bill for MTM services.

After discussions with representatives of national organizations as well as the NCPDP, CMS posted an addendum to its Frequently Asked Question (FAQ) on the CMS website in October 2007. This FAQ now also includes the following: ''While CMS adheres to its foregoing interpretation of the regulations requiring that MTM retail pharmacy services be reported using the X12 837P standard, we recognize that a reasonable argument could be advanced in response to the Department seeking to enforce this regulation, contending that the regulations could be read to instead direct the use of the NCPDP, Version 5.1 standard for such services. We further realize that notice and comment rulemaking, which the Department anticipates initiating in the near future will resolve the apparent ambiguity of these regulatory provisions. In light of the foregoing planned rulemaking and the uncertain outcome of any enforcement action, we elect not to take enforcement action against those covered entities that continue to use the NCPDP, Version 5.1 standard for this transaction.''

The implementation guides for both adopted standards accommodate the transaction, including the use of the appropriate code sets, and neither guide states clearly which standard applies for billing retail pharmacy services and supplies. This is a unique situation—no other HIPAA transactions can be adequately supported by two implementation guides. Based upon the input we have received from the industry on the use of these standards, we believe that allowing for the use of either the NCPDP or ASC X12 standards would accommodate prevailing business practices, ensure efficiency, and prevent redundant costs. For example, a pharmacy provider would no longer need to bill two separate claims (that is, one for a drug, and a separate claim for the supplies associated with the drug's administration). Health plans already accept both transaction types, and have the systems in place to adjudicate the retail and professional claims using either transaction. Therefore we do not believe this will be

an additional burden to plans. We do not believe that the proposed approach would be disruptive to current industry practice, as we have stated, and we do not believe that there will be any negative impact on providers or consumers in accommodating this existing business process. Rather, we believe our proposed approach would be the least disruptive to the industry because it accommodates prevailing business practices and permits entities to use the standard that is most appropriate, efficient and accurate for processing certain kinds of pharmacy transactions. Furthermore, the NCPDP standard accommodates the billing of supplies and services as well, if not more effectively than the X12 standard, because it was designed by the industry, with a specific focus on the full set of requirements for all types of pharmacy transactions. Both Version D.0 and Version 5010 accommodate the billing of supplies and services. This is also consistent with NCVHS recommendations dated June 17, 2004.

We solicit comments on the proposal to adopt both the NCPDP standard and the X12 standard for billing retail pharmacy supplies and professional services.

*E. Modifications to the Descriptions of Standards*

We propose to revise the descriptions of the transactions at § 162.1301, § 162.1401, and § 162.1501 to more clearly specify the senders and receivers of those transactions.

In the Transactions and Code Sets rule, we identified eight health care transactions and adopted standards for each of them. Included in most of the descriptions of those transactions is a specification of ''to whom'' and ''from whom'' the transaction is transmitted. This specification enables covered entities to be able to determine more easily when they may be conducting transactions for which a HIPAA standard is adopted and, therefore, when they need to comply with the transaction standard. However, descriptions for three of the transactions do not specify the ''to'' and ''from'' criteria—that is, the sender and receiver are not identified. This lack of specificity creates confusion and uncertainty in the industry about when a particular electronic transmission meets the definition of a transaction. In addition, in 2003 the Secretary's Advisory Committee on Regulatory Reform recommended that we adopt ''to'' and ''from'' data submission requirements for all of the standard transactions. We wish to make our existing policies as clear as possible, and we use this proposed rule as the opportunity to do so.

In this proposed rule, we would revise descriptions for three of the standard transactions to ensure that ''to'' and ''from'' requirements are specified.

1. Enrollment and Disenrollment in a Health Plan Transaction

In § 162.1501, the text does not specify the sender of the transmission. We propose to clarify, by revising the regulation text, that 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. The Version 5010 Implementation Guide also defines the transaction this way: ''The 834 is used to transfer enrollment information from the sponsor of the insurance coverage, benefits, or policy to a payer.''

We note that when enrollment and disenrollment information is currently sent electronically from a sponsor to a health plan, a sponsor that is not otherwise a covered entity is not required to use the transaction standard because, as a non-covered entity, HIPAA does not apply to it. A sponsor is an employer that provides benefits to its employees, members or beneficiaries through contracted services. Numerous entity types act as sponsors in providing benefits, including, for example, unions, government agencies, and associations. While it is not mandatory for plan sponsors that are not covered entities to use the transaction standard, such an entity may nevertheless voluntarily use the standard or may contract with a health care clearinghouse to translate nonstandard data into a standard transaction on its behalf in order to take advantage of available efficiencies and cost saving opportunities through EDI.

2. Referral Certification and Authorization Transaction

In § 162.1301, the text does not indicate who the senders and receivers of the referral certification and authorization transactions are—it simply states that the transmission is a request or response. We therefore propose to clarify the senders and receivers by stating that the referral and certification authorization transaction is any of the following transmissions:

- A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.
- A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.
- A response from a health plan to a health care provider to a request described in the first or second bullet above.

3. Health Care Claim Status Transaction

In § 162.1401, the text does not indicate who the senders and receivers of the health care claim status transaction are—it simply states that the transmission is an inquiry or response. We therefore propose to clarify the parties to this transaction by stating that the health care claim status transaction is the transmission of either of the following:

- An inquiry from a health care provider to a health plan to determine the status of a health care claim, or
- A response from a health plan to a health care provider about the status of a health care claim.

*F. Proposed Compliance and Effective Dates*

We propose to revise § 162.900 to reflect that, for the Medicaid pharmacy subrogation transaction, all covered entities, except for small health plans, would be required to be in compliance no later than 24 months after the effective date of the final rule. Small health plans would have an additional 12 months for compliance. Willing trading partners would be able to agree to use the Medicaid subrogation standard voluntarily at any time after the effective date and before the compliance date. For example, covered entities that implement Version D.0 may choose to implement the Medicaid subrogation standard at the same time because such an action can be accommodated in the work flow.

CMS recognizes that transactions often require the participation of two covered entities, and when one covered entity is under a different set of compliance requirements, the second covered entity may be put in a difficult position. For the Medicaid subrogation of pharmacy claims transaction, small health plans would have an extra year to comply with the regulation. Therefore, if a Medicaid agency attempted to transmit Version 3.0 to a small health plan before the small health plan was required to be compliant, the small health plan could reject the transaction. This would require the Medicaid agency to use two versions of the transaction, or to use one compliant version, and one proprietary version, depending on the trading partner agreement with the small health plan for this interim period. We propose to resolve this problem of different

compliance dates by revising the language in § 162.923. Section 162.923, entitled ''Requirements for covered entities'' currently states, ''(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts with another covered entity (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.'' We propose to revise § 162.923 by making paragraph (a) applicable only to a covered entity that conducts transactions with another entity that is required to comply with the transaction standards. We believe that such a change would result in a less disruptive process by recognizing and resolving the difficult position covered entities may face when conducting transactions with trading partners who have different compliance deadlines. Accordingly, we would revise § 162.923 as follows: ''(a) *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.'' If we change § 162.923(a) in this way, a Medicaid agency, which would have a different compliance date than a small health plan with whom it is conducting the subrogation transaction, would not be required to conduct the transaction in the standard format until the date by which the small health plan must be in compliance with the standard.

We invite comments regarding the proposed compliance dates for our proposal to adopt the Medicaid pharmacy subrogation transaction standard. We further propose to revise section § 162.900 to remove the provisions related to the Administrative Simplification Compliance Act of 2001 (ASCA) Public Law 107–105.

The revised transactions descriptions would be effective on the effective date of the final rule.

NCVHS noted that, according to testimony, there were no expected implementation issues with Version D.0, but that implementation of Version 5010 would likely prove slightly more challenging because of the number of standards and the diversity of trading partners. However, because most covered entities will need to program for both Version 5010 and Version D.0, we believe that it is most practical to propose the same compliance dates for both. We propose that for Versions 5010 and D.0, health plans, including small health plans, health care clearinghouses and covered health care providers, be required to be compliant on and after April 1, 2010. We do not propose a 2-year time frame for compliance, as recommended by NCVHS, because we believe the industry has sufficient experience with implementation issues associated with the HIPAA standards to enable them to conduct their design/build activities, and schedule and perform testing within a 12-month period. Furthermore, the ability to implement and use the ICD–10 code set is contingent upon implementation of Version 5010. Since we anticipate timely publication of regulations to adopt the ICD–10 code set, we wish to give the industry sufficient time in which to effectively plan and implement the Version 5010 transaction standards. We anticipate the compliance date for ICD–10 to be in 2011. Presuming that, given this anticipated schedule, and in order to give the industry at least eighteen months of experience with Version 5010, the compliance date for those standards must be April 2010. We have not surveyed the industry broadly, other than the interviews conducted for the impact analysis, and while we acknowledge the logistical and implementation issues associated with the transition to Version 5010 and Version D.0, we maintain that the industry is capable of planning and designing the technical and operational infrastructure requirements in time for the proposed deadline. We believe that the benefits of the new versions, the potential for mitigating existing inefficient work arounds, and streamlining business processes will outweigh any benefits to be derived from a two-year compliance time frame recommended by the NCVHS. We specifically ask for industry comment on the timing and the costs of this proposed implementation schedule.

We also do not propose an additional year for small health plans to comply because we believe this allowance is unnecessary. Small health plans have had sufficient time to be compliant with the HIPAA transaction standards as well as the NPI, and to have made the appropriate investments in technology and infrastructure, as have their larger counterparts. The system and business process changes to accommodate Version 5010 and Version D.0 are not significant enough to warrant an additional year for those organizations that should now have sufficient experience with the standards.

We did consider, as an alternative, a proposal in which all health plans and all health care clearinghouses would be required to be compliant one year after the effective date, and covered health care providers would be required to be compliant 12 months later. In this way, providers would have ample time to test with their trading partners, and problems would be identified and resolved timely. We are not proposing the staggered compliance date option. Our discussion of the issues follows.

NCVHS testimony and subsequent industry input clearly support the adoption of Version 5010 for the affected X12 transactions and Version D.0 for the NCPDP transactions, but also confirm that it would be a significant undertaking for the industry, particularly in light of other potential Health IT initiatives such as migrating from the ICD–9 to ICD–10 code sets and implementing the new standards for claims attachments after that final rule is published.

The difficulties associated with implementation of the first set of HIPAA transaction standards and the National Provider Identifier (NPI) standard highlights the criticality of testing to ensure that transactions can be successfully exchanged between trading partners before the compliance date. The testing process is complex and time-consuming, especially for health plans and health care clearinghouses, which must test with very large numbers of trading partners. Historically, industry testing of the HIPAA standards has been concentrated at the very end of the compliance period, often resulting in insufficient time to identify and resolve all of the problems soon enough; this compression of the testing process has led to late identification of problems and has necessitated relief in the form of a flexible enforcement approach and contingency plans to avoid widespread noncompliance and cash flow disruption.

The July 2007 NCVHS letter, referenced earlier in this document, also recommended moving to a staggered compliance schedule for most of the standards proposed in this rule, which would require health plans and health care clearinghouses to be prepared for trading partner testing at the end of the first year of the implementation period, and to allow the second year to be used for testing. According to the NCVHS, this schedule would ensure that covered entities have ample time for communication, outreach, internal and external testing, corrective action, and

implementation. The NCVHS also recommended that CMS adopt certain levels of compliance for the standards. For example, Level 1 compliance would mean that the covered entity could demonstrate that it could create and receive compliant transactions. Level 2 compliance would demonstrate that covered entities had completed end-to-end testing with all of their partners.

Testing appears to be the key to successful timely implementation of standards. In fact, the NCVHS letter noted that testifiers emphasized that there was a need to test Version 5010 in real-life settings to ensure its interoperability and ability to support the transactions. Three types of testing needs were identified: (1) Testing of the standards for workability; (2) conformance testing of products and applications that send and/or receive the transactions; and (3) end-to-end testing to ensure interoperability among trading partners. NCVHS observed that, with the previous HIPAA transaction standards implementation, these three types of testing occurred unevenly, resulting in delays that could be minimized or avoided by staggering the various types of testing.

To accommodate an effective testing schedule, a variety of options for staggering the implementation of the Version 5010 and D.0 modifications were offered by testifiers to the NCVHS. There was a proposal to NCVHS that the compliance date for plans and clearinghouses could be a year before the date for providers in order to facilitate end-to-end testing. Alternatively, different compliance dates could be assigned to different transactions (for example, implement the claim and related transactions first). Testifiers at the July 30, 2007 hearings also attested to the importance of allowing dual processing (old plus new versions) for a sufficient period to allow end-to-end testing to occur.

Because of the importance of testing in achieving a smooth transition to the updated standards, we did consider proposing two different compliance dates for covered entities—a strategy in which health plans and health care clearinghouses would have to be compliant 1 year before covered health care providers to allow for adequate testing. However, such a proposal would shorten the overall implementation period for the entire industry and we believe it would present a number of other potential challenges to the industry.

First, a staggered implementation schedule would require all entities to use dual systems for the duration of the testing period, which could add to the cost of implementation, in part because plans and clearinghouses would have to implement a robust trading partner tracking system to know which providers were testing Version 5010, which were using Version 4010, and then, which successfully completed testing and had fully converted to Version 5010. Providers would have additional operational costs to manage their own testing and implementation schedule with plans and clearinghouses. The logistics could be complex, costly, and disruptive. Second, staggered compliance dates could impact plan-to-plan COB transactions because plans and providers would be implementing Version 5010 at different times. In order to conduct compliant Version 5010 transactions, all plans would have to be compliant at the same time, and all providers would have to be using Version 5010 as well, to take advantage of plan-to-plan COB. In addition, compliance in the case of a staggered implementation schedule would mean that, on the compliance date for plans and clearinghouses, those entities would have to be able to send and receive compliant transactions. However, it would be inappropriate to require plans and clearinghouses to reject noncompliant transactions received from providers during the one year period before providers would be required to be compliant, since the providers would not be required under this proposal to be able to conduct compliant transactions until the end of that period.

We believe we have the authority under the statute to propose different compliance dates for different entity groups, and we believe that exercising that authority could be in the interest of the industry to facilitate an orderly and effective transition to the use of the standards. However, for the reasons noted above, we are not proposing this approach. We are, however, interested in comments on the advantages and disadvantages of a staggered implementation schedule, specifically with respect to its effect on the testing process.

Although we are not proposing a staggered compliance schedule, we strongly encourage health plans and clearinghouses to begin to get their systems ready as early as possible, and providers to work with their trading partners to schedule testing timely as well. We also encourage clearinghouses and vendors to take advantage of the market opportunity to develop leading edge tools for implementing Version 5010, and support early testing for their provider clients. We note that NCVHS recognized the widespread use of compliance testing services, which allow entities to test products and applications to ensure they can create and accept compliant transactions. We agree that such services could simplify end-to-end testing by ensuring that individual products are compliant in advance. While HHS does not recognize or promote any specific organizations or tools for such services, we do support the use of such testing services for software and/or applications that would demonstrate a covered entity's ability to create, send, and receive compliant transactions.

We anticipate that upon publication of this proposed rule in the **Federal Register**, the industry will actively initiate and/or complete planning for implementation of Version 5010. While not included under the auspices of this proposed rule, we also acknowledge the impact of the implementation of the ICD–10 code set on the Version 5010 and Version D.0 implementation timelines. Once the Version 5010/Version D.0 and ICD–10 final rules are published, we estimate that the industry will begin documenting the requirements for the necessary system changes for each standard, initiate and/or complete any gap analyses, and then undertake design and system changes. The Version 5010/Version D.0 rule implementation would progress first, based on the need to have those updated standards in place prior to ICD–10 implementation in order to accommodate the increase in the size of the fields for the ICD–10 code sets. In the case of Version 5010 and Version D.0, system testing could commence approximately 8 months prior to a Version 5010 compliance date. We anticipate that ICD–10 testing could start shortly after the Version 5010 compliance date, and approximately one year prior to the October 2011 compliance date. Upon publication of these proposed rules for both Version 5010/Version D.0 and ICD–10 in the **Federal Register**, HHS, through CMS, plans on proactively conducting outreach and education activities, as well as engaging industry leaders and other stakeholder organizations to provide a variety of educational and communication programs to their respective constituencies. These activities would include roundtable conference calls with the industry, including Medicare contractors, fiscal intermediaries and carriers; health plans, clearinghouses, hospitals; physicians; pharmacies, other providers; and other stakeholders. CMS will also develop and make available ''Frequently Asked Questions'' on the website, fact

sheets, and other supporting education and outreach materials for partner dissemination. Other potential activities will be identified and developed based on stakeholder input.

The draft proposed timeline shown below is for preliminary planning purposes only, and represents our best estimate, given our current knowledge, of what an implementation timetable might look like. It is subject to revision as updated information becomes available.

DRAFT PROPOSED TIMELINE FOR ICD–10 AND VERSIONS 5010/D.0 IMPLEMENTATION

| ICD–10 | Version 5010/D.0 |
|---|---|
| 8/08: Publish proposed rule | 8/08: Publish proposed rule. |
| | 9/08: Industry begins requirements documentation for systems changes; CMS and industry initiate education and outreach. |
| 12/08: CMS and industry begin ongoing education and outreach. | |
| | 4/09: Industry builds and tests systems changes (internal and external testing). |
| 06/09: Industry begins design documentation. | |
| 12/09: Industry builds and internally tests systems changes. | |
| | 4/10: Compliance date for all covered entities. |
| 07/10–10/11: Conduct testing with trading partners. | |
| 10/11: ICD–10 compliance date for all covered entities. | |

We solicit industry and other stakeholder comments on our timeline assumptions and our proposed education and outreach strategy.

In sum, the challenges and difficulties encountered with previous standards implementation have informed the industry, which we believe now more meaningfully appreciates the benefits of collaboration, communication, and coordinated testing in making a substantial difference in successful implementation. Furthermore, we believe the industry is eager to move forward with Versions 5010 and D.0, and an aggressive timetable will be the right incentive to move the industry to proactive action and collaboration. We invite public comment on our proposed compliance dates.

