ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN141–1b; FRL–7213–6]

Approval and Promulgation of State Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Indiana Department of Environmental Management (IDEM) on July 18, 2000 with additional material submitted on January 11, 2002 and March 13, 2002. The revised SIP pertains to vapor tightness standards for the loading of gasoline cargo tanks at bulk gasoline terminals and pipeline breakout stations in Indiana. The purpose of this action is to approve amendments to Indiana's gasoline transport testing requirements which will tighten current state rules. In the Final Rules section of this **Federal Register**, EPA is approving as described herein, the State's SIP revision, as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we receive no adverse comments in response to that direct final rule we plan to take no further action in relation to this proposed rule. If EPA receives significant adverse comments, in writing, which have not been addressed, we will withdraw the direct final rule and address all public comments received in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document.

DATES: EPA must receive written comments on this proposed rule by July 1, 2002.

ADDRESSES: You should mail written comments to: Patricia Morris, Acting Chief, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

You may inspect copies of the State submittal and EPA's analysis of it at: Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Francisco J. Acevedo, Environmental Protection Specialist, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3299.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we'', ''us'', or ''our'' are used we mean EPA.

Table of Contents

I. What Action Is EPA Taking Today?

In this action, we are proposing to approve changes to Indiana's gasoline transport testing requirements contained in 326 IAC 8–4 and 326 IAC 20–10. Our approval makes the changes to the Indiana rules part of the federally enforceable SIP.

II. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: May 9, 2002.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. 02–13517 Filed 5–30–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS–0003–P]

RIN 0938–AK64

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

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes to adopt modifications to certain standards for retail pharmacy transactions 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. This rule proposes to adopt the National Council for Prescription Drug Programs (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, in place of NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0 (Version 1.0), February 1996, for the following standards for retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; and coordination of benefits.

Additionally, we propose to modify the standard for the health care payment and remittance advice transaction as the standard for retail pharmacy transactions by adopting, in place of the current standard, the ASC X12N 835—health care claim payment/advice. We also propose to adopt the 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, as the referral certification and authorization transaction standard, to replace the current standard, ASC X12N 278, for retail pharmacy transactions only.

This rule also proposes to repeal the adoption of National Drug Codes as the standard medical data code set for reporting drugs and biologics in all standard transactions, except those for retail pharmacy transactions, for which standards have been adopted.

DATES: Comments will be considered 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–0003–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 & Medicaid Services, Department of Health and Human Services, Attention: CMS–0003–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: CMS0003@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: Marilyn Abramovitz, (410) 786–5939 and Gladys Wheeler, (410) 786–0273.

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 make the changes proposed in this rule. Because this proposed rule is in direct response to those industry requests, 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, in Room C5–12–17, at the headquarters Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. To make an appointment to view the public comments, please call telephone number (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

On August 17, 2000, we published the Standards for Electronic Transactions final rule in the **Federal Register** (65 FR 50312). That regulation implemented some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It adopted standards, in 45 CFR part 162, for eight electronic transactions and for code sets to be used in those transactions. It also contained requirements concerning the use of these standards by health plans, health care clearinghouses, and certain health care providers. (Please refer to that rule for a detailed discussion of electronic data interchange, the statutory background, and an analysis of the public comments received during the promulgation of the rule.) The compliance dates set forth in the rule are October 16, 2002 for all covered entities, with the exception of small health plans, for which the compliance date is October 16, 2003.

A. The Standards for Retail Pharmacy

The Standards for Electronic Transactions final rule (65 FR 50312), published on August 17, 2000, adopted transaction standards for eight different transactions, some of which are transactions for retail pharmacy. In this section of the proposed rule, we address only those retail pharmacy transaction standards that would be affected by the modifications proposed herein. The standards adopted in the final rule for retail pharmacy transactions for health care claim status, enrollment and disenrollment in a health plan, and health plan premium payments, would not be affected by the changes proposed in this rule. The August 17, 2000 final rule adopted the National Council for Prescription Drug Programs (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 0 (Version 1.0), February 1, 1996, as the standards for the retail pharmacy sector for the following transactions: health care claims or equivalent encounter information, eligibility for a health plan, health care payment and remittance advice, and coordination of benefits. The rule also adopted the ASC X12 N278 Request for Review and Response as the standard for the referral certification and authorization transaction to be used for retail pharmacy transactions.

