

subtitle A, subchapter C, part 162 as follows:

**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 Pub. L. 104—191, 110 Stat. 2021—2031, and sec. 264 of Pub. L. 104—191, 110 Stat. 2033—2034 (42 U.S.C. 1320d—2 (note)).

2. Revise § 162.920(a)(2)(i) and (ii) to read as follows:

**§ 162.920 Availability of implementation specifications.**

- (a) \* \* \*
- (2) \* \* \*

(i) The Telecommunication Standard Implementation Guide, Version 5, Release 1, September 1999, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1302, and 162.1802.

(ii) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1302, and 162.1802.

\* \* \* \* \*

3. In § 162.1002, republish the introductory text, and revise paragraphs (c) and (f) to read as follows:

**§ 162.1002 Medical data code sets.**

The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets:

\* \* \* \* \*

(c) *National Drug Codes (NDC)*, as maintained and distributed by HHS, in collaboration with drug manufacturers, for reporting the following in retail pharmacy transactions for which standards have been adopted:

- (1) Drugs.
- (2) Biologics.

\* \* \* \* \*

(f) *The Healthcare Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services except drugs and biologics. These items include, but are not limited to, the following:

- (1) Medical supplies.
- (2) Orthotic and prosthetic devices.
- (3) Durable medical equipment.

4. In § 162.1102, republish the introductory text, and revise paragraph (a) to read as follows:

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

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

\* \* \* \* \*

5. In § 162.1202, republish the introductory text, and revise paragraph (a) to read as follows:

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

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) *Retail pharmacy drugs.* The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

\* \* \* \* \*

6. In § 162.1302, add paragraph (a) to read as follows:

**§ 162.1302 Standard for referral certification and authorization.**

\* \* \* \* \*

(a) *Retail pharmacy referral certification and authorization.* The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

(b) [Reserved]

7. Revise § 162.1602 to read as follows:

**§ 162.1602 Standard for health care payment and remittance advice.**

Dental, professional, and institutional health care claims and remittance

advice. The Secretary adopts the ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091 as the standard for the health care payment and remittance advice transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

(b) [Reserved]

8. In § 162.1802, republish the introductory text and revise paragraph (a) to read as follows:

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

The Secretary adopts the following standards for the coordination of benefits information transaction:

(a) *Retail pharmacy drug claims.* The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. The implementation specifications are available at the addresses specified in § 162.920(a)(2).

\* \* \* \* \*

CMS-0003-P  
DBB 02/22/2002 4:10 PM

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)  
Dated: March 20, 2002.

**Tommy G. Thompson,**  
*Secretary.*  
[FR Doc. 02–13614 Filed 5–24–02; 4:51 pm]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Part 162**

[CMS-0005-P]

RIN 0938-AK76

**Health Insurance Reform: Modifications to Transactions and Code Set Standards for Electronic Transactions**

**AGENCY:** Office of the Secretary, HHS.  
**ACTION:** Proposed rule.

**SUMMARY:** This rule proposes to adopt modifications to certain standards adopted in our regulations entitled “Health Insurance Reform: Standards for Electronic Transactions” published in the **Federal Register** on August 17, 2000 (65 FR 50312), which

implemented some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. The proposed modifications are a result of the Designated Standard Maintenance Organization (DSMO) process to maintain standards adopted by the Secretary and to process requests for adopting new standards or modifying adopted standards.

**DATES:** We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 1, 2002.

**ADDRESSES:** In commenting, please refer to file code CMS-0005-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS-0005-P, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

Comments may also be submitted electronically to the following e-mail address: [CMS0005@cms.hhs.gov](mailto:CMS0005@cms.hhs.gov). For e-mail procedures, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Stanley Nachimson, (410) 786-6153.

**SUPPLEMENTARY INFORMATION:**

*Public Comments:* Normally, we provide a 60-day public comment period for a proposed rule; for this rule, however, there is a 30-day comment period. After publication of the Standards for Electronic Transactions final rule (65 FR 50312), we received an overwhelming response from the affected industry and industry representatives requesting that we modify the standards. The changes we are proposing already were subjected to the public DSMO process and were discussed and approved by the National Committee on Vital and Health Statistics (NCVHS) in public sessions.

Therefore, we believe it is unnecessary to provide more than a 30-day comment period for this rule.

*Inspection of Public Comments:* Comments received timely will 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, please call (410) 786-9994.