## III. Collection of Information Requirements

The burden associated with the information collection requirements contained in § 162.1102, § 162.1202, § 162.1301, § 162.1302, § 162.1401, § 162.1402, § 162.1501, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 of this document are subject to the PRA; however, these information collection requirements are currently approved under OMB control number 0938–0866. This package will be revised to incorporate any proposed additional transaction standards and proposed modifications to transaction standards not currently captured in the PRA package associated with OMB approval number 0938–0866.

## IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## V. Regulatory Impact Analysis

### *A. Overall Impact*

We have examined the proposed impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258 (February 26, 2002) and further amended by Executive Order 13422 (January 18, 2007), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as further amended) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This proposed rule is anticipated to have an annual benefit on the economy of $100 million or more, and would have economically significant effects, making it a major rule under the Executive Order and the Congressional Review Act. We believe that covered entities have already largely invested in the hardware, software and connectivity necessary to conduct the new version of the standards, and the new standard proposed. We anticipate that the adoption of these new versions and the new standard would result in costs that would be outweighed by the benefits. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the proposed rulemaking.

### *B. Regulatory Flexibility Analysis*

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, a small entity is one with between $6.5 million and $31.5 million in annual revenues or is a nonprofit organization. For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and

States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of the proposed regulation, and where we had difficulty, or were unable to find information, we solicit industry comment. We believe that the conversion to Versions 5010 and D.0 would have an impact on virtually every health care entity, since at least some personnel in every covered entity would have to adjust to certain new business rules and procedures to accommodate the improvements in the data available from the transactions.

In our analysis, we combine Versions 5010 and D.0 because these two standards would be implemented at the same time, and in some cases are dependent on each other. For example, a health plan may use Version 5010 to send a remittance advice notification to a pharmacy, even though the pharmacy has used Version D.0 to submit its claim. This means that both the health plan and the pharmacy will have to implement both Version 5010 and Version D.0 in order to effectively exchange transactions. Similarly, a pharmacy may use Version 5010 to bill for supplies (for example, syringes), yet use Version D.0 for the retail pharmacy service of the insulin. The pharmacy will have to implement both Versions 5010 and D.0.

Table 27a in the impact analysis presents the implementation costs of Versions 5010, D.0 and 3.0 on all entities we anticipate would be affected by the rule. The data in that table are used in this analysis to provide cost information.

Because most health care providers are either nonprofit or meet the SBA's size standard for small business, we treat all health care providers as small entities. For providers, the changes may be minimal involving no more than a software upgrade for practice management and billing systems. Thus, we expect that the vast majority of physicians and practitioners will need to make relatively small changes in their systems and in their processes. We include pharmacies in this analysis, and consider some of them to be small businesses, and they are thus represented in our tables and the accompanying narrative. A number of health plans are considered small businesses, but we were unable to identify data for these entities, and therefore solicit industry feedback to complete this analysis for the final rule. We address clearinghouses and Pharmacy Benefit Managers (PBMs) in our discussion, but we do not believe that there are a significant number of clearinghouses that would be considered small entities because of the consolidation that has been occurring in the marketplace over the past 5 years. This was confirmed by a number of associations, including the Maryland Commission for Health Care. PBMs are excluded from the analysis because we have no data to indicate that they would qualify as a small entity. For example, as of 2006, the top four PBMs in the country accounted for about 75 percent of the prescription market, and of the top 10 PBMs, the largest showed revenues of more than $35 billion, with the smallest having revenues of $75 million (*http://www.managedcaremag.com/archives/0609/0609.pbms.html*). We invite comment and data from the industry regarding our assumptions.

State Medicaid agencies are excluded from this analysis because they have annual estimated revenues that exceed the small entity threshold of $31.5 million under the regulatory flexibility analysis guidelines. Furthermore, States are not considered small entities in any Regulatory Flexibility Analysis.

Initial Regulatory Flexibility Analysis (IRFA)

1. Number of Small Entities

In total, we estimate that there are more than 300,000 health care organizations that may be considered small entities either because of their nonprofit status or because of their revenues. On the provider side, practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $6.5 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*) lists 97 billing companies on its web site. It notes that these are only ones with Web sites.

The Business Census data shows that there are 4,786 firms considered as health plans and/or payers (NAICS code 5415) responsible for conducting transactions with health care providers. In the proposed rule's impact analysis, we use a smaller figure based on a report from AHIP. But for purposes of the RFA, we did not identify a subset of small plans, and instead solicit industry comment as to the percentage of plans that would be considered small entities.

We identified the top 78 clearinghouses/vendors in the Faulkner and Gray health data directory from 2000—the last year this document was produced. Health care clearinghouses provide transaction processing and translation services to both providers and health plans.

We identified nearly 60,000 pharmacies, using the National Association of Chain Drug Stores Industry Profile (2007, *http://www.nacds.org*), and for the purposes of the initial regulatory flexibility analysis we are proposing to treat all independent pharmacies reported in the Industry Profile as ''small entities.'' The number of independent pharmacies reported for 2006 is approximately 17,000 entities. We specifically invite comments on the number of small pharmacies.

Based on Figure 2 of the Industry Profile, independent pharmacy prescription drug sales account for 17.4 percent of total pharmacy drug sales of $249 billion sales for 2006. Allocating the 5010 and D.0 costs based on the share of prescription drug revenues to independent pharmacies (the small businesses), implementation costs are expected to range between $7.06 and $13.7 or 0.00 and 0.03 percent of revenues. These figures indicate that there is minimal impact, and the affect falls well below the HHS threshold, referred to at the beginning of this section.

2. Costs for Small Entities

To determine the impact on health care providers we used Business Census data on the number establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each NAICS code. Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For other providers, we assumed that the costs to implement the 5010 would be accounted for at the level of firms rather than at the individual establishments. Therefore, we reported the number of firms for all other providers.

Since we are treating all health care providers as small entities for the purpose of the initial regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for provider type. Table 1 shows the impact of the Version 5010 implementation costs as a percent of the provider revenues. For example, dentists, with

reported 2005 revenues of $87.4 billion and costs ranging from $299 million to $598 million have the largest impact on their revenues of between $0.19 percent and 0.39 percent. We are soliciting comments specifically on the number of providers affected by the proposed rule and information that will help us in our analysis of the burden on providers.

We do not include an analysis of the impact on small health plans here, because we were not able to determine the number of plans that meet the SBA size standard of $6.5 million in annual receipts.

In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the number of clearinghouses that would be considered small entities was negligible. Revenues cited on the Cooperative Exchange Web site (*www.cooperative exchange.org/faq.html*) divided clearinghouses into three revenue categories—small ($10 million); medium ($10 million to $50 million) and large ($50 million or greater). We identified the top 78 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare etc., none of which fit into the category of small entity. Finally, we contacted industry experts who have also been trying to gather revenue data from the industry without success. As referenced earlier, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. We determined that even based on this data, few of the entities would fall into the small entity category, and we do not count them in this analysis.

With respect to Version 3.0, we point out that while we do not know how many health plans/payers will exchange the subrogation standard with Medicaid agencies, those entities would be counted in the health plan category and addressed under the analysis for Version 5010 and D.0. We do not provide a separate analysis here.

In sum, we assumed that the financial burden would be equal to or less than three percent of revenues. HHS policy states that if a rule imposes a burden equal to or greater than three percent of a firm's revenues, it is significant (see: ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services'' at *http://www.hhs.gov/execsec/smallbus.html*). Based on the results of this analysis, we are reasonably confident that the rule will not have a significant impact on a substantial number of small entities. Nevertheless, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the standards proposed in this notice.

Table 2 below summarizes the impact of the rule on the health care industry.

TABLE 2—ANALYSIS OF IMPLEMENTATION OF THE BURDEN OF VERSIONS 5010, D.0 AND 3.0 ON SMALL COVERED ENTITIES

| NAICS | Entities | Total Number of entities | Small entities | Revenue or Receipts ($ millions) | Small entity receipts of total receipts (in percent) | Version 5010/ D.0 annual costs (in millions) | Small entity share of version 5010/ D.0 Costs (in millions $) | Implementation cost revenue-receipts (in percent) |
|---|---|---|---|---|---|---|---|---|
| 6221 | General Acute Care Hospitals (establishments). | 5,386 | 5,386 | 612,245 | 100 | $536–$1,072 | | 0.09–0.18 |
| 6211 | Physicians (firms) | 189,562 | 189,562 | 330,889 | 100 | 250–501 | | 0.08–0.15 |
| 6212 | Dentists (firms) | 118,163 | 118,163 | 87,405 | 100 | 172–344 | | 0.19–0.39 |
| 44611 | Pharmacies (includes 5010 and D.0) | 56,946 | 17,482 | 249,000 | 17.4 | 49–96 | 7.1–13.7 | 0.02–0.03 |

In column 1 we display the NAICS code for class of entity. Column 2 shows the number of entities that are reported in the Business Census for 2006 or ''Chain Pharmacy Industry Profile.''

Column 3 shows the number of small entities that were computed based the Business Census and Survey of Annual Service when the data was available. All health care providers were assumed to be small. We assumed that all independent pharmacies reported in Table 2 of the Industry profile are small entities.

Column 4 shows revenues that were reported for 2005 in the Survey of Annual Services, or in the case of pharmacies, in Figure 2 of the Industry profile. In the case of health plans and third party administrators, we used the consumer payments reported for private health insurance in 2006 in the National Health Expenditure accounts.

Column 5 shows the percent of small entity revenues.

Column 6 shows the implementation costs for Version 5010, D.0 and 3.0 taken from Table 27a of the impact analysis.

Column 7 shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues.

Column 8 presents the percent of the small entity share of implementation costs as a percent of the small entity revenues. As stated in the guidance cited earlier in this section, HHS has established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold.

We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities listed above, which is below the threshold the Department considers as a significant economic impact. As expressed in the Department guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus based on the foregoing analysis, we conclude that some health care providers may encounter significant burdens in the course of converting to the modified Versions 5010 and D.0. However, we are of the opinion that, for most providers, health plans, and clearinghouses the costs will not be significant.

3. Alternatives Considered

As stated in section V.D of this proposed rule, we considered various policy alternatives to adopting Versions 5010, D.0 and 3.0. For Version 5010, one alternative considered was that we not adopt the modifications, but allow the industry to continue using the current versions. This would not have been an appropriate solution because it does

nothing to address the existing shortcomings of the current versions, such as issues with inconsistent instructions, situational rules that preclude the full benefits of standardization for the industry, limited eligibility and secondary payer information, and continued reliance on companion guides from health plans. The existing shortcomings of the currently adopted standards continue to impact the industries' ability to meet evolving business needs and advanced technology.

We considered a number of options for implementing a staggered transition to Version 5010—phasing in the implementation of the new standards by covered entity type. For example, clearinghouses and health plans would modify their systems first, followed by providers. We rejected this option as being too costly and too burdensome. This option would require clearinghouses and health plans, which are largely national, covering multiple states, to maintain and operate both Version 4010/4010A and Version 5010. Programmers would have to accommodate the new standards, but maintain programs for the older version. This could increase the likelihood of errors in payments and incorrect eligibility information, and could create confusion and uncertainty for providers. It is likely that there would be delays in claims processing. We believe the cost of maintaining two systems concurrently would impose a very significant burden on health plans, providers, and clearinghouses.

Another alternative considered and rejected was to delay implementation for small entities. However, because we treat all health care providers as small entities, we did not see any benefit to be gained from delaying implementation of Version 5010 beyond the 18 month implementation period being proposed in the rule, and therefore rejected this alternative.

A final alternative considered was waiting and adopting later versions of the X12 standards. In large part, this is not a feasible option since the adoption of Version 5010 is critical to the use of ICD–10. Given our expectation that use of the ICD–10 code set will be mandated in the next few years, the industry must have experience using Version 5010 in order to effectively implement ICD–10. We recognize that other relevant Federal Rules, current or future, may overlap and/or affect this proposed rule. We do not believe that this proposed rule conflicts with the expected ICD–10 rule, but rather supports the industry's ability to implement that code set in a more timely fashion.

We considered various alternatives to adopting NCPDP Version D.0. One alternative that was considered but not proposed was to do nothing and keep the current Version 5.1 as a HIPAA transaction standard. This option, however, would not support the health care industry's needs for better and enhanced claims information. If the Department continues to require Version 5.1, the enhancements that were made in Version D.0 to improve Part D eligibility and claims processing would put those who rely on this information at a disadvantage.

Another alternative we considered was to stagger the implementation dates for the Version D.0 among the entities that utilize the affected NCPC transaction. This alternative is not feasible since pharmacies, PBMs, and health plans all rely on the information transmitted though the NCPDP transaction. If any one of these three entities is not using the same NCPDP version at the same time, the information needed to process claims and check eligibility would be deficient. Pharmacies need the most current eligibility data from the plans to determine correct coverage and payment information. Plans and PBMs would suffer because they would not have the most current information reflected though the claims data to maintain the beneficiaries' most current benefits.

We considered a number of alternatives to proposing the adoption of the NCPDP 3.0 Medicaid pharmacy subrogation standard. We considered not adopting the standard, which would allow the industry to continue using Version 2.0 or other proprietary electronic and paper formats. This option would mean that the Medicaid plans would have to continue to support multiple formats in order to bill pharmacy claims to third party payers. The current multiplicity of claim formats creates a significant barrier to Medicaid agencies being able to comply with Federal law in ensuring that Medicaid is the payer of last resort.

We also considered adopting the Version 2.0 standard which would require a number of workarounds to be compatible with Version D.0 or other NCPDP claim standards (except for NCPDP, Version 5.1). The NCPDP testified to the NCVHS in January 2008 that adopting Version 3.0 for Medicaid subrogation is a cost-saving tool and will improve the efficiency of those already using Version 2.0. The NCPDP testified that adopting Version 3.0 will make it more feasible for states and payers to invest in system upgrades to accommodate one specific standard. The NCVHS did not recommend any viable alternatives to Version 3.0 for handling Medicaid subrogation transactions because it believes that Version 3.0 adequately addresses the business needs of Medicaid agencies and industry partners.

4. Conclusion

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, we could certify that this proposed regulation would not have a significant economic impact on a substantial number of small entities. However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they are considered covered entities under HIPAA and must comply with the regulations; however, we do not believe the rule would have a significant impact on those entities, for the reasons stated above in reference to small businesses. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately $130 million. This proposed rule contains proposed mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, in excess of the current

threshold. This impact analysis addresses these impacts both qualitatively and quantitatively. In general, each State Medicaid Agency and other government entity that is considered a covered entity would be required to invest in software, testing and training to accommodate the adoption of the modified versions of the standards, and the new standard. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would have a substantial direct effect on State or local governments, could preempt State law, or otherwise have a Federalism implication because even though State Medicaid agencies would be converting to a modified version of an existing standard (Version 4010/4010A to Version 5010 and NCPCP 5.1 to NCPDP D.0) with which they are already familiar, there are expenses for implementation and wide-scale testing. State Medicaid agencies are currently required to conduct pharmacy subrogation, and in accordance with this proposed rule, would be able to use either the new Medicaid pharmacy subrogation standard or contract with trading partners and/or contractors who specialize in this field to fulfill its subrogation requirement, but there would still be some level of implementation costs to bear. With respect to subrogation for pharmacy claims, we note that this proposed rule would not add a new business requirement for States, but rather would mandate a standard to use for this purpose which would be used consistently by all States. There will also be expenditures for States as they convert from Version 5.1 to D.0 for other pharmacy transactions, and this transition will have implementation and testing costs as well, meaning there will be additional fiscal impacts on States based on this rule.

*C. Anticipated Effects*

The objective of this regulatory impact analysis is to summarize the costs and benefits of the following proposals:

- Migrating from Version 4010/4010A to Version 5010 in the context of the current health care environment;
- Migrating from Version 5.1 to Version D.0; and
- Adopting a new standard for the Medicaid subrogation transaction.

We assume for purposes of this analysis that maintaining existing practices with respect to claims submissions for retail pharmacy supplies and services (as discussed in section II.D above) would have no impact on the industry.

The remainder of this section provides details supporting the cost benefit analysis for each of the three above-referenced proposals.

1. Adoption of Version 5010

This portion of the analysis is based on industry research conducted for us by Gartner, Incorporated (Gartner) to assess the costs and benefits associated with the adoption of Version 5010. As part of this endeavor, Gartner worked with us to establish a segmentation strategy to identify the individual segments across the full spectrum of health care that would be affected by the proposed migration to Version 5010. These segments were identified:

Providers

- Hospitals
- Physicians
- Dentists
- Pharmacies

Health Plans

- Commercial Health Plans and Blue Cross/Blue Shield Plans
- Government Plans: Medicare and Medicaid

Clearinghouses and Vendors

- Clearinghouses
- Vendors

Based on this segmentation, Gartner identified and interviewed select credible individuals with representative perspectives. These individuals addressed both the business and technical areas for their respective organizations or associations, and were capable of understanding and articulating the potential cost-benefit of changes to their existing systems and processes. In addition to these interviews, Gartner conducted research to complement the existing data on the current state of HIPAA transactions. This research included dialog and data collection from leading associations and other stakeholder constituencies that represented one or more of the segments identified. We note that we did not interview any ''non-hospital'' institutions, but made the assumption that skilled nursing facilities (SNFs) and other types of organizations may be affiliated with some of the larger hospital systems, which were included in the analysis. Furthermore, we have not broken the data out to reflect any particular sub-segment of the industry, other than hospitals, physicians, dentists and pharmacies. The benefits were based on the total number of all claims throughout the health care system, including non-hospital institutions. We believe that while not all possible organization types were interviewed, the assumptions and findings can be extrapolated to provide fair insight into the financial impacts across the industry. This applies to any federal agency that must comply with the rule; these entities will have similar costs and benefits to their private sector cohorts. We invite public comment and cost or benefit data to support any concerns about the accuracy or consistency in our assumptions and estimates, particularly related to non-hospital institutions.

Throughout this process, Gartner constructed a cost-benefit model that synthesized the findings from the interviews as well as the inputs from the secondary research. This model was developed to estimate the net impact of implementing Version 5010 across the entire health care spectrum inclusive of all of the individual segments. When the model was completed, Gartner conducted a series of internal quality assurance steps, a sensitivity analysis, and peer review to properly validate the results.