B. The Standard Medical Data Code Set for Drugs and Biologics

In the Standards for Electronic Transactions proposed rule (65 FR 25285), we proposed the adoption of National Drug Codes (NDC), as maintained and distributed by HHS in collaboration with drug manufacturers for reporting drugs and biologics, as the standard medical data code set for reporting drugs and biologics in standard transactions. We addressed comments on that proposal in the August 17, 2000 final rule. See 65 FR 50328 for a detailed discussion of the comments and responses. Generally, NDC were favored by commenters as the most appropriate and efficient coding system available for identifying drugs. In the final rule, we adopted NDC as the medical data code set for reporting drugs and biologics in standard transactions. The decision to adopt NDC, rather than another code set such as HCPCS drug codes as the standard medical data code set for reporting drugs and biologics was based upon the following factors:

- NDC have several significant advantages over other formats we considered. The NDC is a unique number that is capable of identifying each drug or biological product. The Food and Drug Administration (FDA) and drug manufacturers assign NDC to approved drugs. The NDC format is an 11-digit number that specifies detailed information about each drug. The first grouping of five numbers represents a labeler code that identifies a drug manufacturer and is assigned by the FDA. The second grouping of four numbers is the product code, which identifies drug strength, dosage form, and formulation, and is assigned by the drug manufacturer. The third grouping of two numbers represents package size and uniquely identifies the package by the quantity of contents and type of package, and is assigned by the drug manufacturer.

• NDC are an existing code set already in moderate use for reporting drugs and biologics by some entities, and in widespread use by retail pharmacies.

• The adoption of NDC as the standard coding system for reporting drugs and biologics on standard transactions would reduce the need for local codes since NDC are assigned on a continuous basis.

II. Provisions of the Proposed Regulations

A. Modification of Standards for Retail Pharmacies

1. Retail Pharmacy Batch Transactions

We propose to adopt modifications to the standards for retail pharmacy batch transactions in §§ 162.1102, 162.1202, and 162.1802. The modifications would be the adoption of the 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, to replace the NCPDP Batch Standard Implementation Guide, Version 1, Release 0, (Version 1.0), February 1996.

We propose to adopt these modifications because the current standard version of the NCPDP Batch Standard Batch Implementation Guide (Version 1, Release 0, February 1, 1996) does not coordinate with the current standard version of the NCPDP Telecommunication Standard Implementation Guide (Version 5, Release 1, September 1999 (version 5.1)). As a practical matter, it was our intent to adopt the batch standard that is the equivalent companion to the telecommunication standard. However, the NCPDP has confirmed with us that Batch Standard Version 1.0 is only compatible with Telecommunication Standard Version 3, Release 2 (Version 3.2). As currently written, our regulations do not permit batched transactions. If the regulations in 45 CFR part 162 were to remain unchanged as of October 16, 2002 (the compliance date for most covered entities), in order to be in compliance with our rules at 45 CFR part 162, as they are currently written, covered entities conducting retail pharmacy transactions would technically not be able to batch transactions but would have to conduct all transactions individually. Therefore, we are proposing to modify our regulations and adopt Batch Standard Version 1, Release 1 (Version 1.1), as the Batch Standard Batch Implementation Guide in place of the NCPDP Batch Standard Batch Implementation Guide Version 1, Release 0 (Version 1.0.)

2. Referral Certification and Authorization Transaction

For retail pharmacy transactions only, we propose to modify the standard for the referral certification and authorization transaction by adopting the NCPDP Telecommunication Guide, Version 5 Release 1, September 1999 as the standard in place of the ASC X12N 278—Health Care Services Review-Request for Review and Response as the standard for the Referral Certification and Authorization transaction. It has come to our attention that, in fact, the ASC X12N 278 is not appropriate for retail pharmacy prior authorization transactions. We have consulted with the NCPDP and the National Association of Chain Drug Stores and have concluded that the ASC X12N 278 implementation specification does not support data critical to retail pharmacy prior authorization transactions. The implementation specification could not be changed to support the transaction before we issued the final regulation because the X12 standards development process for modifying standards could not be completed in time. Because the NCPDP standard adequately supports this transaction for retail pharmacy, and is currently in widespread industry use, we propose to modify the referral certification and authorization standard by adopting the NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), supporting Telecommunication Version 5.1 for the NCPDP Data Record in the Detail Data Record, in place of the ASC X12N 278. This modification will not affect the standards for dental, professional, and institutional referral certification and authorization transactions.

In the proposed rule titled CMS–0005–P, published elsewhere in this **Federal Register**, we are proposing to amend the same section by redesignating the existing text as paragraph (b), revising paragraph (b), and adding introductory text.