*Electronic Comments:* We will consider all electronic comments that include the full name, postal address, and affiliation (if applicable) of the sender and are submitted to the electronic address identified in the **ADDRESSES** section of this preamble. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at 7500 Security Boulevard, Baltimore, MD 21244.

*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 can 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.access.gpo.gov/nara/index.html>.

## I. Background

### A. Legislation

The Congress included provisions to address the need for standards for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, which became

effective on August 21, 1996. Through subtitle F of title II of that statute, the Congress added to title XI of the Social Security Act (the Act) a new Part C, titled Administrative Simplification. Pub. L. 104-191 affects several titles in the United States Code. The purpose of this part is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care system in general by encouraging the development of a health information system through the establishment of standards and requirements to facilitate the electronic transmission of certain health information.

Part C of title XI consists of sections 1171 through 1179 of the Act. These sections define various terms and impose several requirements on the Secretary, health plans, health care clearinghouses, and certain health care providers.

We discussed the legislation in greater detail in the Standards for Electronic Transactions final rule (Transactions Rule) published on August 17, 2000 (65 FR 50312), and in a final rule for Privacy of Individually Identifiable Health Information (Privacy Rule) published on December 28, 2000 (65 FR 82462). Rather than repeating the discussion here, we refer the reader to those documents for further information about electronic data interchange and the statutory background.

Section 1172 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 any health information in electronic form in connection with a transaction covered by 45 CFR part 162.

In general, section 1172 of the Act requires any standard adopted by the Secretary under this part to be a standard that has been developed, adopted, or modified by a standard setting organization (SSO). The Secretary may adopt a different standard if the standard will substantially reduce administrative costs to providers and health plans compared to the alternatives, and the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of Title 5, United States Code.

Section 1172 of the Act also sets forth consultation requirements that must be met before standards are adopted by the Secretary. In the case of a standard that is developed, adopted, or modified by an SSO, the SSO must consult with the following Data Content Committees (DCCs) 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. In the case of any other standard, the Secretary is required to consult with each of the above-named groups before adopting the standard and must also comply with the provisions of section 1172(f) of the Act regarding consultation with the National Committee on Vital and Health Statistics (NCVHS).

#### B. The Transactions Rule

The SSOs have developed a broad range of implementation instructions for implementing standards for particular industry sectors, for example, instructions on how to use the ASC X12N 837 to claim payment for hospital services. The implementation instructions for implementing standards are detailed and highly specific. Section 1172(d) of the Act requires the Secretary to establish specifications for implementing each of the adopted standards, which were adopted in the Transactions Rule. However, because the implementation instructions are voluminous, they were incorporated by reference in the Transactions Rule. This approach, to incorporate by reference, commonly is used by the Office of the Federal Register when external standards developed by SSOs are adopted as national standards. The approach allows the agency to avoid publication of extraordinarily voluminous documents.

#### C. Designated Standard Maintenance Organizations

The Transactions Rule acknowledged the need for a group of organizations to maintain the standards for health care transaction standards adopted by the Secretary, and to receive and process requests for adopting new standards or modifying adopted standards. "Designated Standard Maintenance Organization" (DSMO) is the term used in the Transactions Rule to identify the organizations designated by the Secretary to undertake those functions. Section 162.910 of the Transactions Rule sets forth the conditions under which an organization may be designated a DSMO by the Secretary and the functions to be performed by a DSMO. On August 17, 2000, the Secretary published a **Federal Register** notice (65 FR 50373) designating the following six organizations (three SSOs and three DCCs) as DSMOs. The organization names are followed by their respective websites. All of the SSOs (X12, NCPDP, and HL 7) that

developed standards that the Secretary adopted or expects to propose in the near future were designated as DSMOs:

- Accredited Standards Committee X12 (ASC X12) (<http://www.x12.org>).
- Health Level Seven, Inc. (HL 7) (<http://www.hl7.org>).
- National Council for Prescription Drug Programs (NCPDP) (<http://www.ncpdp.org>).
- National Uniform Billing Committee (NUBC) (<http://www.nubc.org>).
- National Uniform Claim Committee (NUCC) (<http://www.nucc.org>).
- Dental Content Committee of the American Dental Association (<http://www.ada.org>).