Affected Entities

All HIPAA covered entities would be affected by this proposed rule. Covered entities include all health plans, all health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. We note that health care providers may choose not to conduct transactions electronically. Therefore, they would be required to use these standards only for transactions that they conduct electronically. See the Transactions and Code Sets rule for a discussion of affected entities (65 FR 50361).

Covered entities would incur a number of one-time costs to implement Version 5010. These costs would include analysis of business flow changes, software procurement or

customized software development, integration of new software into existing provider/vendor systems, staff training, collection of new data, testing, and transition processes. Systems implementation costs would account for most of the costs, with system testing alone accounting for 60 to 70 percent of costs for all covered entities. Ongoing operational costs are expected to initially grow as transmissions increase, but would result in lower costs per transaction as higher volumes are handled. The costs would be offset by the benefits of increased Electronic Data Interchange (EDI) and operational savings.

Through the interview process, Gartner estimated the cost of implementing Version 5010 by establishing an estimated baseline cost for implementing Version 4010/4010A for each individual entity. Subsequently, it determined the comparative costs for Version 5010 as a percentage of the total estimated Version 4010/4010A costs. Since the costs of implementing Version 4010/4010A are now more quantifiable, this methodology provided the most reliable means of estimating the Version 5010 costs. Most sources agreed that Version 5010 costs would represent 20 to 40 percent of the total cost of implementing Version 4010/4010A. This is because the Version 4010/4010A implementation represented a shift to completely new standards, while Version 5010 is a less complex move from one version of a standard to another. Most start up investments, such as hardware procurement made during the Version 4010/4010A implementation, would not need to be repeated for Version 5010. The estimated total cost for implementing Version 4010/4010A during its 2 year implementation period for each segment is: $4,661 million for hospitals; $2,175 million for physicians; $1,493 million for dentists; $336 million for pharmacies; $18,021 million for private plans/health plans: $1,202 million for government plans and $125 million for clearinghouses. In calculating the minimum and maximum costs for implementing Version 5010, the 20 and 40 percent ranges have been applied to each of the minimum and maximum estimates for implementing Version 4010/4010A, except for pharmacies. In analyzing cost projections for the pharmacy industry, we use an estimate of 20 percent because, as will be explained below, some portion of the implementation costs would be addressed by the pharmacy efforts to comply with Version D.0.

The current limitations of Version 4010/4010A and anticipated benefits of Version 5010 are discussed in detail in Section II.A. This cost benefit analysis considers those anticipated benefits in analyzing how affected entities would convert to key financial and business advantages, including:

- Lower transaction costs resulting from movement from paper to electronic transactions and;
- Reduction in staff resource time resulting from a decrease in phone calls to check eligibility and claim status and obtain referral authorizations via electronic transactions that provide the same information;

Gartner estimated the benefits of implementing Version 5010 by identifying three specific categories of savings: (1) Savings due to better standards for electronic claims transactions; (2) cost savings due to an increase in use of the electronic *claims transactions* by more covered entities; and (3) operational savings due to increased use of electronic auxiliary transactions by more covered entities. We refer to auxiliary transactions as those non-claims electronic transactions such as eligibility and referral requests and responses. The savings categories are further described as follows:

- Savings due to better standards—increased use of the electronic claims transactions resulting in a decreased need for manual intervention
- Cost Savings—increased use of claims related electronic transactions by entities that had not used them before (remittance advice, claims status)
- Operational Savings—increased use of auxiliary, non-claims electronic transactions by entities that had not used them before (eligibility requests and responses).

Each savings category is explained in more detail in the assumptions section below and we encourage readers to refer back to this assumptions section during the review of the cost benefit analysis.

All financial analysis is calculated over a 10-year planning horizon, including an assumption that there would be a 2-year implementation period. System implementation costs are assumed to be incurred over that 2-year implementation period and are distributed evenly in our analysis. Benefits are assumed not to be realized until post-implementation, in 3 to 10 years.

Assumptions for Version 5010 Impact Analysis

In calculating the costs and benefits, Gartner made a number of assumptions, based on interview data and secondary research. The interviews provided information that was used to reflect the size of the industry segments, the segment implementation costs, and the application of benefits and savings. We provide those assumptions and estimates here for reference throughout this portion of the impact analysis. We are specifically soliciting comments on the assumptions related to costs and benefits, as they are presented in this section of the proposed rule.

In Table 2 below, we show the projected annual claims volumes for providers over a ten-year period. Gartner projected the annual increase in the number of claims at four percent, and used the base from the estimates that were identified in the Claims Attachments proposed rule. These figures are used as a base to calculate the provider benefits.

TABLE 2—ANNUAL CLAIM VOLUME PROJECTIONS (IN MILLIONS)

| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 |
|---|---|---|---|---|---|---|---|---|---|---|
| Physician (low) | 3,186 | 3,313 | 3,446 | 3,583 | 3,727 | 3,876 | 4,031 | 4,192 | 4,360 | 4,534 |
| Physician (high) | 4,142 | 4,307 | 4,480 | 4,659 | 4,845 | 5,039 | 5,241 | 5,450 | 5,668 | 5,895 |
| Hospital (low) | 796 | 828 | 861 | 896 | 932 | 969 | 1,008 | 1,048 | 1,090 | 1,134 |
| Hospital (high) | 1,036 | 1,077 | 1,121 | 1,165 | 1,212 | 1,260 | 1,311 | 1,363 | 1,418 | 1,475 |
| Dentist (low) | 540 | 561 | 584 | 607 | 631 | 657 | 683 | 710 | 738 | 768 |
| Dentist (high) | 660 | 686 | 713 | 742 | 772 | 802 | 834 | 868 | 903 | 939 |
| Total claims (low) | 4,552 | 4,702 | 4,891 | 5,086 | 5,290 | 5,501 | 5,721 | 5,950 | 2,264 | 6,607 |
| Total claims (high) | 5,837 | 6,071 | 6,314 | 6,566 | 6,829 | 7,102 | 7,386 | 7,681 | 7,989 | 8,309 |

Table 3 below reflects the estimated current adoption rate for each of the HIPAA standards, and the projected rate of adoption for each of the modified versions of the standards over the 10-year planning horizon. For the enrollment (834) and payroll deducted and other group premium payment (820) standards, we assume utilization would apply only to health plans since providers do not use either of these two standards. We assume that acceptance rates would gradually increase in the first 5 years after implementation, through 2016, and after that time would remain level.

TABLE 3—CURRENT AND PROJECTED RATES OF USE FOR HIPAA STANDARDS ACROSS ALL COVERED ENTITIES—OVER 10 YEARS [IN PERCENT]

| Standard | Current Acceptance | Increase (minimum) | Increase (maximum) |
|---|---|---|---|
| 837—claims | 75 | 2 | 5 |
| 835—remittance advice | 60 | 5 | 10 |
| 278—referral request & response | **0 | 10 | 20 |
| 276/277—claims status request & response | 10 | 10 | 20 |
| 270/271—eligibility request and response | 10 | 10 | 20 |
| 834—enrollment/disenrollment | 3 | 0 | 0 |
| 820—premium | 2 | 0 | 0 |

Source: Gartner interviews and secondary research.
** Minimal use—while there is not quite zero percent uptake, the use of this transaction is so minimal, it does not register on any scale; therefore, we state its current acceptance rate as negligible.

General Assumptions for the Cost-Benefit Analysis for Providers and Health Plans

For the cost benefit analysis for each of the provider segments—hospitals, physicians, pharmacies, and dentists as well as the health plans, we apply the following set of assumptions, which are listed below. (These assumptions will not be repeated in each individual section of the impact analysis to follow.) Benefits that would accrue to each provider segment include:

- All providers currently using 835/837 messages would accrue benefits in the way of savings (for example, through reduced phone calls).
- Physicians that have not yet implemented 835/837 would accrue future savings through lower transaction costs for these electronic exchanges.
- An expected uptake of between 2–5 percent in the first five years following implementation, for all providers implementing 837 transactions (for example, 75 percent in 2010; 77 percent in 2015).
- An expected uptake of between 5–10 percent over ten years for all providers for 835 transactions.
- Costs and benefits for the Coordination of Benefit transaction (COB) are included in the estimates for the 837 claim standard transaction and are not broken out separately.
- Providers would benefit from fewer phone calls to health plans to check eligibility or claims status for auxiliary transactions (270/271, 276/277, 278).
- An expected increase in the usage of auxiliary transactions across the entire provider community and new adopters would see net benefits that would compound the aforementioned benefits as adopters utilize EDI more often.

The operational savings would result from reductions in manual efforts, particularly phone calls that must be made to resolve issues with a transaction that is manual today, such as a claim status or eligibility check. Each phone call avoided for a claim transaction is estimated to save 10 minutes of time for a provider's staff member, and each required manual intervention avoided is estimated to save 5 minutes of time. The following are estimates of the potential volume of avoided phone calls for providers:

- 835—A reduction in phone calls between 1.45 percent and 2.90 percent as a percentage of pended claims. This would equate to millions of phone calls for providers in the first year with increasing amounts in subsequent years as claim volumes increase.
- 837—A reduction in phone calls between 0.28 percent and 0.70 as a percentage of pended claims. This also would equate to millions fewer phone calls for all providers.
- For all other transactions, the current call volume would be reduced proportional to their total transaction volume. Because of the smaller volumes for these transactions, the additional savings was deemed to be too small for inclusion into the overall model.

Cost savings from reduced phone calls were estimated based on annual loaded compensation for plan or provider staff members (customer service, claims or billing) at $40,000 and billing/claims resources at $60,000 which equates to $0.32 per minute and $0.48 per minute respectively.

As a corollary to the operational and uptake benefits identified for the providers, health plans would expect corresponding benefits including:

- For 835/837 messages, plans would receive benefits in the way of savings through reduced phone calls related to ambiguity in the current messages.
- As uptake of the 835/837 transactions increase between trading partners, there would be savings through lower transaction costs; in other words, unit costs would decrease.
- For auxiliary transactions (270/271, 276/277, 278), plans would receive benefit in the way of operational savings through reduced phone calls.

Since we would expect an increase in the market for auxiliary transactions within the physician community as new uptake occurs with trading partners, plans would receive some cost savings through lower transaction costs.

Explanation of Cost Calculations

To determine the costs for each sub-segment (that is, hospitals, physicians, and dentists), we established an estimate for what the total approximate Version 4010/4010A costs were for an individual entity within that sub-segment (based on the interviews and other data available through research) and then applied an estimated range of 20 to 40 percent of those costs to come up with estimated minimum and maximum costs for Version 5010. The range was accepted as a realistic proxy by all providers and plans who participated in the interviews. Through the course of the interviews, we identified more granular cost categories and reviewed these with the participants to help analyze and validate overall cost estimates by entity.

Table 4 below shows Gartner's estimates of costs for Version 4010/

4010A implementation, which again, were calculated based on estimates of implementation for each individual entity within a segment, and multiplying that estimate by the number of entities.

TABLE 4—GARTNER ESTIMATED TOTAL COST FOR IMPLEMENTATION OF VERSION 4010/4010A

| Segment | Costs (in millions) |
|---|---|
| Hospitals* | $4,661 |
| Physicians | 2,175 |
| Dentists | 1,493 |
| Pharmacy | 336 |
| Private Plans | 18,021 |
| Government Plans | 1,202 |
| Clearinghouses | 125 |

Source: Gartner interviews and secondary research.

*Includes some long term care and skilled nursing facilities when connected to a hospital or hospital system.

Table 5 reflects our assumptions regarding the percent of the total costs allocated to each cost category (for example, testing and training) for the provider and plan segments. Specifically, we estimated that 60 percent of all implementation costs would go towards testing for providers, and 70 percent for plans. We invite comment from the industry on these assumptions and estimates, particularly on the assumption that there would be no new hardware costs for implementing Version 5010, since the interviews did not yield information on providers who do not currently have electronic capability.

TABLE 5—PERCENTAGE AND TOTAL AMOUNTS FOR COST ITEMS USED FOR VERSION 5010 CALCULATIONS—PROVIDERS AND HEALTH PLANS

| Cost item | Percent of total costs | |
|---|---|---|
| | Providers | Health plans |
| Hardware Procurement | 0 | 0 |
| Software Costs | 15 | 10 |
| Transmission Costs | 0 | 0 |
| New Data Collection | 0 | 0 |
| Customized Software Development | 5 | 2.5 |
| Testing Cost | 60 | 70 |
| Training Costs | 5 | 2.5 |
| Transition Costs | 15 | 15 |

TABLE 5—PERCENTAGE AND TOTAL AMOUNTS FOR COST ITEMS USED FOR VERSION 5010 CALCULATIONS—PROVIDERS AND HEALTH PLANS—Continued

| Cost item | Percent of total costs | |
|---|---|---|
| | Providers | Health plans |
| Totals | 100 | 100 |

Source: Gartner interviews and secondary research.

Transition costs, which we assume will occur in the third year of implementation, are defined as the post-implementation costs for monitoring, maintaining, and adjusting the upgraded systems and related processes with trading partners until all parties reach a ''steady state.'' An example of this type of cost might be additional bug fixes and the associated testing required on the Version 5010 platform after the system has been fully cut over. In addition, some interviewees expected there to be some laggards in implementing Version 5010 after the regulation timeline and expected to incur additional costs during this transition period as a result of late entrants. We note that we do not include hardware costs even for providers who might move from a paper-based system to an EDI system because we do not believe that the number of providers who have no electronic capability is very high. We do believe that providers who move away from a paper-based system are likely to have software and/or vendor costs, and we account for this. We invite stakeholder comment on these assumptions, and welcome any data regarding the number of providers who do not have any hardware to support electronic transactions.

Explanation of Benefits and Savings Calculations

In our analysis, we assume that benefits would accrue in three categories which arise from: (1) Better standards—improvements in the claims standards which would increase their usability and reduce manual intervention; (2) an increase in the adoption and use of the electronic claim transactions themselves, which would result in financial savings through an increased use of EDI; and (3) an increase in use of the auxiliary transactions, such as eligibility, claims status, and referral, which would reduce manual intervention (personnel involvement) and increase efficiencies and cash flow. For ease of understanding, we label the three savings categories as Better Standards, Cost Savings and Operational Savings, though all three represent savings to the entities. We further explain each category again here, and include the ''titles'' we have given them:

(1) Better standards or savings due to improved claims standards: The improvements in Version 5010 that would reduce manual intervention to resolve issues related to the claim or remittance advice, due to ambiguity in the standards;

(2) Cost savings or savings due to new users of claims standards: Increased use of electronic transactions for claims and remittance advice that would accrue to parties who had previously avoided the electronic transactions because of their deficits and shortcomings; and

(3) Operational savings or savings due to increased auxiliary standards usage: Increase use of auxiliary transactions through EDI that would result from a decrease in manual intervention to resolve issues with the data (handled through phone calls or correspondence).

To calculate the savings in the ''better standards'' savings category, which is specific to the increased use of electronic transactions for claims and remittance advice, we use data from a 2007 report compiled by America's Health Insurance Plans (AHIP) which indicated that savings due to EDI were in the range of $.73 per transaction. Using the $.73 as the baseline, Gartner used the interviews to refine this estimate for both providers and plans. We apportion the amount between providers and plans, and based on the interviews, anticipate that providers would receive at least $.55 in savings for moving transactions from paper to EDI and plans would benefit by at least $.18. All of the operational benefits were based on reduced phone calls and manual intervention as a percentage of total claims. Because we do not have any concrete numbers for how many claims the private plans process versus the government plans, we used the percentage of covered lives as stated in the Harvard/JFK School of Public Policy study as the best way to approximate how much of the benefits would go to private plans versus government plans (82 percent covered lives in private plans versus 16 percent for government plans) (Harvard JFK School of Public Policy—''Health care delivery covered lives—Summary of Findings—2007'') We further assumed that there are no material differences in the number of claims handled with the government-covered lives versus private-covered lives.

Table 6 details the business activities such as manual interventions and phone

calls that make up the calculations for the other two categories of projected savings: Cost and operational savings related to an increase in users of the electronic transactions for claims, and an increase in use of the auxiliary transaction standards by all covered entities. Where we speak of ''manual intervention,'' we mean that a human resource must take some action related to a particular claim or inquiry because the transaction has been delayed, pended or rejected.

Calculations are based on the number of interventions and the amount of time spent per intervention, multiplied by the average cost per intervention (based on average salaries for certain full-time employees). Affected entities can use the categories and calculations shown here to compare against their own operations, in order to evaluate the proposed impact to their own organization.

Based on industry interviews, we identified the average annual compensation packages, amount of time for certain business activities (manual interventions) related to claims and other transactions, and determined the cost per minute for these activities. According to Gartner's interviews, and for purposes of this analysis, we estimate the average annual compensation package (salary plus benefits) for a health plan or plan service representative to be $40,000 and for a provider billing specialist to be $60,000. The cost per minute for a service representative is $0.32 ($40,000/(2080*60)) and for a provider representative is $0.48. We invite industry comment on these estimates.

TABLE 6—PHONE CALLS AND MANUAL INTERVENTIONS REQUIRED BY PROVIDERS AND HEALTH PLANS DUE TO LACK OF EDI OR NON USE OF EDI

| Industry segment | Amount of time |
|---|---|
| Providers: | |
| Time taken by a provider billing agent to process manual intervention for a pended claim. | 10 minutes.<br>Example: 10 minutes × .48 = $4.80 per call |
| Time taken by a provider billing agent to process non Auto adjudicated claims. | 6 minutes. |
| Time taken by a provider's office staff member to find out Eligibility information. | 5 minutes. |
| Time taken by a provider billing agent to find out the status of the claim | 12 minutes. |
| Time taken by a provider's office staff member to find out the status of a referral. | 10 minutes. |
| Health Plans: | |
| Time taken by a plan claims processor to process manual intervention for a pended claim. | 5 minutes. |
| Time taken by a plan claims processor to process non Auto adjudicated claims. | 5 minutes. |
| Time taken by a plan customer service representative to give eligibility information. | 5 minutes. |
| Time taken by a plan customer service representative to give status of the claim pended claim. | 8 minutes. |
| Time taken by a plan Utilization Review representative to give status of a referral. | 8 minutes. |

Source: Gartner interviews and secondary data.

