§ 416.1002 Definitions.

* * * * *

Compassionate allowance means a determination or decision we make under a process that identifies for expedited handling claims that involve impairments that invariably qualify under the Listing of Impairments in appendix 1 to subpart P of part 404 of this chapter based on minimal, but sufficient, objective medical evidence.

* * * * *

■ 19. Amend § 416.1015 by revising the introductory text of paragraph (c), removing the word "or" at the end of paragraph (c)(2), redesignating paragraph (c)(3) as paragraph (c)(4), and adding a new paragraph (c)(3) to read as follows:

§ 416.1015 Making disability determinations.

* * * * *

(c) Disability determinations will be made by:

* * * * *

(3) A State agency disability examiner alone if you are not a child (a person who has not attained age 18), and the claim is adjudicated under the quick disability determination process (*see* § 416.1019) or as a compassionate allowance (*see* § 416.1002), and the initial or reconsidered determination is fully favorable to you. This paragraph will no longer be effective on November 12, 2013 unless we terminate it earlier or extend it beyond that date by publication of a final rule in the **Federal Register;** or

* * * * *

■ 20. Amend § 416.1019 by revising paragraphs (b) introductory text, (b)(1), (b)(2), and (c) to read as follows:

§ 416.1019 Quick disability determination process.

* * * * *

(b) If we refer a claim to the State agency for a quick disability determination, a designated quick disability determination examiner must do all of the following:

(1) Subject to the provisions in paragraph (c) of this section, make the disability determination after consulting with a State agency medical or psychological consultant if the State agency disability examiner determines consultation is appropriate or if consultation is required under § 416.926(c). The State agency may certify the disability determination forms to us without the signature of the medical or psychological consultant.

(2) Make the quick disability determination based only on the

medical and nonmedical evidence in the file.

* * * * *

(c) If the quick disability determination examiner cannot make a determination that is fully favorable, or if there is an unresolved disagreement between the disability examiner and the medical or psychological consultant (except when a disability examiner makes the determination alone under § 416.1015(c)(3)), the State agency will adjudicate the claim using the regularly applicable procedures in this subpart.

[FR Doc. 2010–25502 Filed 10–12–10; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS–0009–N]

RIN 0938–AM50

Health Insurance Reform; Announcement of Maintenance Changes to Electronic Data Transaction Standards Adopted Under the Health Insurance Portability and Accountability Act of 1996

AGENCY: Office of the Secretary, HHS.

ACTION: Notification.

SUMMARY: This document announces maintenance changes to some of the Health Insurance Portability and Accountability Act of 1996 standards made by the Designated Standard Maintenance Organizations. The maintenance changes are non-substantive changes to correct minor errors, such as typographical errors, or to provide clarifications of the standards adopted in our regulations entitled "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards," published in the **Federal Register** on January 16, 2009. This document also instructs interested persons on how to obtain the corrections.

FOR FURTHER INFORMATION CONTACT:
Denise Buenning, (410) 786–6711
Gladys Wheeler, (410) 786–0273

SUPPLEMENTARY INFORMATION:

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated the adoption of standards for electronically conducting certain health

care administrative transactions between certain entities. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled "Administrative Simplification." Part C of title XI of the Act consists of sections 1171 through 1180. These sections define various terms and impose several requirements on the Department of Health & Human Services (HHS), health plans, health care clearinghouses, and certain health care providers concerning the electronic transmission of health information.

On August 17, 2000, we published a final rule in the **Federal Register** (65 FR 50312) entitled "Health Insurance Reform: Standards for Electronic Transactions" (hereinafter referred to as the Transactions and Code Sets rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards developed by standard setting organizations (SSOs) for eight electronic transactions, and code sets to be used in those transactions. The SSOs are organizations that are accredited by the American National Standards Institute (ANSI), and that develop industry standards for, among others, the HIPAA transactions. We adopted standards developed by the Accredited Standards Committee X12 (hereinafter referred to as ASC X12) and the National Council for Prescription Drug Programs (NCPDP). We defined those transactions and specified the adopted standards at 45 CFR part 162, subparts I and K through R. Designated Standard Maintenance Organizations (DSMOs) receive, manage, and process requested changes to the adopted standards in accordance with the process identified in the HIPAA regulations at § 162.900. A description of the DSMO process can be found in the May 31, 2002 proposed rule (67 FR 38050). Both ASC X12 and NCPDP are DSMOs.