The six organizations signed a Memorandum of Understanding (MOU) agreeing to undertake the functions specified in § 162.910 and to follow a framework of cooperation with each other and HHS. The initial term of the MOU is 3 years and is automatically renewed for subsequent 1-year periods. The MOU document sets forth a general process to be followed by the DSMOs when a request is made to change the HIPAA standards. The DSMOs designated a steering committee to facilitate implementation of the MOU. In order to manage the change request process, the signatory organizations agreed to:

- Allow open public access
  - Provide for timely review
  - Cooperate and communicate
  - Consider all viewpoints
  - Evaluate the impact of each change request
  - Maintain a national perspective
  - Conform to law
- A web site (<http://www.hipaa-dsmo.org>) was established for requesting changes. For additional information regarding the general change request management process, see the MOU document which is available at: [www.hipaa-dsmo.org/mou.pdf](http://www.hipaa-dsmo.org/mou.pdf).

After the initial standards were adopted in the Transactions Rule, a significant number of change requests were submitted through the DSMO process. Many of those change requests were for changes that were considered by the submitters to be essential to permit initial implementation of the standards throughout the entire healthcare industry. Those essential changes address specific details or elements within the implementation specifications.

You can review all change requests reviewed by the DSMOs and sent to NCVHS for adoption as addenda to the final rule at <http://hipaa-dsmo.org/crs/fasttrack.pdf>. (Nonessential changes are still addressed by the general change

request management process set forth in the MOU.) The procedure for electronically submitting change requests to the DSMOs and specific details on submitted requests such as business needs and disposition are available at the DSMO change request web site: <http://www.hipaa-dsmo.org>.

The DSMOs as a group presented their list of proposed modifications that they judged essential for implementation to the NCVHS. The NCVHS held public hearings on those proposed changes (transcripts of those hearings are available at <http://www.ncvhs.hhs.gov>). The NCVHS made its own determination about the modification requests and recommended that the Secretary adopt all of the changes proposed by the DSMOs as modifications to the national standards.

## II. Provisions of the Proposed Regulations

The Secretary reviewed the changes recommended by the NCVHS and is proposing their adoption in this rule.

### A. Summary

This rule proposes to make some limited technical modifications to some of the transactions standards, specifically the implementation specifications, adopted in the Transactions Rule by adopting those changes identified by the DSMOs, and approved by the NCVHS, as necessary to permit initial implementation of the standards within the industry. Details of the proposed modifications are not set forth specifically in this document, but are available at <http://hipaa-dsmo.org/crs/fasttrack.pdf>. A summary of those details follows:

A total of 231 change requests were submitted to the DSMOs for consideration. 85 requests were rejected because the implementation specifications already met the specified business need, or the business need was not well substantiated. 21 requests were recommended for future changes. 6 requests were withdrawn by the submitter. 7 requests were referred to the Department as policy issues. The remaining 115 change requests were approved and are included in the draft addenda. They fell into 2 categories—48 maintenance changes (minor error corrections, clarifications) and 67 modifications to the standards. Details of these 67 modifications include:

- Changing required data elements to situational (about 20 % of changes) Submitters pointed out several data elements that were required by the original standards, but were really only needed in some situations. These data

elements were made situational in the addenda, with clearly defined situations. Examples are:

1. Provider Taxonomy codes on claims—many health plans store this information on their systems when providers enroll, so there is no need to continually send this information. The code will now only be reported “when adjudication is known to be impacted by the code.”

2. Date last seen by physician (used for certain physical therapy claims)—this is only needed by Medicare, so usage was changed from required on all claims to “required on Medicare claims.”

- Removal of certain data elements (about 20% of changes)

Several data elements were removed since they do not appear to be needed.

Examples are:

1. Referral date
2. Estimated date of birth

- Allowing certain items to be reported via external code sets rather than data elements in the transaction (about 20% of changes)

There were several instances where codes could be used to indicate certain data elements. This will allow external code set organizations to easily update codes and reporting, as opposed to having the DSMOs make changes to the standards.

Examples are:

1. Special program indicator codes
2. Newborn birth weights

- Adding additional functionality to some transactions (about 40% of changes) Requestors suggested several additional data elements, codes, or loops to enable them to do certain business functions in the transactions. These include:

1. Cross-referencing two subscriber IDs (surviving spouse and dependents)
2. Sending a patient’s primary care physician number

The DSMOs and the NCVHS determined that these proposed modifications would respond to industry requests for changes that would facilitate HIPAA implementation.