The formulas for the three savings categories are as follows:

(1) Better standards: Number of estimated claims transactions (835/837) requiring a phone call times the number of minutes per call, times the average cost per minute (for example: 1,000 claims × 10 minutes × $0.48 = $4,800)

(2) Cost savings (new use of EDI for 835/837): Number of transactions converted from paper to EDI (estimated to have a range of 2 to 5 percent over 10 years) times estimated cost savings per transaction (total savings of $0.73, where the provider benefit is $0.55 and the plan benefit is $0.18).

(3) Operational savings for increased use of EDI for auxiliary transactions: Number of estimated transactions (for the 270/271, 276/277, 278) requiring a phone call times the number of minutes per call times the average cost per minute. For example: 1,000 transactions × 10 minutes × 0.48 = 4,800.

Other data points of relevance to this analysis include the number of health care claims exchanged between covered entities. Based on its research, Gartner assumed a low estimate of 4,522 million and a high estimate of 5,837 million claims annually, beginning in 2010. Table 7 depicts the percent of transactions that are electronic, and their disposition. Gartner also assumes that 14 percent of all claims annually are pended, meaning that they are not paid upon receipt, and may be held for additional information.

TABLE 7—DISPOSITION OF CLAIMS TRANSACTIONS

| | Percent |
|---|---|
| Electronic Claims | 75 percent. |
| Auto Adjudication of electronic claims | 71 percent. |
| Pended claims | 14% (of all claims). |
| Cost savings from electronic transactions | $0.73 ($0.55 for providers; $0.18 for plans). |

Source: AHIP Report: ''An Updated Survey of Health Care Claims Receipt and Processing Times,'' May 2006.

1. Health Care Providers

As discussed above, providers are covered entities under HIPAA if they transmit health information in electronic form in connection with a HIPAA transaction. Providers are not required by HIPAA to conduct transactions electronically, but if they do, they must use the HIPAA standards adopted by the Secretary. However, Medicare providers, with a few limited exceptions, are required to submit Medicare claims electronically under the Administrative Simplification Compliance Act of 2001 (ASCA) Public Law 107–105. Providers may conduct the following transactions: Health care claims or equivalent encounter information, health care payment and remittance advice, eligibility for a health plan, referral certification and authorization, and health care claim status. They do not conduct the enrollment and disenrollment in a health plan or health plan premium payment transactions. Many providers submit claim transactions electronically, and somewhat fewer accept electronic remittance advices. Usage of the auxiliary transactions (eligibility, claim status, and referral/authorization) is much lower than the claims transactions.

Providers that conduct a transaction electronically would be required to implement Version 5010 of that transaction. As stated, we assume that the improvements in Version 5010 would result in more providers conducting those transactions electronically. Use of the claims transaction (837) is already high for providers and would be moderately affected by improvements in Version 5010. While the 835 remittance advice is also used, there are a number of technical issues that have hampered its wide-scale deployment. These issues were discussed in the preamble of this proposed rule. Utilization overall would increase due to the technical improvements in Version 5010. More providers will use any or all of the non-claims electronic transactions because the improvements will make them more useful. The auxiliary transactions for eligibility, claims status and referrals currently have relatively low utilization under Version 4010/4010A because of the perceived lack of business value. We believe adopting these modifications will change that trend. For example, the Version 4010/4010A eligibility transaction only requires that minimum data about an individual patient and his/her coverage be returned on the response, and that minimum data set is not useful to providers. Thus, very few providers or health plans have implemented this transaction, preferring instead to use existing voice and interactive voice response (IVR) systems. Improvements in the Front Matter section and instructions for Version 5010 would yield a modest increase in use, which would have a positive financial impact on providers and health plans. Our assumptions regarding the providers' current acceptance of the transactions and the projected adoption rate are shown in Table 2 in the assumptions section. In the remainder of this section, we discuss the costs and benefits of implementing Version 5010 for each segment of the provider industry, including hospitals, physicians, pharmacies and dentists.

a. Hospitals

For purposes of this cost/benefit analysis, hospitals were divided into three categories based on bed-size (See table 8 below).

TABLE 8—HOSPITAL BREAKDOWN

| Hospital size | Number of hospitals |
|---|---|
| 400+ Bed Hospitals | 521 |
| 100–400 Bed Hospitals | 2,486 |
| Fewer than 100 bed hospitals | 2,757 |
| Total | 5,764 |

Source: AHA Hospital Statistics 2007 edition.

Hospitals have pursued various implementation models of the HIPAA standards, including Direct Data Entry (DDE), internally managed EDI, use of clearinghouses or billing vendors, and a variety of hybrids of these models. All of these implementation models were considered in this analysis. Larger hospitals typically have pursued hybrid models but favor the use of clearinghouses and internally managed EDI where possible. Smaller hospitals typically rely more heavily on direct data entry, clearinghouses, and/or billing vendors to manage their EDI operations.

A subset of hospitals have reached a level of maturity with Version 4010/4010A transactions and believe that many of the benefits that would be attained by converting to Version 5010 have been mostly achieved. In other words, some hospitals have already taken extensive advantage of EDI, and of the auto adjudication opportunities afforded by Version 4010/4010A, so there may be only incremental benefits for that group, through adoption of Version 5010. These hospitals typically have implemented the full set of transactions (including the eligibility and claim status transactions). Based on the Gartner research, hospitals falling into this category include the 521 hospitals with 400+ beds as well as 20 percent of the mid-sized hospitals with 100–400+ beds and 10 percent of the hospitals with less than 100 beds. These hospitals have consistently deployed an internally managed EDI system and/or a hybrid solution and have invested in substantial development efforts to create workarounds to any problem segments within Version 4010/4010A that were particularly important to their organization. For this subset, the transition to Version 5010 may be more streamlined than for the smaller or less advanced entities because there would be fewer new system and business changes, and more expertise available to resolve implementation issues. However, the benefits would also be less pronounced because those hospitals that have implemented the full suite of transactions with the majority of their partners have already realized the benefits associated with moving from paper, phone or fax transactions to electronic transactions.

Some hospitals (mid-sized and small) have not yet taken full advantage of technical solutions to maximize the use or benefits of the HIPAA standards, and continue to depend on a variety of manual efforts to conduct the various business functions. The transition to Version 5010 would provide significant benefits with respect to a reduction in these manual procedures, resulting in decreased costs and increased efficiencies.

We anticipate the total cost for all hospitals to implement Version 5010 would be within a range of $932 million to $1,864 million. This estimated cost was calculated by applying a 20 percent (minimum) and 40 percent (maximum) factor to the estimated cost of implementing Version 4010/4010A. We provided the cost estimates for Version 4010/4010A for each industry segment in the assumptions section above. While the average costs by hospital would vary based on size and complexity of the hospital system, they would fall within the 20–40 percent range compared to the investments made for implementing Version 4010/4010A. Smaller hospitals typically rely on a billing vendor and/or a clearinghouse for a large majority of their electronic claims exchanges. We assume that these hospitals implemented the 837 transactions only. We assume these hospitals are subject to vendor release schedules and would be dependent on these partners to upgrade their current transactions to the Version 5010 standards. Furthermore, these

smaller hospitals may have to absorb some costs for testing, as testing would represent a significant portion of the overall costs for implementation. Nonetheless, we assume that these costs would be lower for this group than for the larger entities. We assume that many of these hospitals have regulatory compliance clauses in their vendor contracts, which would result in many costs largely being absorbed by their vendors. Our assumptions are based on industry interviews which indicate that small organizations will rely on their vendors for most of the heavy lifting for testing. We believe the impact on the individual entity will be minimal, comparatively. However, we welcome comments and data from the industry and other stakeholders on this matter.

Hospitals would enjoy savings and benefits in the same three categories we identified earlier in the assumptions section of this analysis. Savings due to better standards are estimated to be a minimum of $403 million. Cost savings, due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be a minimum of $67 million. (This figure is derived by multiplying the number of claims times the savings of $.55 per claim (from the AHIP report).) The operational savings for use of the auxiliary transactions (270/271, 276/277, 278) are projected to be a minimum of $1,313 million. (This figure is calculated by taking the number of calls that would be avoided, times the time each of those calls would take times the cost per call.) The benefits related to increased use of the auxiliary transactions would be realized in a reduction in the amount of time that manual intervention would be needed to address the same ''issues'' that can be handled by a transaction. In other words, use of electronic eligibility transactions would save a provider's employee 10 minutes of time per avoided manual intervention or phone call to verify eligibility.

We specifically solicit industry comments on the assumptions made here relative to the costs and benefits for hospitals for the implementation of Version 5010. Table 9b below shows the costs and benefits for all hospitals.

TABLE 9—VERSION 5010 COST BENEFIT SUMMARY FOR HOSPITALS

[In millions]

| | Minimum | Maximum | |
|---|---|---|---|
| Costs: | | | |
| System Implementation | $792 | $1,584 | |
| Transition | 140 | 280 | |
| Total costs | 932 | 1,864 | |
| Benefits: | | | Formula: |
| Operational Savings—better standards. | 403 | 1,096 | Number of estimated transactions (835/837) requiring a phone call × number of minutes per call × $ average cost per minute. |
| Cost Savings—increase in electronic claims transactions. | 66 | 219 | Number of transactions converted from paper to EDI × estimated cost savings per transaction ($.55). |
| Operational Savings—increase in use of auxiliary transactions. | 1,314 | 3,414 | Number of estimated transactions (270/271, 276/277, 278) requiring a phone call × number of minutes per call x $ average cost per minute. |
| Total benefits | 1,783 | 4,729 | |
| Net Benefits | 851 | 2,865 | |

b. Physicians and Other Providers

Physicians have also pursued a variety of implementation models for the HIPAA transactions. They are largely dependent on the requirements of their trading partners (the health plans with whom they conduct transactions) and the services of their vendors and clearinghouses, who provide a range of support and technology, to process the transactions. A full range of implementation methods were considered in this analysis. Larger physician practices have pursued direct transmission with health plans, but many mid-sized practices and small physician practices are dependent on the use of clearinghouses and rely on billing vendors to manage their EDI operations.

For purposes of this cost benefit analysis, Gartner divided physicians practices into four size-based categories, as shown in table 10 below:

TABLE 10—PHYSICIAN BREAKDOWN BY PRACTICE SIZE

| Practice size | Number of practices |
|---|---|
| 100+ Physicians | 393 |
| 50–100 Physicians | 590 |
| 3–49 Physicians | 38,961 |
| 1–2 Physicians | 194,278 |
| Total | 234,222 |

Source: AMA.

Within these four types of practices, a distinction can be drawn between the groups with more than 50 physicians (large practices) and those that are less than 50 physicians (small practices).

For the large physician practices, as in large hospitals, there are greater levels of acceptance as well as more diversified implementations of the Version 4010/4010A standards. Therefore, the bulk of the costs associated with the implementation of Version 5010 for large practices would be in the category of testing, which we estimate at 60 percent of costs, as explained in the general assumptions section earlier in this document.

The majority of the small physician practices currently utilize vendor supplied practice management software, billing vendors, and/or clearinghouses to handle their HIPAA EDI transactions. For small providers that are PC-based or have client-server systems that rely on vendor-supplied software, we do not believe the provider would bear any immediate costs for the software upgrades. Based on Gartner's interviews and our own experience with the industry, most software maintenance contracts offer free upgrades to accommodate regulatory changes, and we believe that most contracts have clauses that require vendors to be compliant with mandatory standards. However, as with each provider category in which we identified dependence on vendors, there are still testing costs that must be addressed. The impact on those providers that have such contracts would be postponed

until the contract is renewed, and would be mitigated by market factors.

We anticipate that the total conversion cost for physicians would be in the range of $435 million and $870 million. (This was calculated by taking the base of $2,175 million (for implementing Version 4010/4010A), and multiplying that number by version 5010 implementation factor of 20 percent (minimum) and 40 percent (maximum)).

As with hospitals, physicians are positioned to receive the same benefits of using Version 5010, including the previously mentioned savings, through reduced phone calls and reduced manual intervention. Physicians would experience savings and benefits in the three categories as follows: Savings due to better standards is estimated to be $1,613 million. Cost savings, due to an increase in use of the electronic claims transactions (837 and 835) is estimated to be $269 million. (This figure is derived by multiplying the number of claims times the savings of $.55 per claim, as noted in the AHIP study.) The operational savings for use of the auxiliary transactions (270/271, 276/277, 278) is projected to be $5,250 million. (The narrative for these calculations has been provided elsewhere, and the formulas appear in the cost benefit table for hospitals.) Again, we invite public comment on these figures and assumptions, particularly on the assumption that there would be no new hardware costs for implementing Version 5010, since the interviews did not yield information on providers who do not currently have electronic capability. Table 11 below summarizes the cost-benefits for physicians:

TABLE 11—VERSION 5010 COST BENEFIT SUMMARY FOR PHYSICIANS—IN MILLIONS

| | Minimum | Maximum |
|---|---|---|
| Costs: | | |
| System Implementation | $370 | $740 |
| Transition | 65 | 131 |
| Total Costs | 435 | 870 |
| Benefits: | | |
| Operational Savings—better standards | 1,612 | 4,378 |
| Cost Savings—increase in electronic claims transactions | 270 | 874 |
| Operational Savings—increase in use of auxiliary transactions | 5,251 | 13,562 |
| Total Benefits | 7,133 | 18,814 |
| Net Benefits | 6,698 | 17,944 |

c. Dentists

There are an estimated 175,000 dentists currently covered under HIPAA. However, the dental community has not yet widely adopted the HIPAA standards, in large part because the standards did not meet their practical business needs, particularly for claims and remittance advice. The improvements in Version 5010 would increase the potential value of the HIPAA standards for dentists, and should increase utilization. Currently, the typical dental practice relies on vendor solutions and clearinghouses to handle their Version 4010/4010A HIPAA transactions, and, therefore, the costs for implementing Version 5010 would largely fall on vendors as a cost of doing business. The majority of the dental costs would stem from testing and other related services not covered by any pre-negotiated upgrades with their vendors. Implementation costs for Version 5010 are anticipated to be in the range of $299 million (20 percent) to $598 million (40 percent) based on using the same implementation factor of the Version 4010/4010A implementation costs of $1,493 million.

The benefits derived from implementing Version 5010 for dentists would be the same as those for the other provider segments, as described in the assumptions section of this analysis. For example, based on improvements in Version 5010, we anticipate that for dental practices, there would be an increase in the adoption rate of 2 to 5 percent in the 837 transactions, and 5 to 10 percent in 835 transactions, over a ten-year period.

Increased utilization of the standards would occur because of improvements that specifically affect dental practices. For example, increased utilization of the 837 would occur because the standard now accommodates certain dental terminology to differentiate dental services from medical services. Version 4010/4010A does not allow for reporting diagnoses codes that are required for some specialty claims such as oral and maxillofacial surgery. This has resulted in challenges for this segment of the industry because many of these services are billed using the professional claim, but the professional claim does not have a way to provide tooth numbers or other tooth-related information. These claims often had to be submitted on paper. The ability to report those codes in Version 5010, with the tooth numbers, would provide a standard means for these claims to be submitted electronically. The 835 would be more widely adopted for its ability to post receivables automatically.

In general, we believe dentists would achieve these benefits from operational savings, which would result in:

- Reduced time to determine eligibility
- Reduced manual effort to prepare claims
- Reduced burden to complete account posting
- Greater visibility into claims status

We also expect that dental practices would derive similar benefits as physicians, in the way of savings through reduced phone calls for claims transactions as well as for auxiliary transactions (270/271 and 276/277). For dentists that have not yet implemented 835/837, there would be savings through increased use of EDI. Dentists would experience savings and benefits in the three categories as follows: Minimum savings due to better standards is estimated to be $274 million; minimum cost savings due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be $45 million. (Again, this figure is derived by multiplying the number of claims times the savings of $.55 per claim, as noted in the AHIP study.) The operational savings for use of the auxiliary transactions (270/271, 276/277, and 278) is projected to be a minimum of $889 million. (The narrative for these calculations has been

provided in the assumptions section.) Table 12 below shows the cost benefit summary for the dental industry.

TABLE 12—VERSION 5010 COST BENEFIT SUMMARY FOR DENTISTS—IN MILLIONS

| | Minimum | Maximum |
|---|---|---|
| Costs: | | |
| System Implementation | $254 | $508 |
| Transition | 45 | 90 |
| Total Costs | 299 | 598 |
| Benefits: | | |
| Operational Savings—better standards | 274 | 699 |
| Cost Savings—increase in electronic claims transactions | 45 | 56 |
| Operational Savings—increase in use of auxiliary transactions | 889 | 2,173 |
| Total Benefits | 1,208 | 2,928 |
| Net Benefits | 909 | 2,330 |

d. Pharmacies

Pharmacies are currently using Version 4010/4010A of the 835 and 837 transactions in their current business practices, most often for the remittance advice (835) and pharmacy supplies and services (837). Pharmacies would transition to the use of Version 5010 when the final rule becomes effective, in particular for the 835 transaction. For retail pharmacy claims, pharmacies primarily use Version 5.1. Since we are proposing to replace Version 5.1 with Version D.0 in this regulation, and many of the system changes, costs and benefits for implementing both Version 5010 and Version D.0 would result from related efforts, we have combined the impact analysis for Version 5010 and Version D.0. That analysis is detailed later in Section 3 of this analysis.

e. Health Plans

According to estimates provided by Gartner, there are nearly 4,000 health plans in the United States. For the purposes of this analysis, we divided plans into four categories based on their size: National and Super Regional Private Plans; Large Private Plans; Mid-Sized Private Plans, and Small Private Plans, as shown in table 13 below.

TABLE 13—HEALTH PLAN BREAKDOWN

| Plan size | Number of plans |
|---|---|
| National and Super Regional | 12 |
| Large | 75 |
| Mid-sized | 325 |
| Small | 3,537 |
| Total | 3,949 |

Within these four types of private plans (as described above), there are two distinct scenarios that emerged: Small/Midsized Plans and Large/National/Super-Regional Plans.