On August 22, 2008, we published a proposed rule in the **Federal Register** (73 FR 49742) entitled "Health Insurance Reform: Modifications to Electronic Data Transactions Standards and Code Sets" (hereinafter referred to as the Modifications proposed rule) proposing to modify the HIPAA transaction standards by adopting updated versions of the standards. On January 16, 2009, we published a final rule in the **Federal Register** (74 FR 3296) entitled Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards (hereinafter referred to as the Modifications final rule), that adopted updated versions of the standards for

the electronic transactions originally adopted under HIPAA. We refer readers to the regulations cited above for a detailed discussion of the standards for electronic transactions and information about electronic data interchange, the statutory background, and the regulatory history.

In the Transactions and Code Sets rule, we defined the terms "modification" and "maintenance of standards." We explained that, when a change is substantial enough to justify publication of a new version of an implementation specification, such change is considered a modification, and must be adopted by the Secretary through regulation (65 FR 50322). Maintenance, on the other hand, describes the activities necessary to support the use of a standard, including technical corrections to an implementation specification. Maintenance changes are typically changes that are obvious to readers of the implementation guides, are not controversial, and are essential to implementation (68 FR 8388, (February 20, 2003)). We note that regulatory action is not required to make maintenance type changes to the HIPAA adopted standards (65 FR 50322).

II. Provisions of the Notification

A. ASC X12 Version 5010 HIPAA Transaction Standards

We adopted ASC X12 standards for the following eight HIPAA administrative transactions: (1) Health care claims or equivalent encounter information; (2) health care payment and remittance advice; (3) coordination of benefits; (4) eligibility for a health plan; (5) health care claim status; (6) enrollment and disenrollment in a health plan; (7) referral certification and authorization; and (8) health plan premium payments. In the January 16, 2009 Modifications final rule, we adopted the ASC X12 Technical Reports Type 3, Version 005010 (hereinafter referred to as Version 5010) to replace the currently adopted Version 4010/4010A1 standard for the eight HIPAA transactions (74 FR 3296).

1. Errata Notification

Following publication of the Modifications final rule, ASC X12 notified HHS that they were receiving feedback from the industry regarding errors that had been overlooked during ASC X12 standards review process. These errors were not identified in the comments submitted during the public comment period for the Modifications proposed rule, and therefore are not

reflected in the Version 5010 standards adopted in the Modifications final rule.

After the industry reported these errors, ASC X12 compiled a summary and in February 2010 as required under the DSMO process, initiated consultations with HHS and the National Committee on Vital and Health Statistics (NCVHS), an advisory body to HHS on health data, statistics and national health information policy. (For a complete discussion of this NCVHS process, we refer readers to the August 22, 2008 proposed rule (73 FR 49742). ASC X12 then balloted and completed approval for these changes to the Version 5010 standards in accordance with the established ASC X12 approval process, in July 2010.

2. Errata Classification

ASC X12 issued errata to Version 5010 in July 2010. It has categorized the errata as both Type 1 and Type 2. These errata constitute maintenance changes under the HIPAA regulations, not modifications. The ASC X12 defines errata as: (1) Publication variances from approved X12 Committee actions (publication errors); or (2) editorial corrections such as spelling, punctuation, spelling out abbreviations or acronyms.

ASC X12 further defines Type 1 and Type 2 errata as follows:

• Type 1 Errata change the constraints of the base standard, but do not change the base standard itself. The sender and receiver must implement the Type I Errata in order to conduct a successful interchange.

• Type 2 Errata supplement a published Technical Report Type 3 (TR3) with minor changes that clarify or correct the TR3 Report. Implementation Guide constraints are not changed, and the sender and the receiver do not have to implement the errata to conduct a successful interchange.