3. Health Care Payment and Remittance Advice Transaction

In the August 17, 2000 final rule, we adopted the ASC X12N 835 as the standard for dental, professional, and institutional transactions for the health care payment and remittance advice transaction. We adopted the NCPDP Telecommunications Standard Implementation Guide, Version 5 Release 1, September 1999 as the standard for retail pharmacy drug claims and remittance advice transactions. However, since publication of the final rule, we have concluded that the NCPDP Telecommunications Standard and batch equivalent do not sufficiently support the remittance advice data for this transaction. Consequently, it would not be possible for covered entities to comply with the NCPDP standards for retail pharmacy drug claims and remittance advice transactions. Therefore, we propose to modify the standard for the health care payment and remittance advice transaction for retail pharmacy transactions by adopting the ASC X12N 835 in place of the NCPDP standard. With the implementation of this proposal, the ASC X12N 835 would be the only standard for health care payment and remittance advice transactions. All covered entities, including retail pharmacies (§ 162.1602), would be required to use ASC X12N 835 when conducting a health care payment and remittance advice transaction.

B. Medical Data Code Set for Drugs and Biologics

We propose to repeal the adoption of NDC as the standard medical data code set for reporting drugs and biologics in all standard transactions, except for retail pharmacy transactions, for which standards have been adopted in § 162.1002(c). We would make a conforming change to § 162.1002(f) to specify that the Healthcare Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, would not be required for reporting drugs and biologics. The result of this repeal would be no standard medical data code set in place for reporting drugs and biologics on standard transactions that are not retail pharmacy (hereafter, referred to as nonretail pharmacy transactions).

The absence of a code set standard would not preclude the use of NDC for reporting drugs and biologics by covered entities on standard transactions. Covered entities could continue to report drugs and biologics as they preferred, for example, according to trading partner agreements or as reported before the adoption.

1. Reasons for Proposed Repeal

Since publication of the final rule, numerous health care industry concerns about the use of NDC have been reported. Although the intent of the final rule was to standardize the reporting of drugs and biologics by using one coding system, the industry has indicated that this may not be practical within the industry at this time. The magnitude and scope of issues concerning the implementation of NDC

for reporting drugs and biologics in standard transactions, and the relevance of those issues to industry goals of administrative simplification and HIPAA compliance, prompted HHS to re-examine the adoption of NDC.

The following concerns reported by the industry since publication of the final rule illustrate the industry's view of the escalating cost burden for institutional and professional health care providers who are unfamiliar with the use of NDC.

a. Compliance with the NDC standard for electronic transactions by health care providers on professional claims would require the expansion of data field sizes in nearly all modules of physician practice management systems in order to store and display the thousands of available NDC. Some financial estimates for health care providers suggest complete systems re-engineering and replacements or both would be necessary. The industry has reported that the costs of changing from using HCPCS to NDC for reporting drugs and biologics on institutional claims could exceed an institution's costs for adopting all other combined HIPAA standard transactions.

b. The National Uniform Billing Committee (NUBC) outlined its concerns with the requirement to use NDC on institutional claims, particularly hospital claims, in a letter to former Secretary Donna Shalala, dated September 22, 2000. The following issues were raised by the NUBC in that letter:

- Reporting specific drugs on institutional claims introduces a systems technology requirement that is inconsistent with inpatient claims submission and institutional provider reimbursement, which commonly are based on a Diagnosis-Related Group or per diem payment methodology.
- NDC formats indicate how a drug was acquired but provide no information related to actual dosages administered. Although the NDC second grouping of four numbers identifies drug strength, dosage form, and formulation of the product, it does not reflect the administered dose. An NDC for multiple billing increments is not formulated.
- Operational issues of systems incompatibility among institutional pharmacies, inpatient medical records, and inpatient accounting systems compound expensive system retooling with major training initiatives. Physicians typically order drugs for patients through the hospital pharmacy department by name, unit, and dosage frequency. The pharmacy department does not reference the NDC to pull the drug or initiate a charge transaction. Typically, an NDC is not recorded in a patient's medical record. There is little or no electronic linkage and communication among institutional drug inventory, patient billing, and medical records computer systems.
- Typical institutional patient accounting systems and professional health care provider practice management systems do not accommodate the 11 digits inherent to NDC assignment.
- The lack of sufficiently defined benefits for health care providers for required system upgrade costs to accommodate NDC risks the alternative of providers submitting paper claims to avoid the costs of reporting NDC. Attempts by industry experts to develop a complete 1:1 crosswalk from the currently used HCPCS codes to NDC have been unsuccessful. Different NDC may be assigned to the same drug to identify the various manufacturers of that drug. In contrast, because the HCPCS code is more generic and does not reference the manufacturer, only one code applies to the drug.