The large plans could be characterized as having implemented the full set of 4010/4010A transactions but often did not have trading partners for certain auxiliary transactions. They have already developed workarounds for many of the problems that were identified as being solved in Version 5010. Furthermore, their maturity in working with the Version 4010/4010A transaction set was at a point where they had extracted most of the value from the standards in place.

Small plans resembled the larger plans in that they had implemented the full set of transactions. However, the smaller plans had not developed as many workarounds for Version 4010/4010A limitations as their larger peers. As a result, Version 5010 may serve to provide this segment more benefit on average than their larger peers. In order to calculate health plan implementation costs, we calculated the costs within a factor of 20 to 40 percent of the costs for implementing Version 4010/4010A. Overall, private health plans recognize the importance of continuing to maintain and upgrade the national standards and perceive there to be qualitative benefits that warrant considerations beyond just the quantifiable net benefit from the change.

The benefit for all private plans falls between $5,780 and $15,114 million. Private plans would experience savings and benefits in the three categories as follows: savings due to better standards is estimated to be in a range of $1,283 million to $3,430 million; cost savings, due to an increase in use of the electronic claims transactions (837 and 835) is estimated to be in a range of $111 million and $278 million. (This time, the estimate is derived by multiplying the total number of all claims (physician, hospital, and dental) times the savings of $.18 per claim for plans, as noted in the AHIP study.); the operational savings for use of the auxiliary transactions (270/271, 276/277, and 278) is projected to be in a range of $4,386 million to $11,406 million. (The narrative for these calculations has been provided earlier.) Table 14 depicts total plan cost benefits summary.

TABLE 14—VERSION 5010 COST BENEFIT SUMMARY FOR PRIVATE HEALTH PLANS—IN MILLIONS

| | Minimum | Maximum |
|---|---|---|
| Costs: | | |
| System Implementation | $3,064 | $6,128 |
| Transition | 541 | 1,081 |
| Total Costs | 3,604 | 7,209 |
| Benefits: | | |
| Operational Savings—better standards | 1,283 | 3,430 |

TABLE 14—VERSION 5010 COST BENEFIT SUMMARY FOR PRIVATE HEALTH PLANS—IN MILLIONS—Continued

| | Minimum | Maximum |
|---|---|---|
| Cost Savings—increase in electronic claims transactions | 111 | 276 |
| Operational Savings—increase in use of auxiliary transactions | 4,386 | 11,406 |
| Total Benefits | 5,780 | 15,112 |
| Net Benefits | 2,175 | 7,903 |

Government Plans

To prepare the cost benefit analysis for government plans, we obtained input from Medicare and from several subject matter experts from Medicaid plans across the country. Other government entities, like the Veteran's Health Administration, were assumed to have similar cost/benefit structure as the Large Private plans and were estimated as such. One of the key findings from the interviews was that even in the case of government plans that have implemented the full set of transactions, there is still a very limited exchange of the auxiliary transactions at this time.

Government systems costs are expected to occur across a number of Federal and state agencies and include transition costs. For Medicare, since its cost structure is different from private plans, total Medicare costs include those that would be expended by the MACs, DME MACs, carriers, intermediaries and other contractors. The costs are high, but the net benefit to Medicare relative to the private plans is slightly more positive. Overall, costs for government plans were similar in nature to private plans, and included analysis, translator/software customization, testing, and training. The cost to government systems in transitioning to Version 5010 is estimated to be within a range of $252 million to $481 million over 10 years. This figure was derived by applying a 20 percent and 40 percent factor onto the cost to implement Version 4010/4010A, which was $1,203 million. The examples in this impact analysis are only illustrative in nature and are based on limited analysis. They are presented to illustrate the potential administrative costs to the Federal government.

Derived benefits accrued for implementing Version 5010 to government plans would be similar to those of private plans. Savings would be acquired from reduced phone calls because current ambiguity in the transactions (such as situational versus required information for some of the key data elements) would be reduced. As with all other affected entities, as more uptake of 835/837 messages occur with trading partners, there would be cost savings through lower transaction costs. The same estimates for increased adoption of the 837 transactions of between 2 and 5 percent and between 5 and 10 percent for the 835 transactions would apply to government plans, and we project similar increases in the use of the auxiliary transactions. Since we projected an increase in the market for the auxiliary transactions within the physician community as new uptake occurs with the trading partners (for example, health plans), the government plans would benefit from cost savings as well, as follows: Minimum savings due to better standards are estimated to be $279 million. Minimum cost savings, due to an increase in use of the electronic claims transactions (837 and 835) are estimated to be $24 million. (Again, this figure is derived by multiplying the number of claims times the savings of $.18 per claim, as noted in the AHIP study.) The minimum operational savings for use of the auxiliary transactions (270/271, 276/277, 278) is projected to be $953 million. (The narrative for these calculations has been provided elsewhere.) Table 15 shows the cost benefit summary for government plans.

TABLE 15—VERSION 5010 COST BENEFIT SUMMARY FOR GOVERNMENT HEALTH PLANS—IN MILLIONS

| | Minimum | Maximum |
|---|---|---|
| Costs: | | |
| System Implementation | $214 | $409 |
| Transition | 38 | 72 |
| Total Costs | 252 | 481 |
| Benefits: | | |
| Operational Savings—better standards | 279 | 746 |
| Cost Savings—increase in electronic claims transactions | 24 | 60 |
| Operational Savings—increase in use of auxiliary transactions | 953 | 2,480 |
| Total Benefits | 1,256 | 3,286 |
| Net Benefits | 1,004 | 2,805 |

f. Clearinghouses and Vendors

Gartner estimates that there are 162 clearinghouses, which includes claims-related transaction vendors. This segment of the HIPAA universe provides a critical service in today's environment. For the purposes of this study, however, any related costs expected to be incurred by these vendors was considered to be a ''cost of doing business'' and were not included in the overall Cost/Benefit impact. Costs were, however, collected from the clearinghouses/vendors and analyzed as best as could be with the information available.

While many providers who use vendor-supplied software may be able to defer the costs of software upgrades, the vendor industry may have to bear, at least initially, the costs of such upgrades. Vendors have not provided data on their costs, and this regulation does not address the costs on the vendor industry, but welcomes input as to the estimated costs and benefits from this industry, for inclusion in the final rule.

For though vendors are not covered entities under HIPAA, their role is significant with respect to the services they provide to health plans and to covered health care provider clients.

We estimate the range of clearinghouse costs to be between $37 million and $45 million for the Version 5010 upgrade over the 3-year implementation period—two years for implementation and a third year for transition. Estimates were determined in the same fashion as the providers and plans. Clearinghouses were estimated to have total Version 4010/4010A costs of approximately $125 million.

We do not estimate that there would be a positive payback related to the Version 5010 upgrade for clearinghouses or vendors, however, there are some discrete benefits that would be realized through this transition including:

- Higher transaction volumes
- Lower service and operational costs (reduced phone calls)
- Operational efficiencies (Lower percent as measured against total costs)
- Increased market size

Because these benefits are predicated on several dependencies and market circumstances beyond our ability to predict with complete accuracy, neither HHS nor Gartner attempted to quantify those in dollar figures. Table 16 below summarizes the clearinghouse costs.

TABLE 16—VERSION 5010 COST BENEFIT SUMMARY FOR CLEARINGHOUSES IN MILLIONS

| Costs | Maximum | Minimum |
|---|---|---|
| System Implementation | $33 | $41 |
| Transition | 3 | 4 |
| Total Costs | 37 | 45 |

Qualitative Benefits

With few exceptions, sources expressed their belief that the advancement of the HIPAA standards was the right thing to do across the industry. Some participants acknowledged that the advancement to Version 5010 would not benefit their organization directly, but they were still in support of the modifications to the standards.

There were a number of benefits that were articulated but not quantified by the participating subject matter and industry experts that may warrant further discussion with the industry. Among the qualitative benefits that were consistently mentioned by interviewees were the following:

- Improved accuracy resulting from simplified messaging.
- A new field specifically to capture certain hospital acquired condition indicators that are so critical to the industry.
- A new field to capture ''Present on Admission'' indicators as directed by the Deficit Reduction Act.
- Resultant quality through greater reliability of clean message exchange.
- Collaborative benefits stemming from the ability to share more information.

It is also important to note that Version 5010 is considered a key dependency to move towards adopting the ICD–10 CM code set for HIPAA transactions. While there is disagreement in the industry about the benefits of adopting ICD–10 in the next few years, such a transition is viewed as positive over the long-term, and is acknowledged as an option that is not available today. In summary, sources agree that all of the qualitative benefits lead to the delivery of an improved quality of care and allow the providers and plans to focus more of their time on patients and less of their time on administration.

3. Version D.0 (and Version 5010 for Pharmacies)

The objective of this portion of the regulatory impact analysis is to summarize the cost and benefits of implementing Version D.0.

Affected Entities

Almost all pharmacies, health care providers, and plans/PBMs already use Version 5.1, as it is the claim format most widely adopted by providers who submit retail pharmacy claims, and health plans that process retail pharmacy claims. These entities currently use the Version 5.1 standard to transmit retail pharmacy claim information between provider and plans/PBMs, and between pharmacies and plans/PBMs. This is accomplished in one of two ways, either through interactive on-line transmission or transmission through batch mode.

Retail pharmacies use Version 5.1 to submit claims to health plans/PBMs when they dispense a prescription medication to a patient who has prescription drug benefits through his/her health insurance coverage. The National Association of Chain Drug Stores (NACDS) estimates that there are more than 38,000 retail pharmacies owned and operated by both national and regional pharmacy chains that process more than 2.3 billion prescriptions annually. Independent community pharmacies, according to the National Community Pharmacist Association (NCPA) represent an additional 18,000 independent retail community pharmacies across the United States, and process 1.4 billion prescriptions annually.

There are approximately 3,950 health plans according to the America's Health Insurance Plans (AHIP) and Gartner research. With regard to PBMs, there are four national pharmacy benefit management companies that process about 75 percent of the more than 3 billion prescriptions dispensed annually in the United States. The remainder are specialized PBMs.

Some health care providers who dispense medications directly to their patients, known as dispensing physicians, may use the Version 5.1 to submit these prescription drug claims on behalf of their patients to the PBMs and/or plans, depending on the patient's health insurance coverage. However, we do not estimate this practice to be widespread and therefore, do not account for it in this impact analysis. We invite comment regarding the number of pharmacy benefit management companies and their respective market share.

Costs

a. Chain Pharmacies

The retail pharmacy industry would be the most impacted by the transition from Version 5.1. to Version D.0. According to the NACDS, there are nearly 200 chain pharmacy companies in the United States. The programming changes to incorporate the new fields that constitute the Version D.0 are performed at systems located at the corporate level, and then these system updates are pushed out to the individual pharmacies within the pharmacy chain. One large national pharmacy chain has estimated that it spent approximately $10 million when it converted to Version 5.1. In comparison, it anticipates that corporate-wide costs for the conversion to Version D.0, including programming, system testing and personnel training, would be around $2 million. Another large national pharmacy chain estimates its migration costs from Version 5.1 to Version D.0 at $1.5 million. Chain pharmacy cost estimates for programming these systems, testing to ensure that systems work with Version D.0, and training of personnel are dependent on the size of the pharmacy chain, its respective proprietary systems, and number of employees that would require training. Overall, industry estimates for conversion to Version D.0 range from $100,000 for a small pharmacy chain to $1 million for

large national pharmacy chains. We assume that these costs would be incurred in the first year of the implementation of Version D.0, in 2010.

We assume that there are 20 large national pharmacy chains and the remaining 180 chains are small chains. Therefore, we estimate costs for the migration from Version 5.1 to Version D.0 to be $20 million for large national pharmacy chains, and $18 million for the remaining 180 small chains, for a total of $38 million. We estimate that these costs would be incurred during the first two years of implementation.

TABLE 17—CHAIN PHARMACY COSTS FOR CONVERSION TO VERSION D.0

| Category | Cost |
|---|---|
| Large pharmacy chains (20 × $1,000,000) | $20,000,000 |
| Small pharmacy chains (180 × $100,000) | 18,000,000 |

b. Independent Pharmacies

Independent pharmacies would also incur costs, the majority of which would result from upgrading their software systems to Version D.0. These costs are harder to estimate. Independent pharmacies use software dispensing packages purchased from pharmacy dispensing software system vendors, and usually pay a monthly maintenance fee and a per-claim cost of anywhere from 4 cents to 10 cents per claim. Maintenance fees are negotiated between the software vendor and the pharmacies, and may take the form of a flat fee, or a fee based on a sliding scale. These maintenance fees would likely increase slightly, as vendors pass along their cost of the upgrade to the pharmacy. We assume this would take place not during the course of an existing contract, but when the pharmacy's contract with the vendor comes up for renewal, likely within two years, in this case 2010 and 2011, the first two years of Version D.0 implementation. Based on industry feedback, we estimate that the average monthly maintenance contract between a pharmacy and a vendor amounts to a range of $400 to $800 per month per pharmacy, with the average industry estimate being about $500. We estimate a range of between .50 and 1 percent maintenance fee increase attributable to the conversion to Version D.0, or an additional $2.50 to $5.00 per month per pharmacy, or $540,000 to $1,080,000 based on 18,000 independent pharmacies ($500 × 0 .50 percent/1 percent × 12 months × 18,000 pharmacies). We solicit industry and stakeholder comment on our cost assumptions.

TABLE 18—INCREASE IN INDEPENDENT PHARMACY MONTHLY MAINTENANCE FEES FOR CONVERSION TO VERSION D.0

| | Percentage of increase to maintenance fees | |
|---|---|---|
| Category | .50% | 1% |
| Number of Independent Pharmacies | 18,000 | 18,000 |
| Average monthly maintenance fee | $500 | $500 |
| Average annual maintenance fee increase | $540,000 | $1,080,000 |

With respect to costs for implementing Version 5010, we use the same pharmacy categories of chains and independents. As stated above, the retail pharmacy industry would be impacted by the transition from Version 4010/4010A to Version 5010 for billing supplies and services, and receiving the remittance advice (835). Similar to the programming changes to accommodate D.0, the upgrade to Version 5010 would be performed at the corporate level, and the system updates would be pushed out to the individual pharmacies within the pharmacy chain. Estimates from the large national pharmacy chains regarding costs for implementation of Versions 5010 and 5.1 are outlined above. These same entities stated that they anticipate corporate-wide costs for the conversion to Version 5010, including programming, system testing and personnel training, would be around 20 percent of the Version 4010/4010A costs. This is consistent with the overall industry estimate that implementation of Version 5010 would represent approximately 20 to 40 percent of the cost of implementing Version 4010/4010A. As with Version D.0, chain pharmacy cost estimates for programming, testing, and training are dependent on the size of the pharmacy chain, their respective proprietary systems, and the number of employees that would require training. We assume that these costs would be incurred in the first 2 years of the implementation of Version 5010, as we do with the other HIPAA standards and other industry segments.

Independent pharmacies would also incur costs, the majority of which would result from upgrading software systems to Version 5010 and Version D.0, as has been discussed. Independent pharmacies use software dispensing packages, and usually pay a monthly maintenance fee and a per-claim cost. We assume that these types of costs for implementing Version 5010 would be incorporated into the costs for implementing Version D.0, and therefore do not add additional costs. Thus, using the same estimates for the number of chain and independent pharmacies, and applying a rate of 20 percent to Version 4010/4010A implementation costs, we estimate costs specific to the migration from Version 4010/4010A to Version 5010 to be a range of $58 million to $114 for system implementation and $10 million to $20 million for transition costs, for a total range of $67 million to $134 million. We assume that these costs would implicitly include testing, as this activity would be executed jointly for Version D.0 and Version 5010. We invite the industry to comment on our assumptions and projected cost estimates, and to provide current data to support alternative theories or view points, as the comparison between Version 4010/4010A costs and Version 5010 implementation costs could be overstated.

We described the benefits for all providers, including pharmacy providers, in the assumptions section of this analysis (for example, better standards and decreased manual effort). We identified the largest benefits for pharmacies in the content requirements in the 835 standard (required fields versus situational or optional fields, and improvements in the specificity of the business rules which will minimize multiple interpretations of the guides). These enhancements would help to reduce manual interventions needed to resolve transaction issues. For example, Version 4010/4010A does not provide instructions for reconciling payments. The new Front Matter section in Version 5010 explicitly details how this information is to be reported in the

summary section of the remittance advice. Thus, benefits and savings would accrue through better standards. For this savings calculation, we use the same formula as for other provider cost savings—multiplying the number of claims that would not require manual intervention, times the cost per call and the number of minutes estimated for each call. Savings due to better standards (837 and 835) are estimated to be in the range of $20 million to $27 million.

c. Health Plans and PBMs

Health plans should see minimal changes in their operations and workflows between Version 5.1 and Version D.0. Version D.0 does not require any substantial or additional data reporting to enhance the eligibility or subrogation/secondary plan aspects of the transaction. Most of that work would be performed by the pharmacy benefit managers (PBMs) that service the plans. Plans would likely continue to provide data to the PBMs weekly via flat file transmission. However, PBMs would have to reprogram their systems to be able to process claims in Version D.0. As with the large pharmacy chains, we estimate the cost for large PBMs to migrate to Version D.0 to be approximately $1 million to $1.5 million per large national PBMs, and approximately $100,000 for specialty PBMs. Due to mergers and acquisitions over the past 4 years, the number of PBMs has dropped from approximately 100 to about 40 total PBMs in the U.S. Of those, we estimate that four are considered large PBMs and would therefore incur approximately $4 million to $6 million in conversion costs to Version D.0, and the remainder would incur $100,000 or $3,600,000 in the aggregate, for a total cost ranging between $8.6 and $10.6 million. We do not estimate any additional costs to health plans for implementing Version 5010 for pharmacies, as all efforts are included in the overall budget towards compliance. We solicit industry comment on these cost assumptions, and additional information regarding how PBM costs affect health plans, and how these costs are passed on to the plans. We also invite comment as to how the change to Version D.0 would affect core systems, and what the costs might be to health plans, particularly large plans with broad operations.

