

October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

■ 18. Add a new Subpart S to read as follows:

Subpart S—Medicaid Pharmacy Subrogation

Sec.

162.1901 Medicaid pharmacy subrogation transaction.

162.1902 Standard for Medicaid pharmacy subrogation transaction.

§ 162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

§ 162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902 (Incorporated by reference at § 162.920):

(a) For the period on and after January 1, 2012, for covered entities that are not small health plans;

(b) For the period on and after January 1, 2013 for small health plans.

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

Approved: December 11, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E9-740 Filed 1-15-09; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS-0013-F]

RIN 0958-AN25

HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule adopts modifications to two of the code set standards adopted in the Transactions and Code Sets final rule published in the **Federal Register** pursuant to certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Specifically, this final rule modifies the standard medical data code sets (hereinafter “code sets”) for coding diagnoses and inpatient hospital procedures by concurrently adopting the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, including the Official ICD-10-CM Guidelines for Coding and Reporting, as maintained and distributed by the U.S. Department of Health and Human Services (HHS), hereinafter referred to as ICD-10-CM, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, including the Official ICD-10-PCS Guidelines for Coding and Reporting, as maintained and distributed by the HHS, hereinafter referred to as ICD-10-PCS. These new codes replace the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2, including the Official ICD-9-CM Guidelines for Coding and Reporting, hereinafter referred to as ICD-9-CM Volumes 1 and 2, and the International Classification of Diseases, 9th Revision, Clinical Modification, Volume 3, including the Official ICD-9-CM Guidelines for Coding and Reporting, hereinafter referred to as ICD-9-CM Volume 3, for diagnosis and procedure codes, respectively.

DATES: The effective date of this regulation is March 17, 2009. The effective date is the date that the policies herein take effect, and new policies are considered to be officially adopted. The compliance date, which is

different than the effective date, is the date on which entities are required to have implemented the policies adopted in this rule. The compliance date for this regulation is October 1, 2013.

FOR FURTHER INFORMATION CONTACT:

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I. Background

A. Statutory Background

The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, enacted on August 21, 1996. HIPAA has helped to improve the Medicare and Medicaid programs, and the efficiency and effectiveness of the health care system in general, by encouraging the development of standards and requirements to facilitate the electronic transmission of certain health information.

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.” Part C of title XI of the Act now consists of sections 1171 through 1180. Section 1172 of the Act and the implementing regulations make 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 for which the Secretary has adopted a standard.

Section 1172(c)(1) of the Act requires any standard adopted by the Secretary of the Department of Health and Human Services (HHS) to be developed, adopted, or modified by a standard setting organization (SSO), except in the cases identified under section 1172(c)(2) of the Act. Under section 1172(c)(2)(A) of the Act, the Secretary may adopt a standard that is different from any standard developed by an SSO if it will substantially reduce administrative costs to health care 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 of the United States Code. Under section 1172(c)(2)(B) of the Act, if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt, section 1172(c)(1) does not apply.

Section 1172 of the Act also sets forth consultation requirements that must be met before the Secretary may adopt

standards. The SSO must consult with the following organizations in the course of the development, adoption, or modification of the standard: National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). For a standard that was not developed by an SSO, the Secretary is required to consult with each of the above-named groups before adopting the standard. Under section 1172(f) of the Act, the Secretary must also rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS) and consult with appropriate Federal and State agencies and private organizations.

Section 1173(a) of the Act requires the Secretary to adopt transaction standards and data elements for the electronic exchange of health information for certain health care transactions. Under sections 1173(b) through (f) of the Act, the Secretary is required to adopt standards for: Unique health identifiers, code sets, security standards for health information, electronic signatures, and the transfer of information among health plans.

Section 1174 of the Act requires the Secretary to review the adopted standards and adopt modifications as appropriate, but not more frequently than once every 12 months in a manner which minimizes disruption and cost of compliance. The same section requires the Secretary to ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets, along with instructions on how data elements encoded before any modification may be converted or translated to preserve the information value of any pre-existing data elements.