The SSOs have incorporated the proposed modifications for each transaction into draft addenda for each implementation specification. These draft addenda represent the final product of the DSMO change request process, in that the requested change successfully completed the DSMO change request process in the form of proposed draft addenda to the adopted implementation specifications. As previously discussed, the original implementation specifications are incorporated by reference. This rule

proposes to adopt the modifications in the draft addenda. The addenda would be incorporated by reference just as are the original implementation specifications. We are soliciting comments specifically on those modifications found in the draft addenda. Comments may be submitted for specific individual proposed modifications or for the proposed modifications collectively. The full text of the draft addenda can be obtained from the Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, Md., 20852-2116; telephone 301-949-9740. They are also available through the Washington Publishing Company on the Internet at [http://hipaa.wpc-edi.com/HIPAAAddenda\\_40.asp](http://hipaa.wpc-edi.com/HIPAAAddenda_40.asp).

#### B. Proposed Modifications

The Transactions Rule established standards for eight electronic transactions, including, when appropriate, specific standards tailored to specific industry sectors, for example, retail pharmacy, institutional, and professional. The modifications proposed here would affect some of the transaction standards (identified below). The new standards would consist of the implementation guide plus the addenda. The addenda are identified below:

1. Health care claims or equivalent encounter information (§ 162.1102).

- a. Dental Health Care Claims. The ASC X12N Addenda to Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097A1 (NPRM Draft Addenda October 2001).

- b. Professional Health Care Claims. The ASC X12N Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098A1 (NPRM Draft Addenda October 2001).

- c. Institutional Health Care Claims. The ASC X12N Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096A1 (NPRM Draft Addenda October 2001).

2. Eligibility for a health plan (§ 162.1202).

Dental, professional, and institutional. The ASC X12N Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092A1 (NPRM Draft Addenda October 2001).

3. Referral certification and authorization (§ 162.1302).

The ASC X12N Addenda to Health Care Services Review-Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094A1 (NPRM Draft

Addenda October 2001). In the proposed rule titled CMS-0003-P, published elsewhere in this **Federal Register** issue, we are proposing to add a new paragraph (a) to this section.

4. Health care claim status (§ 162.1402).

The ASC X12N Addenda to Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company 004010X093A1 (NPRM Draft Addenda October 2001).

5. Enrollment and disenrollment in a health plan (§ 162.1502).

The ASC X12N Addenda to Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company 004010X095A1 (NPRM Draft Addenda October 2001).

6. Health care payment and remittance advice (§ 162.1602).

- a. Dental, professional, and institutional health care claims and remittance advice. The ASC X12N Addenda to Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091A1 (NPRM Draft Addenda October 2001).

#### C. Compliance Dates

The compliance date for the standards for the transactions adopted in the Transactions Rule is October 16, 2002 for covered entities, with the exception of small health plans, for which the compliance date is October 16, 2003 (65 FR 50368). Under § 160.104, the Secretary establishes the compliance date for modifications. The date must not be earlier than 180 days after the adoption date of the modification.

The Administrative Simplification Compliance Act (Pub. L. 107-105) was enacted on December 27, 2001. This law provides an extension to the compliance dates adopted in the Standards for Electronic Transactions final rule of August 17, 2000 (65 FR 50368), for covered entities, with the exception of small health plans, that submit a plan to the Secretary of Health and Human Services indicating how the entity will come into compliance by October 16, 2003. This plan must be submitted to the Secretary before October 16, 2002. Entities that obtain such an extension will also have a corresponding extension of the compliance dates set forth in this proposed rule.

#### III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is

submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The collection of information requirements associated with the transaction regulation are currently approved by OMB under OMB approval number 0938-0866. We are soliciting public comments on each of the above issues for the information collection requirements (ICRs) contained in the sections covered by this proposed rule.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,  
Office of Information Services,  
DCES, SSG,  
Attn: John Burke,  
Room N2-14-26, 7500 Security Boulevard,  
Baltimore, MD 21244-1850; and  
Office of Information and Regulatory Affairs,  
Office of Management and Budget,  
Room 10235, New Executive Office Building,  
Washington, DC 20503,  
Attn: Brenda Aguilar, CMS Desk Officer.

#### IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, 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, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

#### IV. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA)

(September 19, 1980, Pub. L. 96-354). Executive Order 12866 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 annually). An impact analysis was published in the Standards for Electronic Transactions final rule of August 17, 2000 (65 FR 50350). This analysis detailed the significant costs and benefits of adopting standard electronic transactions and codes sets. The analysis assumed that the adopted standards would be able to be implemented successfully by the industry. The changes in this proposed rule are a result of industry analyses that showed certain minor modifications in the adopted standards would be necessary to permit industry compliance with the standards. These modifications would make limited adjustments and corrections to the overall standards and would facilitate the Congressional intent of implementation of national electronic standards. Thus, the impact analysis previously published would reflect industry experience if the changes proposed in this rule are adopted.