TABLE 19—PBM COSTS OF CONVERSION TO VERSION D.0

| Category | Cost |
|---|---|
| Large PBMs (4 × $1,000,000/ $1,500,000). | $4,000,000/ $6,000,000 |
| Specialty PBMs (36 × $100,000). | $3,600,000 |

d. Vendors

Software vendors have commitments to their software clients to maintain compliance with the latest adopted e-prescribing standards. They must incorporate these standards into their software systems, otherwise they would not be able to sell their products competitively in the marketplace. These systems cannot properly function using outdated standards and/or missing key functionalities which the industry has identified as essential to their business operations. We expect that upgrades to these standards are anticipated by vendors, and the cost of programming and/or updating the software is incorporated into the vendor's routine cost of doing business. We further assume they would pass along costs to customers through increases in the cost of licensing and/or monthly maintenance fees, which we previously discussed and estimated to be about 0.50 to 1 percent based on industry interviews. We solicit industry and stakeholder comment on the assumption that vendor costs will be passed on to the customer over time, and solicit feedback on actual costs for vendor software upgrades and impact on covered entities, including the conversion of historical data.

Benefits

a. Pharmacies

Pharmacies need Version D.0 to process Medicare Part D claims. Currently, there are many workarounds in pharmacy systems due to the shortcomings of Version 5.1 in processing ''coordination of benefits'' claims. Pharmacies would benefit from the use of the NCPDP D.0 standard because it provides better guidance than Version 5.1 in Medicare Part D coordination of benefits situations, and now identifies ''patient responsibility'' and ''benefit stage'' to help identify coverage gaps on secondary claims. By processing the claim correctly the first time—sending the right fields, with the right details, and additional fields with detailed pricing segments—the result could be that pharmacies are paid correctly, and patients pay correct co-pays, and there could be fewer pharmacy audits and recoupments.

A recoupment is a request for refund when a pharmacy is erroneously overpaid by a plan. A common reason for a recoupment is that the plan was not aware of a patient's other health insurance coverage, information that can be provided through use of the Version D.0 standard. Currently, there are issues with Version 5.1's misinterpretation of ''coordination of benefits.'' There are extensive customer service issues with many of these claims due to the charging of incorrect co-pays, as the correct values do not exist in Version 5.1. Version D.0 redefines the ''other coverage codes'' and provides claim examples in coordination of benefits situations to eliminate future confusion. Extra information, which would be available in the E1—Eligibility Verification transaction (this transaction resides on the NCPDP Telecom 5.0 standard and provides information on a patient's benefit eligibility at the time of prescription dispensing) would be beneficial to pharmacies as well, but it is the coordination of benefits and more precise pricing fields that would save pharmacies time and money. One industry group estimated that large pharmacy chains could save upwards of $1 million a year due to avoided audits and incorrect payments. For smaller chains, the industry estimates savings would be approximately $100,000 per chain. This does not include the time that pharmacists and pharmacy technician staff spend on these claims trying to process them at the pharmacy level. We assume an annual benefit of $38 million for large and small pharmacy chains in avoided audits and incorrect payments, and a total 10-year benefit of $380 million, and conservatively estimate benefits at 50 percent, or $190 million. We invite industry and stakeholder comments on this assumption.

Table 20 below shows the amount of savings as a result of avoided audits and incorrect payments based on implementation of Version D.0.

[Large and small chain pharmacy avoided audit and incorrect payment savings resulting from Version D.0 (millions)]

| Benefit type | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Large Pharmacy chains (20 × $1M) | $20 | $20 | $20 | $20 | $20 | $20 | $20 | $20 | $20 | $20 | $200 |
| Small Pharmacy Chains (20 × $1M) | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 18 | 180 |
| Total (maximum) | 38 | 38 | 38 | 38 | 38 | 38 | 38 | 38 | 38 | 38 | 380 |
| 50% (minimum) | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 190 |

Based on a study funded by the National Association of Chain Drug Stores (NACDS), ''Pharmacy Activity Cost and Productivity Study'' (*http://www.nacds.org/user-assets/PDF_files/arthur_andersen.PDF*), the average pharmacist spends 1.1 percent of his or her time dealing with third party plan issues. According to NACDS, there are 136,773 pharmacists employed by chain pharmacies, and 94,000 full-time community pharmacists. In 2010, the first year of the migration from Version 5.1 to Version D.0, that number is expected to increase to 244,829, or approximately 7,028 per year based on industry trend information. For these 244,829 full-time pharmacists, 1.1 percent of 2,080 working hours annually equals 22.88 hours per year that a pharmacist spends on third party plan issues, times the study's estimated average pharmacist hourly wage of $60, which equals $1,373 per pharmacist, $1,373 × 244,829 full-time pharmacists equals $336,101,251 in potential productivity savings to be realized by the use of Version D.0 in the first benefit year. However, we recognize that all call backs and inquiries would not be entirely eliminated. Therefore, we conservatively estimate that 25 to 50 percent of the pharmacist's time spent on third party plan questions could be eliminated, for a total first year savings of $84 million to $168 million. Over the next 9 years, we estimate that, based on Department statistics (*http://www.hhs.gov/pharmacy/phpharm/howmany.html*) the number of pharmacists will increase by 1.3 percent per year. We estimate 10-year productivity savings at $1,134 million to $2,268 million. We did not estimate hourly wage increases for the other job types discussed elsewhere in this regulation, and therefore savings calculated for other entities do not include the additional dollar values.

TABLE 21—PHARMACIST PRODUCTIVITY SAVINGS FROM VERSION D.0

| Year | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No. of Pharmacists | 244,829 | 248,012 | 251,236 | 254,502 | 257,811 | 261,162 | 264,557 | 267,996 | 271,480 | 275,010 | 2,596,595 |
| Incremental Pharmacists | | 3,183 | 3,224 | 3,266 | 3,309 | 3,352 | 3,395 | 3,439 | 3,484 | 3,529 | 30,181 |
| Pharmacist Hourly Wages | $60.00 | $63.18 | $66.52 | $70.04 | $73.75 | $76.65 | $80.76 | $85.04 | $89.54 | $94.28 | |
| Hours × Wages × Pharmacists | $336,101,251 | $358,515,508 | $382,375,458 | $407,843,319 | $435,029,477 | $458,013,485 | $488,845,770 | $521,444,688 | $556,175,087 | $593,230,486 | $4,537,574,528 |
| Total (25%) | $84,025,313 | $89,628,877 | $95,593,864 | $101,960,830 | $108,757,369 | $114,503,371 | $122,211,442 | $130,361,172 | $139,043,772 | $148,307,621 | $1,134,393,632 |
| Total (50%) | $168,050,626 | $179,257,754 | $191,187,729 | $203,921,659 | $217,514,738 | $229,006,742 | $244,422,885 | $260,722,344 | $278,087,544 | $296,615,243 | $2,268,787,264 |

According to the same NACDS study, pharmacy staffs spend 0.9 percent of their time dealing with third party plan issues. Although there are usually multiple pharmacy technicians on premises at a given time, for purposes of this analysis we assume that one and one-half pharmacy staff persons per pharmacy are addressing these third party plan issues.

In projecting the growth in the number of pharmacies over the next 9 years, we used data from the NACDS, ''Community Retail Pharmacy Outlets by Type of Store, 1996–2006'' (*http://www.nacds.org/user-seets/pdfs/facts_resources/2006/Retail_Outlets2006.pdf*), which showed that while there were 2 years of negative growth, the average percentage increase in the number of pharmacies was .835 percent per year. We applied this percentage growth factor to our analysis, and calculated benefits based only on the incremental growth in the number of pharmacies, assuming that existing pharmacies would have already accounted for their technician hours. We also assume that the salaries of pharmacy technician staff would rise approximately $.50 cents an hour each year, based on industry data (*http://flahec.org/hlthcarers/pharmtec.htm* and *http://www.nacds.org/wmspage.cfm?parm1=507*) showing that their median hourly earnings rose from $11.73 in 2005, to $12.74 in 2007. Starting our analysis in the year 2010, we project there would be 56,946 pharmacies. We assume that one and one-half full-time pharmacy staff persons per pharmacy would spend 28.08 hours per year on third party plan issues (0.9 percent × 3,140). The hourly wage for one and one-half persons is $21.36 based on a per-technician hourly wage projected at $14.24 (1.5 × $14.24=$21.36) for the year 2010. This 2010 hourly wage is based upon the current average hourly wage of $12.74, increased 0.50 cents per year according to industry trend information. We calculated the 2010 hourly technician wage of $21.36 times the number of hours spent on third party plan issues, 28.08, times the number of pharmacies, 56,946 for a total of $34,155,573 ($21.36 × 28.08 × 56,946). Once again, we recognize that all call backs and inquiries would not be entirely eliminated. Therefore, we conservatively estimate that 25 percent of the pharmacy staff's time spent on third party plan questions could be eliminated, for a total 10 year productivity savings of $98 million to $196 million.

TABLE 22—PHARMACY TECHNICIAN STAFF PRODUCTIVITY SAVINGS FROM VERSION D.0

| Year | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No. of Pharmacies | 56,946 | 57,421 | 57,900 | 58,383 | 58,870 | 59,361 | 59,856 | 60,355 | 60,858 | 61,366 | |
| Incremental No. of Pharmacies | | 475 | 479 | 483 | 487 | 491 | 495 | 499 | 503 | 508 | |
| Technician Hourly Wage (×1.5 techs.) | $21.36 | $21.86 | $22.36 | $22.86 | $23.36 | $23.86 | $24.36 | $24.86 | $25.36 | $25.86 | |
| Hours (28.080) × Wages × No. of Pharmacies | $34,155,573 | $35,246,664 | $36,353,604 | $37,476,561 | $38,615,706 | $39,771,205 | $40,943,228 | $42,131,942 | $43,337,517 | $44,560,847 | $392,592,847 |
| Total (25%) | $8,538,893 | $8,811,666 | $9,088,401 | $9,369,140 | $9,653,926 | $9,942,801 | $10,235,807 | $10,532,986 | $10,834,379 | $11,140,212 | $98,148,212 |
| Total (50%) | $17,077,787 | $17,623,332 | $18,176,802 | $18,738,281 | $19,307,853 | $19,885,603 | $20,471,614 | $21,065,971 | $21,668,759 | $22,280,424 | $196,296,424 |

Health Plans and PBMs

We assume that if pharmacists and technicians realize productivity savings as a result of the use of Version D.0, then conversely, health plans and PBMs would realize commensurate savings though a reduction in pharmacist and technician calls to customer service representatives at health care plans and PBMs.

Using the previous assumptions, we again estimate the annual salary of a typical plan/PBM customer service representative at $40,000, or approximately $19.23 per hour. If pharmacists spend a total of 22.88 hours per year on the phone making third party payer inquiries, we estimate that a customer service representative would spend the same amount of time on the phone answering the pharmacists' third party inquiries. At $19.23 an hour, that would equate to savings of $440 per customer service representative. Additionally, if pharmacy technicians each spend 28.08 hours each year on the phone making third party payer inquiries, this would equate to $540 per customer service representative, for a total savings of $980 per customer service representative. If we apply a conservative benefit assumption of 25 percent, this would equate to productivity savings of $245 per customer service representative.

We have no knowledge of the number of customer service representatives employed by plans and PBMs, and therefore cannot draw any quantitative conclusions from the above analysis. We assume that, even taking a conservative approach by estimating the benefit at 25 percent as we did for the pharmacists and technicians, plans and PBMs would greatly benefit from productivity savings among their customer service representatives in avoided calls from pharmacists and technicians regarding third party payer issues.

We also assume that if pharmacies are realizing savings through avoided audits and returned payments, plans are also receiving a commensurate benefit, but we have no data from industry to support this assumption. We solicit industry and interested stakeholder comments on these benefit assumptions.

With respect to benefits related to implementing Version 5010, we described the benefits for all providers, including pharmacy providers, in the assumptions section of this analysis (better standards and decreased manual effort). We identified the largest benefits for pharmacies in the content requirements in the 835 standard (required fields versus situational or optional fields) and improvements in the specificity of the business rules which will minimize multiple interpretations of the guides. These enhancements will help to reduce manual interventions needed to resolve transaction issues. For example, Version 4010/4010A does not provide instructions for reconciling payments. The new Front Matter section in Version 5010 explicitly details how this information is to be reported in the summary section of the remittance advice. Thus, benefits and savings would accrue through better standards. For this savings calculation, we use the same formula as for other provider cost savings—multiplying the savings from reduced manual intervention by the number of claims and remittance advice transactions that would be affected by the improvements. Savings due to better standards (837 and 835) is estimated to be in the range of $20 million to $27 million.

TABLE 23—COST SAVINGS FOR PHARMACIES DUE TO BETTER STANDARDS FOR VERSION 5010

[In millions]

| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Decrease in phone calls | ..... | ..... | .77 | .80 | .83 | .86 | .90 | .93 | .97 | 1.01 | ..... |
| Time to process call—6 minutes | 0 | 0 | $2 | $2 | $2 | $2 | $3 | $3 | $3 | $3 | $20 |
| Cost per call—$.48/minute | 0 | 0 | $3 | $3 | $3 | $3 | $3 | $4 | $4 | $4 | $27 |

Summary of Version D.0 and Version 5010 for Pharmacy Costs and Benefits

Costs would be incurred by pharmacy chains, independent pharmacies and PBMs in the migration from Version 5.1 to Version D.0. Benefits resulting from avoided audits and incorrect payments, and pharmacist and pharmacy technician productivity savings would accrue to pharmacy chains and independent pharmacies.

TABLE 24—COST BENEFIT SUMMARY FOR PHARMACIES IN MILLIONS FOR VERSION D.0 AND VERSION 5010

| | Minimum | Maximum |
|---|---|---|
| Costs (Chains and independents): | | |
| D.0 Pharmacy Chains Systems Implementation | $18 | $38 |
| D.0 Independent Pharmacies Maintenance Fees | 540 | 1,080 |
| D.0 PBM Programming | 8.6 | 10.6 |
| 5010 System Implementation | 58 | 114 |
| 5010 Transition | 10 | 20 |
| Total Costs | 95.14 | 183.6 |
| Benefits: | | |
| D.0 Pharmacist Productivity Savings | 1,134 | 2,268 |
| D.0 Pharmacy Technician Productivity Savings | 98 | 196 |
| D.0 Avoided Audits and Accurate Payments | 190 | 380 |
| 5010 Operational Savings—better standards | 20 | 27 |
| Total Benefits | 1,442 | 2,871 |
| Net Benefits | 1,346 | 2,870 |

3. Version 3.0

*A. Introduction*

All State Medicaid programs or their business associates that conduct Medicaid pharmacy subrogation transactions for pharmacy claims would be required to use the NCPDP Medicaid Subrogation Standard, Version 3.0 when billing third party payers that may be legally responsible for payment.

Based upon industry analysis and current usage, we have determined that adopting a standard for the subrogation transaction would result in one-time conversion costs for Medicaid State agencies, or their business associates, as well as the third party payers of Medicaid claims. This includes primarily pharmacy benefit managers (PBMs) and claims processors as well as medical health plans that process their claims in house. Some third party payers would incur system upgrade costs directly and others would incur them in the form of a fee paid to a contractor. We project that the accrued savings that would result from the administrative simplification of adopting a HIPAA standard for Medicaid pharmacy subrogation would be ongoing and offset any immediate expenditures.

*B. Current Medicaid Claims Processing Environment*

Approximately 37 States are currently billing a major portion of their Medicaid pharmacy subrogation claims electronically. At the time of this impact analysis, 33 of the 37 States were using a contingency fee contractor to bill their claims. This means that these States have hired a contractor to seek reimbursement from third parties and the contractor keeps a portion of the recoveries. The other four States were billing electronically without the use of a contractor. The remaining 14 States were billing primarily all of their Medicaid pharmacy subrogation claims on paper.

It is important to note that since some payers currently require the use of their own unique billing format, States and contractors with electronic billing capability have found it necessary to bill a substantial amount of subrogation claims on paper.

In addition, due to the current challenges of having to use various formats to meet the needs of different payers, some States, on occasion, recoup the subrogation monies directly from pharmacy providers, and the providers are responsible for billing the payers. The impact on pharmacy providers for implementing the NCPDP subrogation format is discussed in section D of this proposed rule.

*C. Impact Analysis on State Medicaid Programs*

The current Version 2.0 for standard Medicaid pharmacy subrogation, with some modifications to accommodate various third party payers, is being widely used. Therefore, some of the costs referenced in this impact analysis have already been absorbed.

The costs for States that currently bill electronically to upgrade their systems to Version 3.0 for Medicaid subrogation transactions, and to transition from paper Medicaid subrogation claims to electronic Version 3.0, would be outweighed by the benefits accrued to States. The following sections provide details to support this conclusion. We invite public comments on this conclusion.

1. Impact on States That Use a Contingency Fee Contractor

For the 33 States that contract out their Medicaid pharmacy subrogation billing processes, there would be no direct costs. Contingency fee contractors generally keep a percentage, from 6 percent to 15 percent, of the monies they recover from third parties. It is expected that these contractors would absorb the upfront costs. If the standard is adopted, we project that reimbursement to States would increase proportionally to a projected increase in volume of electronic claims, and as a result, the contractors would recover their cost on the back-end, as they would be recouping additional contingency fees based on the volumes.

Our estimates are based on the assumption that virtually all paper subrogation claims would be converted to electronic transactions because currently, some States only conduct subrogation on paper. With the adoption of Version 3.0 as a HIPAA standard, all States (or their contractors) will be required to utilize Version 3.0 when transmitting Medicaid subrogation claims to plans or payers.

2. Impact on States Converting From Paper

The total costs and benefits to the Federal government and State Medicaid programs are arrayed in Tables 24a and 24b at the end of this section.

a. Cost of Development

The typical steps to be taken in the implementation of the Version 3.0 include:

- Completing an analysis to identify gaps and weaknesses in existing process.
- Participating in internal meetings for project management and control.
- Completing documentation requirements necessary for project management.
- Providing translator training to development staff.
- Completing new translator maps for both the outgoing NCPDP claim and the returning NCPDP response files.
- Completing legacy system changes to accommodate the NCPDP transactions.
- Completing acceptance testing.