The NUBC believes that the NDC coding system is suited more for inventory control and is not appropriate for institutional provider billing, and that the reporting of NDC pertains to retail pharmacy claims only and should not be applicable to institutional claims.

c. HHS posted an e-mail address on its Administrative Simplification web site in October 2000 (*http://www.aspe.hhs.gov/admnsimp/index.htm).* HHS directed inquiries about the August 17, 2000 final rule on standards for electronic transactions to this e-mail address. HHS responses to these inquiries are posted to a ''Frequently Asked Questions'' location on the web site. HHS received and posted numerous separate inquiries reiterating concerns similar to those expressed by the NUBC in its September 22, 2000 letter to former Secretary Shalala referenced above under section II.B of this proposed rule.

d. After publication of the final rule, the Workgroup for Electronic Data Interchange (WEDI) (which is named in the Social Security Act (the Act) as one of the organizations with which the Secretary must consult in adopting HIPAA Administrative Simplification standards) established a Strategic National Implementation Process (SNIP) for consistent industry implementation of the HIPAA Administrative Simplification standards. SNIP workgroups have reiterated some of the concerns expressed by the NUBC about NDC.

e. The NUBC submitted a formal request through the Designated Standards Maintenance Organization (DSMO) process on November 28, 2000 to change the Institutional Implementation Guide to make NDC ''Not Used'' for inpatient claims.

f. A large provider workgroup for implementing HIPAA standards suggested that NDC not be required for reporting drugs and biologics on professional or institutional claims. The workgroup submitted this request through the DSMO process on January 31, 2001 and recommended paper and electronic claim transaction consistency in reporting codes for drugs and biologics. The workgroup stated that neither the institutional nor the professional paper claim can accommodate the 11-digit NDC in the space where a 5-position HCPCS code currently is reported and that HCPCS drug codes should be used to report drugs and biologics on paper and electronic claims for institutional and professional health care providers.

g. The Subcommittee on Standards and Security of the National Committee on Vital and Health Statistics (NCVHS) held public hearings on HIPAA implementation issues on February 1, 2001. Health care industry representatives presented testimony on concerns relating to use of NDC. Those who testified and other attendees are members of health care industry workgroups that support HIPAA and are involved in HIPAA implementation activities. Concerns expressed in the testimony include:

- NDC use by hospitals is limited to the purchase of drugs and maintaining inventory control. The fact that NDC are not (1) used within hospitals for order entry from pharmacies, (2) written in patients' medical records, or (3) accommodated in patient accounting systems, means that extensive system conversions and enhancements are required for institutions to achieve HIPAA compliance.

Additional ancillary staff training on the use of NDC also would be required. Potential for medication errors increases when new system interfaces for drug dispensing systems are created. Routine repackaging of drugs in convenient quantities and brand substitutions by hospitals complicate NDC reporting because many NDC can represent a single drug. The complicated problems with calculating and capturing drug dose information when partial or fractional units are administered makes reporting burdensome and subject to errors.

- While costs could vary with facility size, hospitals estimate a minimum cost

of $200,000 per hospital facility, or a total of $1,296,000,000 for approximately 6480 affected hospital entities, to transition from HCPCS to NDC for reporting drugs and biologics. The expense to expand fields, accommodate thousands of NDC, and upgrade physicians' practice management systems for HIPAA compliance could exceed 10 percent of the total practice management system cost, increasing the financial burden for professional health care providers. Institutional health care providers do not report any accrued benefits from using NDC, despite the high costs for conversion, because drugs are rarely reported on claims. Hospital inpatient claims are paid prospectively based on Diagnosis-Related Groups or per diem basis. Only procedures and diagnoses are recorded. Most drugs are not individually submitted for line-item payment.

- Some industry representatives identified perceived deficiencies in the NDC maintenance process that could potentially result in the re-use of an NDC and the possibility that an NDC for a particular drug could change over time.

h. In a letter to the Secretary, dated February 22, 2001, the NCVHS described the problems with the requirement to use NDC to report drugs and biologics on the standard institutional and professional claims, and the impact of those problems on the health care industry for meeting HIPAA compliance dates. The NCVHS recommended that the Secretary retract the adoption of NDC as the standard medical data code set for reporting drugs and biologics in standard transactions other than retail pharmacy transactions, and that HCPCS codes as well as NDC continue to be used in the standard institutional and professional claim transactions. The NCVHS further stated that it believes that no drug coding system in existence today meets all the needs of the health care industry, and that future needs of the health care industry are for a drug coding system that can be used efficiently for drug inventory, pharmacy transactions, patient care, billing arenas, and ensuring patient safety.