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

extend the time for compliance for small health plans.

B. Regulatory Background: Adoption and Modification of HIPAA Code Sets

The Transactions and Code Sets final rule (65 FR 50312) published in the **Federal Register** on August 17, 2000 (hereinafter referred to as the "August 17, 2000 final rule") implemented some of the requirements of the Administrative Simplification subtitle of HIPAA, by adopting standards for eight electronic transactions for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard). We established these standards at 45 CFR parts 160, subpart A, and 162, subparts A, and I through R. The "Modifications to Electronic Data Transaction Standards and Code Sets" final rule, published on February 20, 2003 (68 FR 8381) (hereinafter referred to as the "February 20, 2003 final rule"), modified the implementation specifications for several adopted transactions standards, among other provisions. Please refer to the August 17, 2000 final rule and the February 20, 2003 final rule for detailed discussions of electronic data interchange and an analysis of the public comments received during the promulgation of both rules.

In the August 17, 2000 final rule, we also adopted standard code sets for use in those transactions, including:

- International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) Volumes 1 and 2 (including the Official ICD-9-CM Guidelines for Coding and Reporting) as maintained and distributed by the Department of Health and Human Services (HHS), for coding diseases, injuries, impairments, other health problems and their manifestations, and causes of injury, disease, impairment, or other health problems.
- ICD-9-CM Volume 3 (including the Official ICD-9-CM Guidelines for Coding and Reporting) as maintained and distributed by HHS, for procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals regarding prevention, diagnosis, treatment, and management.

ICD-9-CM Volumes 1 and 2, and ICD-9-CM Volume 3 were already widely used in administrative transactions when we promulgated the August 17, 2000 final rule, and we decided that adopting these existing code sets would be less disruptive for

covered entities than modified or new code sets. Please refer to the August 17, 2000 final rule for details of that discussion, as well as a discussion of utilizing ICD-10-CM and ICD-10-PCS as a future HIPAA standard code set (65 FR 50327). Please refer to the August 17, 2000 final rule; "Standards for Privacy of Individually Identifiable Health Information" (65 FR 82462), published in the **Federal Register** on December 28, 2000; Standards for Privacy of Individually Identifiable Health Information; Final Rule (67 FR 53182) published in the **Federal Register** on August 14, 2002; and "the Modification to Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS" proposed rule (hereinafter referred to as the "August 22, 2008 proposed rule") (73 FR 49796), published in the **Federal Register** on August 22, 2008 for further information about electronic data interchange and the regulatory background.

II. ICD-9-CM

The 9th revision of the International Classification of Diseases (ICD-9) was originally developed and maintained by the World Health Organization (WHO). While it was originally designed to classify causes of death (mortality), the scope of ICD-9 was expanded, through the development of the U.S. clinical modification, to include non-fatal diseases (morbidity). The Centers for Disease Control and Prevention (CDC) developed and maintains a clinical modification of ICD-9 for diagnosis codes which is called "ICD-9-CM Volumes 1 and 2." The Centers for Medicare & Medicaid Services (CMS) maintains an additional clinical modification of ICD-9 for inpatient hospital procedure codes, which is called "ICD-9-CM Volume 3." The Secretary adopted CDC's ICD-9-CM in 1979 for morbidity applications. ICD-9-CM has been used since 1983 as the basic input for assigning diagnosis-related groups for Medicare's Inpatient Prospective Payment System. ICD-9-CM Volumes 1 and 2, and ICD-9-CM Volume 3 were adopted as HIPAA code sets in 2000 for reporting diagnoses, injuries, impairments, and other health problems and their manifestations, and causes of injury, disease, impairment, or other health problems in standard transactions.

A. ICD-9-CM, Volumes 1 and 2 (Diagnosis)

CDC developed ICD-9-CM, Volumes 1 and 2. It produced a clinical modification to the WHO's ICD-9 by adding more specificity to its diagnosis codes. ICD-9-CM diagnosis codes are three to five digits long, and are used by

all types of health care providers, including hospitals and physician practices. The code set is organized into chapters by body system. For a discussion of the structure of the ICD-9-CM diagnosis code sets, please refer to the August 22, 2008 proposed rule (73 FR 49798).