Since States have already made the necessary investments in developing electronic transaction capabilities to meet HIPAA mandates and they anticipate upgrading their systems in order to adopt the NCPDP D.0 standard for processing claims, we expect that additional infrastructure costs would be relatively small. Costs would be significantly reduced because the Medicaid subrogation standard Version 3.0 utilizes the data elements in, and operates in conjunction with, the version D.0 claim standard.

We captured data from the State of Illinois, which recently adopted Version 2.0 for pharmacy subrogation as a stand-alone systems upgrade. The cost for development was estimated at $220,000 for staff and mainframe systems. This figure does not include costs on the Local Area Network (LAN) where the translator development and testing occurred, or connectivity setup costs performed by another agency. Illinois is the only state that has recently converted to Version 2.0 and was able to provide cost data. Alabama is in the process of converting to Version 2.0, but its implementation is being done in conjunction with other system upgrades, and the costs specific to Medicaid subrogation could not be isolated.

Since we believe it is unlikely that a State would choose to use the Medicaid pharmacy subrogation standard as a stand-alone upgrade, but instead would implement it in conjunction with Version D.0, we project the cost to be lower. Therefore, we would expect the cost of adopting the Medicaid subrogation standard in conjunction with adopting the Version D.0 to range from $50,000 to $150,000 per State. The State would be responsible for 10 percent of the $50,000 to $150,000 per State, and the Federal government would reimburse the State 90 percent of the design, development, and installation costs related to changes in their Medicaid Management Information Systems (MMIS).

Of the 14 States that bill paper, we project that seven would incur

development costs in order to conduct their own billing and the other seven would hire a contingency fee contractor to conduct their billing.

However, since we have received a limited amount of data, we solicit comments from States.

b. Costs of Adopting and Implementing Trading Partner Agreements (TPAs) With Third Party Payers

Once a State has a system in place to process pharmacy claims using the Medicaid subrogation standard, the State typically enters into ''Trading Partner Agreements'' with other payers in order to conduct subrogation electronically. This involves—

- Outreach activities.
- Meetings to assure that the strategy developed will accomplish a successful implementation.
- Connectivity for file transfers and to mitigate the values in various fields in outgoing NCPDP claim transactions and the returning NCPDP response transaction.
- Modifications to accommodate the needs in the translator maps and legacy systems.
- Acceptance testing and deployment scheduling.

According to the AHIP, there are four national PBMs that process about 75 percent of all prescriptions dispensed annually, and there are a small handful of specialized PBMs. Based on information provided by States and business associates, we expect that approximately forty (40) third party payers, primarily PBMs and claims processors as well as a few large health plans that process claims in-house, would be affected.

Based on estimates from some at least two States (Illinois and Alabama) that have recently, or are in the process of, billing electronically, the cost to adopt and implement their first trading partner agreements are estimated to range from $14,000 to $20,000. We believe that as States and payers gain experience in negotiating these agreements and the number of these agreements increases, the cost would be significantly reduced. Therefore, we estimate the cost for a State to establish and implement trading partner agreements with payers to range from $5,000 to $15,000 for each trading partner agreement. It is projected that each State would enter into a trading partner agreement with an average of 15 payers. The anticipated costs per State would range from $75,000 to $225,000. Since we believe that one half of the 14 States would hire a contractor, the costs for the other seven States to adopt a trading partner agreement with 15 plans would range from $525,000 to $1.6 million. The State would be responsible for 50 percent of the cost since the Federal government reimburses States 50 percent of their administrative costs, related to the proper and efficient administration of the Medicaid program.

3. Impact on States That Bill Electronically (Without the Use of a Contingency Fee Contractor)

a. Cost of Development

For the four States that are currently conducting pharmacy subrogation transactions electronically, the changes would be minimal and the cost impact would be much less than for the States that currently bill paper to convert to Version 3.0.

b. Costs of Adopting and Implementing Trading Partner Agreements With Third Party Payers

The cost to adopt and implement a trading partner agreement would be the same: $5,000 to $15,000, for these States as it would be for the States that are converting from paper to electronic billing. The only difference is that these States would have already established trading partner agreements with some payers and would be setting up trading partner agreements with additional payers. We would estimate that these four States would each establish trading partner agreements with an additional 12 payers for a total cost ranging from $20,000 to $60,000.

4. Medicaid Savings

We have determined that the accrued savings to States would outweigh the costs based on the fact that after implementation, Medicaid agencies would no longer have to keep track of and use various electronic formats for different payers. This would simplify their billing systems and processes and reduce administrative expenses.

Based on our data, we estimate the total number of paper Medicaid pharmacy subrogation claims to be between 2.5 and 3.4 million annually. We are seeing a trend where States that have historically ''paid and chased'' pharmacy claims are implementing cost avoidance systems. By doing so, States are requiring pharmacy providers to bill third party payers before billing Medicaid, thereby reducing the need for Medicaid subrogation. We expect this trend to continue.

According to a study by Milliman in 2006, and referenced by the American Medical Association (AMA) on their Web site, electronic claims can save an average of $3.73 per clean claim filed. Based on this study, the Medicaid program stands to save an estimated $12.7 million annually once Version 3.0 is fully implemented, beginning in the third year of implementation. For the third and fourth year when Version 3.0 is fully implemented, the administrative savings will be distributed equally between the States and the Federal government. The total savings over the 10 year period is estimated to be $17.6 million. After the fourth year, savings will essentially cease as States transition to routine use of the standard.

Rather than using the assumptions that the AHIP study referenced earlier in this analysis for Version 5010, we use the study referenced by the AMA because it identifies savings for the entity that generates the claim, which, in the case of subrogation, is the Medicaid agency. We believe that this $3.73 savings estimate represents the savings potential of overhead, labor, and other indirect benefits applicable to Medicaid. The AMA report referencing the study can be found at: *http://www.ama-assn.org/ama/pub/category/18185.html.* Select ''Follow the Claim'' to be taken to the report. The study itself can be found at *http://transact.webmd.com/milliman_study.pdf.*

The savings represents both State agencies and the Federal government, as the Federal government would share 50 percent of any administrative savings. We did not receive specific data from Medicaid agencies on subrogation savings, and therefore welcome industry input and data to validate or enhance these assumptions during the public comment period.

In addition to the administrative savings, we anticipate that Medicaid would realize programmatic savings resulting from an increase in claims paid due to increased efficiency in electronic claims processing using Version 3.0. We do not have sufficient data to accurately project the actual savings; therefore, we solicit public comments.

We do not anticipate a significant change in volume in subrogation claims in future years. Even though the trend shows an increase in prescriptions overall, States are becoming more efficient in avoiding payment on the front-end which results in fewer subrogation claims on the backend.

*D. Impact on Medicaid Pharmacy Providers*

In situations where Medicaid has been unable to successfully bill third parties, due to the current challenges of having to use various formats to meet the needs of different payers, States sometimes recoup the subrogation monies from pharmacy providers and it

is left up to the providers to bill the appropriate third party payers. Use of a standard format should enable States to bill third parties successfully and therefore help to alleviate this administrative burden on providers. We do not estimate this practice to be widespread and therefore do not account for it in this impact analysis.

*E. Impact on Third Party Payers (Includes Plan Sponsors, Pharmacy Benefit Managers (PBMs), Prescription Drug Plans (PDPs) and Claims Processors)*

Insurers, employers and managed care plans are sometimes referred to as plan sponsors. A majority of plan sponsors use a PBM to manage prescription drug coverage and handle claims processing. Some plan sponsors administer the prescription coverage in-house, but contract with a claims processor just to handle claims adjudication. A few of the larger plan sponsors perform their own claims processing. The total costs and benefits to third party payers are arrayed in Table 25a and Table 25b at the end of this section.

1. Impact on Plan Sponsors That Use a PBM or Claim Processor

As mentioned earlier, there are four PBMs that handle about 75 percent of all prescription orders dispensed annually in the United States, and a handful of specialized PBMs. These PBMs have contracts with hundreds of plan sponsors. We estimate that about 10 PBMs and processors are already accepting the Version 2.0 subrogation standard from States or their contractors.

For the majority of plan sponsors that contract out their claims adjudication to PBMs or claims processors, the costs of implementing Version 3.0 and establishing trading partner agreements would be minimal. The PBMs and claims processors would likely absorb the upfront cost and recover their expenses from their hundreds of plan sponsors on the back-end. This could be done by charging a flat fee or by increasing the amount of the transaction fees that are charged to plans sponsors for processing Medicaid claims. These fees would be offset for plan sponsors since they would no longer be paying higher fees for processing paper claims.

2. Impact on Plan Sponsors That Do Not Use a PBM or Claim Processor

There may be a few large payers, primarily insurers and managed care organizations that administer their own claims adjudication. These payers would have already made the necessary investments in developing electronic capabilities to meet HIPAA mandates. We anticipate that the payers would upgrade their systems in order to adopt the Version D.0 for processing claims from providers. Version 3.0 utilizes a number of the data elements found in Version D.0. Therefore, we expect that additional infrastructure costs would be relatively small.

a. Costs of Development

We estimate the development costs to individual payers that would need to implement Version 3.0 for the Medicaid pharmacy subrogation standard, Version 3.0 to be similar to the cost for State Medicaid programs which would be in the $50,000 to $150,000 range. We estimate that there are about 20 payers that do not contract with a PBM and they would need to upgrade their systems at a total cost of $1 to $3 million. However, since we do not have sufficient data to accurately project actual costs, we solicit comments from third party payers.

b. Costs of Adopting and Implementing Trading Partner Agreements With States

We estimate the plan sponsor's costs of adopting and implementing a trading partner agreement with a State would be similar to the cost estimated for State Medicaid programs, which would range from $5,000 to $15,000 per agreement.

We anticipate that approximately 40 States would utilize a contingency fee contractor, therefore, the process for setting up trading partner agreements with a contractor versus 40 individual States would be streamlined and much less costly. We estimate the cost per plan sponsor for establishing agreements to include all of the States to range from $60,000 to $180,000. However, since we do not have sufficient data, we solicit comments from plan sponsors.

In addition to the administrative costs, we anticipate that the increased efficiency in claims processing would result in payers paying out more for Medicaid subrogation claims that would have otherwise been denied. We do not have sufficient data to estimate the potential costs. We invite public comments on the costs for the increase in Medicaid subrogation adjudicated claims.

3. Savings Impact

Savings from the application of electronically conducting subrogation may vary, but even small savings per claim can have a large impact on administrative costs when dealing with large claim volumes.

According to a survey conducted by AHIP in May 2006, electronic claims are roughly half the cost of paper claims. The average cost of processing a clean electronic claim was 85 cents, nearly half the $1.58 cost of processing a clean paper claim. Pended claims requiring manual or other review cost $2.05 on average per claim to process.

We do not have data for the States to distinguish the proportion of clean claims versus those that require manual review. Using the assumption that 50 percent of claims require manual review, the savings of converting 3.4 million paper claims to electronic transmission would be $3.3 million. Use of the standard would provide a source of ongoing savings for the industry.

We do not anticipate a significant change in volume in subrogation claims in future years. Even though the trend shows an increase in prescriptions overall, States are becoming more efficient in avoiding payment on the front end which results in fewer subrogation claims on the backend. The following tables (Table 25a/b and 26a/b) show the estimated State, Federal and payer costs and benefits for implementing Version 3.0.

TABLE 25a—ESTIMATED STATE AND FEDERAL COSTS IN MILLIONS—FOR YEARS 2010–2019 FOR IMPLEMENTATION OF VERSION 3.0

| Cost type | Government plans | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Development | Federal—Minimum | $.158 | $.158 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | $.316 |
| | Federal—Maximum | .472 | .472 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | .944 |
| | State—Minimum | .018 | .018 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | .036 |
| | State—Maximum | .052 | .052 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | .104 |
| Trading Partner Agreements | Federal—Minimum | .191 | .191 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | .382 |
| | Federal—Maximum | .580 | .580 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1.160 |
| | State—Minimum | .191 | .191 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | .382 |
| | State—Maximum | .580 | .580 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1.160 |

TABLE 25b—ESTIMATED STATE AND FEDERAL BENEFITS—IN MILLIONS—FOR YEARS 2010–2019 FOR IMPLEMENTATION OF VERSION 3.0

| Benefit type | Government plans | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| General Benefit | Federal—Minimum | $1.16 | $2.33 | $4.7 | $4.7 | $0 | $0 | $0 | $0 | $0 | $0 | $12.9 |
| | Federal—Maximum | 1.59 | 3.17 | 6.4 | 6.4 | 0 | 0 | 0 | 0 | 0 | 0 | 17.59 |
| | State—Minimum | 1.16 | 2.33 | 4.7 | 4.7 | 0 | 0 | 0 | 0 | 0 | 0 | 12.9 |
| | State—Maximum | 1.59 | 3.17 | 6.4 | 6.4 | 0 | 0 | 0 | 0 | 0 | 0 | 17.59 |

TABLE 26a—ESTIMATED PAYER COSTS—IN MILLIONS—FOR YEARS 2010–2019—FOR IMPLEMENTATION OF VERSION 3.0

| | | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Costs: | | | | | | | | | | | | |
| Development | Payer—Minimum | $.500 | $.500 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1 |
| | Payer—Maximum | 1.5 | 1.5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| Trading Partner Agreements | Payer—Minimum | 1.2 | 1.2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2.4 |
| | Payer—Maximum | 3.6 | 3.6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7.2 |

TABLE 26b—ESTIMATED PAYER BENEFITS—IN MILLIONS—FOR YEARS 2010–2019—FROM IMPLEMENTATION OF VERSION 3.0

| General Savings | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Payer—Minimum | $.600 | $1.24 | $2.475 | $2.475 | $0 | $0 | $0 | $0 | $0 | $0 | $6.79 |
| Payer—Maximum | .800 | 1.65 | 3.3 | 3.3 | 0 | 0 | 0 | 0 | 0 | 0 | 9.05 |

*D. Alternatives Considered*

We considered a number of alternatives for each of the proposals and eliminated each of them in favor of the recommendations in this proposed rule.

For each of the three sections of this proposed rule, one alternative considered was to make no changes to the status quo. That would mean that the current versions of X12N (Version 4010/4010A) and NCPDP (Version 5.1) would continue to be the adopted standards for HIPAA transactions, and that a standard would not be adopted for Medicaid subrogation transactions. In each case we rejected this alternative because such a decision would not only continue to hamper adoption of EDI for all covered entities, it would potentially preclude the industry from implementing the ICD–10 code set for the HIPAA administrative transactions. We note that Version 4010/4010A cannot accommodate ICD–10 codes, while Version 5010 can. Keeping version 4010/4010A as the standard would result in impeding the expansion of EDI.

Moreover, if we continue to use Version 4010/4010A, the industry would continue to use a number of workarounds to be able to use the standards and would continue the reliance on companion guides, which is counter to the concept of standardization. The NCPDP testified to the NCVHS in July 2007 that adopting Version 5010 is a cost-saving measure that would improve the efficiency of those already using Version 4010/4010A, and encourage others to adopt and use more of the standards.

For Version D.0, we considered not adopting this modification and leaving intact the requirement to use Version 5.1. However, we rejected this alternative because we believe Version 5.1 has become outdated and is not efficient or effective in processing Medicare Part D prescription drug benefit program claims. We also considered waiting to adopt Version D.0 at a later date, but felt it was important to advance the use of Version D.0 to encourage standards adoption by the industry and enable the industry to reap the improved benefits of the standard as soon as possible.

For Medicaid subrogation transactions, we considered allowing the industry to continue using the proprietary formats currently in use. However, this would not have the desired effect of increasing the use of EDI, or of moving the industry towards a uniform standard.

With respect to the proposed adoption of the Version 3.0 Medicaid subrogation standard, we considered the following alternatives:

- Not adopt Version 3.0 and permit the industry to continue using Version 2.0 proprietary electronic and paper formats. This would require the Medicaid agencies to support multiple formats in order to bill pharmacy claims to third party payers. The current multiplicity of claim formats creates a significant barrier to Medicaid agencies being able to comply with Federal law in ensuring that Medicaid is the payer of last resort. Using the Version 2.0 standard would require a number of workarounds to be compatible with version D.0 or other NCPDP claim standards except for Version 5.1.
- The NCPDP testified to the NCVHS in January 2008 that adopting Version 3.0 for Medicaid subrogation is a cost-saving tool and would improve the efficiency of those already using Version 2.0. It also would make it more feasible for other states and payers to invest in system upgrades to accommodate one specific standard. The NCVHS did not recommend any viable alternatives to Version 3.0 for handling Medicaid subrogation transactions because they purported that Version 3.0 adequately addresses the business need for Medicaid agencies and industry partners.

Summary of Costs and Benefits for This Proposed Rule

The final tables, 27a and 27b, are the compilation of the minimum and maximum costs and benefits for all of the standards being proposed in this NPRM.