In relation to the prior impact analysis, this rule would impose no additional burdens and create no additional costs. All of the proposed changes in this rule are required to facilitate successful implementation of the standards. Their implementation would, in fact, avoid costs that were not anticipated in the initial impact analysis. Therefore, no additional impact analysis under Executive Order 12866 is required.

It is estimated that substantial costs would incur for the health care industry without the adoption of these proposed changes. The proposed changes eliminate the need for expensive computer system changes, and in some cases, facilitate an implementation that might not have been possible without the proposed changes. The industry has approved these proposed changes as an essential component to their HIPAA implementation.

A total of 231 change requests were submitted to the DSMOs for consideration. 85 requests were rejected because the implementation specifications already met the specified business need, or the business need was not well substantiated. 21 requests were

recommended for future changes. 6 requests were withdrawn by the submitter. 7 requests were referred to the Department as policy issues. The remaining 115 change requests were approved and are included in the draft addenda. They fell into 2 categories—48 maintenance changes (minor error corrections, clarifications) and 67 modifications to the standards. Details of these 67 modifications include:

- Changing required data elements to situational (about 20% of changes)

Submitters pointed out several data elements that were required by the original standards, but were really only needed in some situations. These data elements were made situational in the addenda, with clearly defined situations. Examples are:

1. Provider Taxonomy codes on claims—many health plans store this information on their systems when providers enroll, so there is no need to continually send this information. The code will now only be reported “when adjudication is known to be impacted by the code.”

2. Date last seen by physician (used for certain physical therapy claims)—this is only needed by Medicare, so usage was changed from required on all claims to “required on Medicare claims.”

- Removal of certain data elements (about 20% of changes)

Several data elements were removed since they do not appear to be needed. Examples are:

1. Referral date.
2. Estimated date of birth.

- Allowing certain items to be reported via external code sets rather than data elements in the transaction (about 20% of changes)

There were several instances where codes could be used to indicate certain data elements. This will allow external code set organizations to easily update codes and reporting, as opposed to having the DSMOs make changes to the standards.

Examples are:

1. Special program indicator codes.
2. Newborn birth weights.

- Adding additional functionality to some transactions (about 40% of changes)

Requestors suggested several additional data elements, codes, or loops to enable them to do certain business functions in the transactions. These include:

1. Cross-referencing two subscriber IDs (surviving spouse and dependents).
2. Sending a patient's primary care physician number.

These changes recognize that several pieces of information initially required

by the standards were unduly burdensome to collect, so have been changed to only be collected in a more limited set of circumstances.

One particular example is that of the provider information to be collected for each service on a hospital claim. The initial standards required that this information be collected if the provider is different for each service (which it usually is in a hospital—radiologists read x-rays, physical therapists provide therapy, etc.). Many hospitals said that their systems do not routinely collect the different providers for each claim, that this information is not currently used by health plans for processing most claims, and it would be extremely burdensome to collect such information.

As a result, the condition under which this information was collected was revised in the implementation guide to state “Required when the line level information is known to impact adjudication”. This will substantially reduce the number of claims for which this information needs to be collected.

There are other examples of data elements that have been removed or will be required under more limited circumstances.

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. On November 17, 2000, the Small Business Administration (SBA) published a final rule (65 FR 69432) changing the small business size standards for the health care industry. This SBA final rule became effective December 18, 2000. The size standards that the SBA now uses are those defined by the North American Industry Classification System. Before that, the SBA used size standards as defined by the Standard Industrial Codes. The size standard is no longer a uniform \$5 million in annual revenues for all components in the health care sector. Rather, the size standard now ranges from \$6 million to \$29 million. The regulatory flexibility analysis for this proposed rule is linked to the aggregate regulatory flexibility analysis for all the Administrative Simplification standards that appeared in the final rule on Standards for Electronic Transactions (65 FR 50312), published on August 17, 2000, which predated the SBA change. It is appropriate, for purposes of this proposed rule, to continue to use the \$5 million small business size standard that was in effect at the time of publication of the final rule on Standards for Electronic Transactions. Nonprofit organizations are considered small entities. Small government jurisdictions with a population of less

than 50,000 are considered small entities. Individuals and States are not considered small entities. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all retail pharmacies are considered to be small entities. We have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may 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. We have determined that this proposed rule would not have a significant impact on a substantial number of small rural hospitals. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule would have no mandated consequential effect on State, local, or tribal governments, or on the private sector.