Neither Type 1 or Type 2 Errata can change the underlying base ASC X12 transaction standard or associated internal code sets (*http://www.x12.org/newsletters/tr/index.cfm).*

3. Errata Distribution

The errors that were identified by the industry, and ASC X12's balloted and approved response that was completed July 2010, are contained in the errata posted to the ASC X12 Web site, at *http://www.x12.org,* and are available free of charge for purchasers of Version 5010. In the interest of broad stakeholder outreach, CMS also posted a link for the ASC X12 errata to its Web site, at *http://cms.gov/ICD10.*

B. NCPDP Telecommunication Standard D.0

We adopted NCPDP standards for the following retail pharmacy drug transactions: Health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization, coordination of benefits; and Medicaid pharmacy subrogation. In the Modifications final rule, we adopted the NCPDP Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2) in place of the NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) and equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 1 (Version 1.1), for the HIPAA retail pharmacy drug transactions.

1. Change Notification

Following publication of the Modifications final rule, NCPDP and industry stakeholders notified HHS that corrections were needed for errors in Version D.0 that had been either unintended mistakes or overlooked during the NCPDP standards review process. Those errors were not identified in the comments submitted during the public comment period for the Modifications proposed rule, and therefore are not reflected in the standards adopted in the Modifications final rule.

After the industry reported these errors, NCPDP compiled a summary of the needed corrections and their proposed remedies, and in April 2010 initiated consultations with HHS and the NCVHS. NCPDP balloted the changes and approved them, in accordance with the established NCPDP approval process, in August 2010. Each of the error corrections to Version D.0 are maintenance changes, as that term is defined under the HIPAA regulations.

2. NCPDP Change Distribution

The errors that were identified by the industry, and NCPDP's balloted and approved response that was completed in August 2010, are contained in the August 2010 publication of NCPDP Editorial Document posted to the NCPDP Web site, at *http://www.ncpdp.org.* The publication of the changes is available free of charge for purchasers of Version D.0. In the interest of broad stakeholder outreach, CMS also posted a link for the NCPDP August 2010 Editorial Document to its Web site, at *http://cms.gov/ICD10.*

It is important that HIPAA covered entities, vendors, and third party billers obtain the ASC X12 Version 5010 and the NCPDP Version D.0 error corrections and include them in their implementation of Version 5010 and Version D.0 standards. It should be noted that the HIPAA compliant versions include the error corrections. The Version 5010 and Version D.0 HIPAA compliant standards should be incorporated into systems as soon as possible. There is urgency for entities to do so quickly in light of the HHS-specified Version 5010 and Version D.0 January 1, 2011 testing date and the January 2012 implementation date. In addition, adhering to these time frames is critical for meeting the requirements to implement Version 5010 and Version D.0 prior to the October 2013 implementation date for the ICD–10 code set.

The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 and Errata may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970–4480; Fax: (703) 970 4488. They also are available through the Internet at *http://www.X12.org.*

The implementation specifications and the NCPDP D.0 Editorial Document may be obtained from the National Council for Prescription Drug programs, 9240 East Raintree Drive, Scottsdale, AZ 85260; Telephone (480) 477–1000; Fax: (480) 767–1042. They are also available through the Internet at *http://www.ncpdp.org.*

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Approved: October 6, 2010.

Kathleen Sebelius,
Secretary.

[FR Doc. 2010–25684 Filed 10–8–10; 11:15 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB76

Health Information Technology: Revisions to Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this interim final rule with a request for comment to remove the implementation specifications related to public health surveillance.

DATES: *Effective Date:* This interim final rule is effective October 13, 2010.

Comment Date: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on November 12, 2010.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments, identified by RIN 0991–AB76, by any of the following methods (please do not submit duplicate comments).

• *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word. *http://www.regulations.gov.*

• *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies.

• *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification,

commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

ARRA American Recovery and Reinvestment Act of 2009
CDC Centers for Disease Control and Prevention
CFR Code of Federal Regulations
EHR Electronic Health Record
HHS Department of Health and Human Services
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HL7 Health Level Seven
NAICS North American Industry Classification System
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
ONC–ATCB ONC-Authorized Testing and Certification Body
PHSA Public Health Service Act
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
UMRA Unfunded Mandates Reform Act of 1995