The Office of the Secretary recognizes the need to develop specific criteria for evaluating drug coding systems, and it is initiating steps for coordinating efforts with other agencies and representatives from the health care industry in the evaluation and development of any future proposed drug coding systems.

2. Alternative Under Consideration: Comment Solicited

An advantage to not adopting a replacement standard code set for NDC for reporting drugs and biologics in nonretail pharmacy standard transactions at this time is that the industry and HHS would have time to fully evaluate the alternatives available and explore the possibility of the development of a new drug coding system that could meet the current and future needs of the health care industry. However, we recognize that the industry may prefer the certainty of an established standard at this time. We also are considering, as an alternative to not adopting any standard in place of the NDC, the adoption of HCPCS as the code set for reporting drugs and biologics for nonretail pharmacy transactions. As discussed above, the HCPCS code set is in widespread use today by many health care providers that are not retail pharmacies. Were we to adopt HCPCS, we would amend § 162.1002(c) to reflect the adoption of NDC as the standard medical data code set for reporting drugs and biologics in standard transactions for retail pharmacy transactions. We would also amend § 162.1002(f) to reflect the adoption of the HCPCS coding system as the standard medical data code set for reporting drugs and biologics in nonretail pharmacy transactions. We are particularly interested in whether commenters believe the adoption of HCPCS for reporting drugs and biologics on nonretail pharmacy transactions would present operational problems, and what particular operational problems commenters believe would be presented.

C. Compliance Dates

Under the Act, as reflected in § 160.104, the Secretary establishes the compliance date for modifications to standards. The compliance date must not be earlier than 180 days after the adoption date of the modification. We expect the compliance dates for this proposed rule would be 180 days after the effective date of the subsequent final rule.

Additionally, 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), in which covered entities, with the exception of small health plans, may submit a plan to the Secretary of Health and Human Services indicating how the entity will come into compliance by October 16, 2003. Since this proposed rule is modifying transactions adopted in the Standards for Electronic Transactions final rule of August 17, 2000 (65 FR 50368), The Administrative Simplification Compliance Act will apply to this proposed rule. In order to obtain an extension, covered entities must submit the plan to the Secretary before October 16, 2002.

D. Implementation Specifications and Incorporation by Reference

This rule would not change the availability of the NCPDPs Telecommunication Standard Implementation Guide or the Batch Standard Batch Implementation Guide.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 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; ATTN: CMS–0003–P

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.

V. Regulatory Impact Analysis

We have examined the impacts 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).

The proposed repeal of the NDC for nonretail pharmacy transactions would result in minimal costs or savings since the industry would continue to use the formats that are currently being used in the health care marketplace. This is due to the fact that most covered entities have not begun to implement NDC because they are aware that this regulation is in process. In the absence of this regulation, health plans and providers would incur a significant future cost for implementing the NDC, including:

- Training provider clinical staff to learn to report NDCs.
- Conversion of plan and provider legacy systems to accommodate the larger size of the NDC.
- Modification of provider clinical systems to interface with pharmacy systems to capture the NDC.
- Modification of plan reimbursement systems to crosswalk NDCs to J codes. Publication of this regulation would permit covered entities to avoid these costs. Industry recognizes the benefit of this change, and has demonstrated wide-spread support for it.

The alternative of adopting HCPCS drug codes as a standard for reporting drugs and biologics for covered entity transactions referenced above under section II. B. 2 would also have minimal costs or savings due to its already current widespread use in the health care industry.

The modifications to the standards for retail pharmacy transactions would also neither increase nor decrease the industry costs or savings. Those modifications to the standards are ones that would simply implement changes that reflect the way the particular segment of the affected industry already operates. Therefore, this is not a major rule because it does not have an economically significant effect of $100 million or more.

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 $5 million to $25 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 do not need to prepare analyses under section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandate 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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. The rule as proposed would have little effect, if any, on annual expenditures incurred by State, local, or tribal governments because it would result in the reestablishment of the current status for professional and institutional providers.

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.

This proposed rule would not affect the final impact analysis of the Standards for Electronic Transactions final rule of August 17, 2000 (65 FR 50350). This rule also would not affect the Regulatory Flexibility Analysis (65 FR 50359) or the Federalism implications of that rule (65 FR 50364).

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 § 162.920(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).

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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