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. We have determined that this proposed rule would not significantly affect the rights, roles and responsibilities of States.

In accordance with the provisions of Executive Order 12866, 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 would amend 45 CFR subtitle A, subchapter C, part 162 as follows:

#### 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 Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

2. Revise § 162.1102 (b), (c) and (d) to read as follows:

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

\* \* \* \* \*

(b) *Dental Health Care Claims.* The ASC X12N 837–Health Care Claim Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim Dental, Version 4010, October 2001, Washington Publishing Company, 004010X097A1. The implementation specification is available at addresses specified in § 162.920(a)(1).

(c) *Professional Health Care Claims.* The ASC X12N 837–Health Care Claim: Professional, Volumes 1 and 2, version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, version 4010, October 2001, Washington Publishing Company, 004010X098A1. The implementation specification is available at the address specified in § 162.920(a)(1).

(d) *Institutional Health Care Claims.* The ASC X12N 837–Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2001, Washington Publishing Company, 004010X096A1. The implementation specification is available at the addresses specified in § 162.920(a)(1).

3. Revise § 162.1202(b) to read as follows:

#### § 162.1202 Standards for eligibility for a health plan.

\* \* \* \* \*

(b) *Dental, professional, and institutional.* The ASC X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2001, Washington Publishing Company, 004010X092A1. The implementation specification is available at the addresses specified in § 162.920(a)(1).

\* \* \* \* \*

4. Revise § 162.1302 to read as follows:

**§ 162.1302 Standard for referral certification and authorization.**

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) [Reserved]

(b) *Dental, professional, and institutional referral certification and authorization.* The Secretary adopts the ASC X12N 278—Health Care Services Review-Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review-Request for Review and Response, Version 4010, October 2001, Washington Publishing Company, 004010X094A1 as the standard for the referral certification and authorization transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

5. Revise § 162.1402 to read as follows:

**§ 162.1402 Standard for health care claims status.**

The Secretary adopts the ASC X12N—276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2001, Washington Publishing Company, 004010X093A1 as the standard for the health care claim status transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

6. Revise § 162.1502 to read as follows:

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

The Secretary adopts the ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2001, Washington Publishing Company, 004010X095A1 as the standard for enrollment and disenrollment in a health plan transaction. The implementation specification is available at the addresses specified in § 162.920(a)(1).

7. Revise § 162.1602(b) to read as follows:

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

\* \* \* \* \*

(b) *Dental, professional, and institutional health care claims and*

*remittance advice.* The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091 and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2001, Washington Publishing Company, 004010X091A1. The implementation specification is available at the addresses specified in § 162.920(a)(1).

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

Dated: March 20, 2002.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 02–13615 Filed 5–24–02; 4:53 pm]

**BILLING CODE 4120–01–P**

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 73**

**[DA 02–1198, MB Docket No. 02–116, RM–10233]**

**Digital Television Broadcast Service; Billings, MT**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by KTVQ Communications, Inc., licensee of station KTVQ(TV), NTSC channel 2, Billings, Montana, requesting the substitution of DTV channel 10 for station KTVQ(TV)'s assigned DTV channel 17. DTV Channel can be allotted to at reference coordinates 45–46–00 N. and 108–27–27 W. with a power of 160, a height above average terrain HAAT of 165 meters. Since the community of Billings is located within 400 kilometers of the U.S.-Canadian border, concurrence from the Canadian government must be obtained for this allotment.

**DATES:** Comments must be filed on or before July 15, 2002, and reply comments on or before July 30, 2002.

**ADDRESSES:** The Commission permits the electronic filing of all pleadings and comments in proceedings involving petitions for rule making (*except in broadcast allotment proceedings*). See *Electronic Filing of Documents in Rule Making Proceedings*, GC Docket No. 97–113 (rel. April 6, 1998). Filings by paper can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we

continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistrionix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Scott S. Patrick, Dow, Lohnes & Albertson, PLLC, 1200 New Hampshire Avenue, NW., Suite 800, Washington, DC 20036–6802 (Counsel for KTVQ Communications, Inc.)

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 02–116, adopted May 17, 2002, and released May 24, 2002. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via-e-mail [qualexint@aol.com](mailto:qualexint@aol.com).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.