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**Table 27a: Estimated minimum and maximum costs – in Millions* – for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0**

| Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Cost Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| **5010 Implementation Costs** | Hospitals - Minimum | $396 | $396 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ 792 |
| | Hospitals - Maximum | $792 | $792 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1,584 |
| | Physicians - Minimum | $185 | $185 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $370 |
| | Physicians - Maximum | $370 | $370 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $740 |
| | Dentists - Minimum | $127 | $127 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $254 |
| | Dentists - Maximum | $254 | $254 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $508 |
| | Pharmacy - Minimum | $29 | $29 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $58 |
| | Pharmacy - Maximum | $57 | $57 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $114 |
| | Private Health Plans - Minimum | 1,532 | $1,532 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $3,064 |
| | Private Health Plans - Maximum | 3,064 | $3,064 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $6,128 |
| | Government Health plans - Minimum | $107 | $107 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $214 |
| | Government Health Plans - Maximum | $205 | $204 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $409 |

| Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Cost Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| | Clearinghouses - Minimum | $17 | $16 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $33 |
| | Clearinghouses - Maximum | $21 | $20 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $41 |
| **5010 Transition Costs** | Hospital - Minimum | $0 | $0 | $140 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $140 |
| | Hospitals - Maximum | $0 | $0 | $280 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $280 |
| | Physicians - Minimum | $0 | $0 | $65 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $65 |
| | Physicians - Maximum | $0 | $0 | $131 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $131 |
| | Dentists - Minimum | $0 | $0 | $45 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $45 |
| | Dentists - Maximum | $0 | $0 | $90 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $90 |
| | Pharmacy - Minimum | $0 | $0 | $10 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $10 |
| | Pharmacy - Maximum | $0 | $0 | $20 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $20 |
| | Private Health Plan - Minimum | $0 | $0 | $541 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $541 |
| | Private Health Plan - Maximum | $0 | $0 | $1,081 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1,081 |
| | Government Health Plan - Minimum | $0 | $0 | $38 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $38 |
| | Government Health Plan - Maximum | $0 | $0 | $72 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $72 |
| | Clearing-house - Minimum | $0 | $0 | $3 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $3 |
| | Clearing-house - Maximum | $0 | $0 | $4 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $4 |
| **Medicaid Subrogation - Development** | Federal - Minimum | $.158 | $.158 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ .316 |
| | Federal - Maximum | $.472 | $.472 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ .944 |
| | State - Minimum | .018 | $ .018 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ .036 |
| | State - Maximum | .052 | $ .052 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ .104 |
| | Payers - Minimum | $.500 | $.500 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1 |
| | Payers - Maximum | $1.5 | $1.5 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $3 |
| **Medicaid Subrogation - Trading Partner** | Federal - Minimum | $.191 | $.191 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $.382 |

| Estimated minimum and maximum costs - in Millions* - for years 2010 through 2019 for Implementation of Versions 5010, D.0 and 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Cost Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| **Agreements** | | | | | | | | | | | | |
| | Federal - Maximum | $.580 | $.580 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1.160 |
| | State - Minimum | $.191 | $.191 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $ .382 |
| | State - Maximum | $.580 | $.580 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1.160 |
| | Payers - Minimum | $1.2 | $1.2 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $2.4 |
| | Payers - Maximum | $3.6 | $3.6 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $7.2 |
| **D.0 - Pharmacy Chains Systems Implementation** | Pharmacy - Minimum | $9 | $9 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $18 |
| | Pharmacy - Maximum | $19 | $19 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $38 |
| **Independent Pharmacy Maintenance Fees** | Pharmacy - Minimum | $.270 | $.270 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $.540 |
| | Pharmacy - Maximum | $.540 | $.540 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1.080 |
| **PBM Programming** | PBM-Minimum | $4 | $4 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $8 |
| | PBM-Maximum | $5 | $5 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $10 |
| **Total - Minimum** | | **$2,409** | **$2,406** | **$842** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$5,656** |
| **Total - Maximum** | | **$4,793** | **$4,786** | **$1,678** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$11,257** |

**Table 27b: Estimated minimum and maximum benefits – in Millions* – for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0**

| Estimated minimum and maximum benefits – in Millions* – for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Benefit Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| **5010 Operational Savings – Better Standards** | Hospitals - Minimum | $0 | $0 | $44 | $46 | $47 | $49 | $51 | $53 | $55 | $58 | $403 |
| | Hospitals – Maximum | $0 | $0 | $119 | $124 | $129 | $134 | $139 | $145 | $150 | $156 | $1,095 |
| | Physicians - Minimum | $0 | $0 | $175 | $182 | $189 | $197 | $205 | $213 | $221 | $230 | $1,612 |
| | Physicians - Maximum | $0 | $0 | $475 | $494 | $514 | $535 | $556 | $578 | $601 | $625 | $4,378 |
| | Dentists - Minimum | $0 | $0 | $30 | $31 | $32 | $33 | $35 | $36 | $38 | $39 | $274 |
| | Dentists - Maximum | $0 | $0 | $76 | $79 | $82 | $85 | $89 | $92 | $96 | $100 | $699 |
| | Pharmacy - Minimum | $0 | $0 | $2 | $2 | $2 | $2 | $3 | $3 | $3 | $3 | $20 |
| | Pharmacy - Maximum | $0 | $0 | $3 | $3 | $3 | $3 | $3 | $4 | $4 | $4 | $27 |
| | Private and Govt. Health Plans - Minimum | $0 | $0 | $169 | $176 | $183 | $191 | $198 | $206 | $214 | $223 | $1,560 |
| | Private and Govt. Health Plans - Maximum | $0 | $0 | $453 | $471 | $490 | $510 | $530 | $551 | $573 | $596 | $4,174 |
| | Clearinghouses - Minimum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Clearinghouses - Maximum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| **5010 Cost Savings – Increase in transactions** | Hospital - Minimum | $0 | $0 | $2 | $4 | $6 | $8 | $11 | $11 | $12 | $12 | $67 |
| | Hospital - Maximum | $0 | $0 | $6 | $13 | $20 | $28 | $36 | $37 | $39 | $40 | $219 |
| | Physicians – Minimum | $0 | $0 | $8 | $16 | $24 | $34 | $44 | $46 | $48 | $50 | $270 |
| | Physicians - Maximum | $0 | $0 | $25 | $51 | $80 | $110 | $143 | $149 | $155 | $161 | $874 |
| | Dentists – Minimum | $0 | $0 | $1 | $3 | $4 | $6 | $7 | $8 | $8 | $8 | $45 |
| | Dentists - | $0 | $0 | $2 | $3 | $5 | $7 | $9 | $10 | $10 | $10 | $56 |

| Estimated minimum and maximum benefits - in Millions* - for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Benefit Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| | Maximum | | | | | | | | | | | |
| | Pharmacy - Minimum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Pharmacy - Maximum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Private and Govt. Health Plans - Minimum | $0 | $0 | $9 | $13 | $17 | $18 | $18 | $19 | $20 | $21 | $135 |
| | Private and Govt. Health Plans - Maximum | $0 | $0 | $24 | $33 | $43 | $44 | $46 | $48 | $50 | $52 | $340 |
| | Clearinghouses - Minimum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Clearinghouses - Maximum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| **5010 Operational Savings - increase in auxiliary claim transactions** | Hospital - Minimum | $0 | $0 | $35 | $74 | $117 | $165 | $217 | $226 | $235 | $245 | $1,314 |
| | Hospital - Maximum | $0 | $0 | $90 | $191 | $303 | $428 | $566 | $588 | $612 | $636 | $3,414 |
| | Physicians - Minimum | $0 | $0 | $139 | $294 | $467 | $658 | $870 | $904 | $941 | $978 | $5,251 |
| | Physicians - Maximum | $0 | $0 | $361 | $765 | $1213 | $1711 | $2261 | $2352 | $2446 | $2543 | $13,652 |
| | Dentists - Minimum | $0 | $0 | $24 | $50 | $79 | $111 | $147 | $153 | $159 | $166 | $889 |
| | Dentists - Maximum | $0 | $0 | $58 | $122 | $193 | $272 | $360 | $374 | $389 | $405 | $2,173 |
| | Pharmacy - Minimum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Pharmacy - Maximum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| | Private and Government Health Plans - Minimum | $0 | $0 | $141 | $299 | $474 | $669 | $885 | $920 | $957 | $995 | $5,340 |
| | Private and Government Health Plans - Maximum | $0 | $0 | $367 | $777 | $1233 | $1740 | $2300 | $2392 | $2488 | $2587 | $13,885 |
| | Clearinghouse - Minimum | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| **Medicaid Subrogation - General Benefit** | Federal - Minimum | $1.16 | $2.33 | $4.7 | $4.7 | $0 | $0 | $0 | $0 | $0 | $0 | $12.9 |
| | Federal - Maximum | $1.59 | $3.20 | $6.4 | $6.4 | $0 | $0 | $0 | $0 | $0 | $0 | $17.6 |
| | State - Minimum | $1.16 | $2.33 | $4.7 | $4.7 | $0 | $0 | $0 | $0 | $0 | $0 | $12.9 |
| | State - Maximum | $1.59 | $3.20 | $6.4 | $6.4 | $0 | $0 | $0 | $0 | $0 | $0 | $17.6 |
| | Payer - Minimum | $.600 | $1.24 | $2.475 | $2.475 | $0 | $0 | $0 | $0 | $0 | $0 | $6.8 |

| Estimated minimum and maximum benefits - in Millions* - for years 2010 through 2019 for Implementation of Version 5010. D.0 and Version 3.0 | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Benefit Type** | **Industry** | **2010** | **2011** | **2012** | **2013** | **2014** | **2015** | **2016** | **2017** | **2018** | **2019** | **Total** |
| | Payer - Maximum | $.800 | $1.65 | $3.3 | $3.3 | $0 | $0 | $0 | $0 | $0 | $0 | $9.05 |
| **D.0 Pharmacist Productivity** | Pharmacist -Minimum | $84 | $90 | $96 | $102 | $109 | $115 | $122 | $130 | $139 | $148 | $1,135 |
| | Pharmacist - Maximum | $166 | $179 | $191 | $203 | $217 | $229 | $244 | $260 | $278 | $296 | $2,268 |
| **D.0 Pharmacy Technician Productivity Savings** | Pharmacy - Minimum | $9 | $9 | $9 | $9 | $10 | $10 | $10 | $10 | $11 | $11 | $98 |
| | Pharmacy - Maximum | $17 | $18 | $18 | $19 | $19 | $20 | $20 | $21 | $22 | $22 | $196 |
| **D.0 Avoided Audits and Accurate Payments** | Pharmacy - Minimum | $19 | $19 | $19 | $19 | $19 | $19 | $19 | $19 | $19 | $19 | $190 |
| | Pharmacy - Maximum | $38 | $38 | $38 | $38 | $38 | $38 | $38 | $38 | $38 | $38 | $380 |
| **TOTAL - Minimum** | | $115 | $124 | $915 | $1,332 | $1,779 | $2,285 | $2,842 | $2,957 | $3,080 | $3,206 | $18,635 |
| **TOTAL - Maximum** | | $225 | $243 | $2,332 | $3,402 | $4,492 | $5,894 | $7,340 | $7,639 | $7,951 | $8,271 | $47,779 |

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*E. Accounting Statement and Table*

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an Accounting Statement. This statement must state that we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized Benefits and non-budgetary costs are presented as discounted flows using three percent and seven percent factors.

TABLE 28—ACCOUNTING STATEMENT

[Accounting Statement: Classification of Estimated Expenditures, from FY 2010 to FY 2019 (in millions)]

| Category | Primary estimate (millions) | Minimum estimate (millions) | Maximum estimate (millions) | Source citation (RIA, preamble, etc.) |
|---|---|---|---|---|
| **Benefits** | | | | |
| Annualized Monetized benefits: | | | | |
| 7% Discount | $2,930 | $1,647 | $4,214 | RIA. |
| 3% Discount | $3,151 | $1,769 | $4,532 | RIA. |
| Qualitative (un-quantified) benefits | Wider adoption of standards due to decrease in use of companion guides; increased productivity due to decrease in manual intervention requirements. | | | |
| Benefits generated from plans to providers and pharmacies, providers to plans and pharmacies, and pharmacies to beneficiaries. | | | | |
| **Costs** | | | | |
| Annualized Monetized costs: | | | | |
| 7% Discount | $1,073 | $718 | $1,428 | RIA. |
| 3% Discount | $942 | $630 | $1,254 | RIA. |
| Qualitative (un-quantified) costs | None | None | None. | |
| Cost will be paid by health plans to contractors, programming consultants, IT staff and other outsourced entities; providers will pay costs to software vendors, trainers and other consultants. Clearinghouses will pay costs to IT staff/contractors and software developers; pharmacies will pay costs to contractors, software vendors and trainers, and government plans will pay costs to consultants, vendors and staff. | | | | |
| **Transfers** | | | | |
| Annualized monetized transfers: "on budget". | N/A | N/A | N/A. | |
| From whom to whom? | N/A | N/A | N/A. | |
| Annualized monetized transfers: "off-budget". | N/A | N/A | N/A. | |
| From whom to whom? | N/A | N/A | N/A. | |

In accordance with the provisions of Executive Order 12866, as amended, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects in 45 CFR Part 162**

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter C as set forth below:

## PART 162—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

**Authority:** Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Public Law 104–191, 110 Stat. 2021–2031, and sec. 264 of Public Law 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

## Subpart I—General Provision for Transactions

2. Revise § 162.900 to read as follows:

### § 162.900 Compliance dates for transaction standards and code sets.

(a) *Small health plans.* (1) All small health plans must comply with the applicable requirements of Subparts I through R of this part no later than October 16, 2003.

(2) All small health plans must comply with the applicable requirements of Subpart S of this part no later than [date 36 months after the effective date of the final rule].

*(b) Covered entities other than small health plans.*

(1) All covered entities other than small health plans must comply with the applicable requirements of Subparts I through R of this part no later than October 16, 2003.

(2) All covered entities other than small health plans must comply with the applicable requirements of Subpart S of this part no later than [date 24 months after the effective date of the final rule].

3. Amend § 162.920 as follows:

A. Revise the introductory text and paragraph (a) introductory text.

B. Add paragraphs (a)(10) through (a)(18).

C. Revise paragraph (b) introductory text.

D. Add paragraphs (b)(4) through (b)(6).

The revisions and additions read as follows:

### § 162.920 Availability of implementation specifications.

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, 7500 Security Boulevard, Baltimore, Maryland 21244 or 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/i br_locations.html.*

(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 Type 1 Errata) may be obtained from the Washington Publishing Company, 747 177th Lane, NE., Bellevue, WA, 98008; Telephone (425) 562–2245; and FAX (775) 239–2061. They are also available through the Internet at *http://www.wpc-edi.com/.* All ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 adopted for use under HIPAA and any corresponding addenda are available in three configurations: downloadable PDFs, PDFs shipped on CD, and bound books. A fee is charged for all implementation specifications, including Technical Reports. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

* * * * *

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 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, Washington Publishing Company, 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, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, Washington Publishing Company, 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, Washington Publishing Company, 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, Washington Publishing Company, 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, Washington Publishing Company, 005010X217, and Type 1 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, Washington Publishing Company, 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, Washington Publishing Company, 005010X212, and Type 1 Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company (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, Washington Publishing Company, 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 Medicaid subrogation transactions 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:

* * * * *

(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.

4. Revise § 162.923 paragraph (a) to read as follows:

**§ 162.923 Requirements for covered entities.**

(a) *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

5. Section 162.1102 is amended as follows:

A. Revise the introductory text to paragraph (b).

B. Add a new paragraph (c).

The revisions and additions read as follows:

**§ 162.1102 Standards for health care claims or equivalent encounter information transaction.**

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X224A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1. (Incorporated by reference in § 162.920).

(5) *Retail pharmacy supplies and professional services claims.* (i) The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920); and

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

## Subpart L—Eligibility for a Health Plan

6. Section 162.1202 is amended by—

A. Revising the introductory text to paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

**§ 162.1202 Standards for eligibility for a health plan transaction.**

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, Washington Publishing Company, 005010X279. (Incorporated by reference in § 162.920).

## Subpart M—Referral Certification and Authorization

7. Revise § 162.1301 to read as follows:

**§ 162.1301 Referral certification and authorization transaction.**

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

8. Section 162.1302 is amended by—

A. Revising the introductory text to paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

**§ 162.1302 Standards for referral certification and authorization transaction.**

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, Washington Publishing Company (005010X217), and Type 1 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, Washington Publishing Company, 005010X217E1. (Incorporated by reference in § 162.920).

## Subpart N—Health Care Claim Status

9. Revise § 162.1401 to read as follows:

**§ 162.1401 Health care claim status transaction.**

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

10. Section 162.1402 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text in paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

**§ 162.1402 Standards for health care claim status transaction.**

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, Washington Publishing Company, 005010X212, and Type 1 Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, Washington Publishing Company, 005010X212E1. (Incorporated by reference in § 162.920).

## Subpart O—Enrollment and Disenrollment in a Health Plan

11. Revise § 162.1501 to read as follows:

**§ 162.1501 Enrollment and disenrollment in a health plan transaction.**

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.

12. Section 162.1502 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

**§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.**

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, Washington Publishing Company, 005010X220 (Incorporated by reference in § 162.920).

## Subpart P—Health Care Payment and Remittance Advice

13. Section 162.1602 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

**§ 162.1602 Standards for health care payment and remittance advice transaction.**

* * * * *

(c) For the period on and after April 1, 2010: The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, Washington Publishing Company, 005010X221. (Incorporated by reference in § 162.920).

## Subpart Q—Health Plan Premium Payments

14. Section 162.1702 is amended by—

A. Removing ''on and after October 16, 2003'' and adding in its place ''from October 16, 2003 through March 31, 2010'' in the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The additions read as follows:

**§ 162.1702 Standards for health plan premium payments transaction.**

* * * * *

(c) For the period on and after April 1, 2010: 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, Washington Publishing Company, 005010X218. (Incorporated by reference in § 162.920).

## Subpart R—Coordination of Benefits

15. Section 162.1802 is amended by—

A. Revising the introductory text of paragraph (b).

B. Adding a new paragraph (c).

The revisions and additions read as follows:

**§ 162.1802 Standards for coordination of benefits information transaction.**

* * * * *

(b) For the period from October 16, 2003 through March 31, 2010:

* * * * *

(c) For the period on and after April 1, 2010:

(1) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920).

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, Washington Publishing Company, 005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X224A1. (Incorporated by reference in § 162.920).

(3) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, Washington Publishing Company, 005010X222. (Incorporated by reference in § 162.920).

(4) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, Washington Publishing Company, 005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, Washington Publishing Company, 005010X223A1. (Incorporated by reference in § 162.920).

16. Add a new Subpart S to read as follows:

**Subpart S—Medicaid Pharmacy Subrogation**

Sec.

162.1901 Medicaid pharmacy subrogation transaction.

162.1902 Standard for Medicaid pharmacy subrogation.

**§ 162.1901 Medicaid pharmacy subrogation transaction.**

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.**

The Secretary adopts 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. (Incorporated by reference at § 162.920).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 23, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: May 14, 2008.

**Michael O. Leavitt,**

*Secretary.*

**Editorial Note:** This document was received at the Office of the Federal Register on August 15, 2008.

[FR Doc. E8–19296 Filed 8–15–08; 3:55 pm]

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