B. ICD-9-CM, Volume 3 (Procedures)

Inpatient hospital services procedures are currently coded using ICD-9-CM Volume 3, which was adopted as a HIPAA standard in 2000 for reporting inpatient hospital procedures. Current Procedural Terminology, 4th Edition (CPT-4) and Healthcare Common Procedure Coding System (HCPCS) are used to code all other procedures. The ICD-9-CM procedure codes, which are maintained by CMS, are three to four digits long and organized into chapters by body system (for example, musculoskeletal, urinary and circulatory systems, etc.). For a discussion of the structure of the ICD-9-CM procedure code set, please refer to the August 22, 2008 proposed rule (73 FR 49798).

C. Limitations of ICD-9-CM

In the August 22, 2008 proposed rule (73 FR 49799), we discussed the shortcomings of ICD-9-CM. The ICD-9-CM code set is 29 years old, its approximately 16,000 procedure and diagnosis codes are insufficient to continue to allow for the addition of new codes, and, because it cannot accommodate new procedures, its capacity as a fully functioning code set is diminished. Many chapters of ICD-9-CM are full, and in others the hierarchical structure of the ICD-9-CM procedure code set is compromised. This means that some chapters can no longer accommodate new codes, so any additional codes must be assigned to other, typically unrelated chapters (for example, inserting a heart procedure code in the eye chapter of the code set). The ICD-9-CM code set was never designed to provide the increased level of detail needed to support emerging needs, such as biosurveillance and pay-for-performance programs (P4P), also known as value-based purchasing or competitive purchasing. For a detailed discussion of the shortcomings of the ICD-9-CM code set, please refer to the August 22, 2008 proposed rule (75 FR 49799).

D. Maintaining/Updating ICD-9-CM (Volumes 1, 2, and 3)

Recognizing the need for ICD-9-CM to be a flexible, dynamic statistical tool to meet expanding classification needs, the ICD-9-CM Coordination and Maintenance Committee was created in

1985 as an open forum for receiving public comments on proposed code revisions, deletions, and additions. The Committee is co-chaired by CDC and CMS; CDC maintains ICD-9-CM Diagnosis Codes (Volumes 1 and 2), and CMS maintains ICD-9-CM Procedure Codes (Volume 3).

As discussed in the August 22, 2008 proposed rule (73 FR 49805), we will rename the ICD-9-CM Coordination and Maintenance Committee as the ICD-10 Coordination and Maintenance Committee at the point when ICD-10 becomes the new HIPAA standard. Until that time, the ICD-9-CM Coordination and Maintenance Committee will continue to update and maintain ICD-9-CM. For a discussion of maintaining and updating code sets, please refer to the August 22, 2008 proposed rule (73 FR 49798-49799).

III. ICD-10 and the Development of ICD-10-CM and PCS

The ICD-10 code sets provide a standard coding convention that is flexible, providing unique codes for all substantially different health conditions. It also allows new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols. ICD-10-CM and ICD-10-PCS provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes. ICD-10-PCS has the capability to readily expand and capture new procedures and technologies.

A. ICD-10-CM Diagnosis Codes

CDC's National Center for Health Statistics (NCHS) developed the ICD-10-CM code set, following a voluntary consensus-based process and working closely with specialty societies to ensure clinical utility and subject matter expert input into the process of creating the clinical modifications, with comments from a number of prominent specialty groups and organizations that addressed specific concerns or perceived unmet clinical needs encountered with ICD-9-CM. NCHS also had discussions with other users of the ICD-10 code set, specifically nursing, rehabilitation, primary care providers, the National Committee for Quality Assurance (NCQA), long-term care and home health care providers, and managed care organizations to solicit their comments about the ICD-10 code set. There are approximately 68,000 ICD-10-CM codes. ICD-10-CM diagnosis codes are three to seven alphanumeric characters. The ICD-10-CM code set provides much more

information and detail within the codes than ICD-9-CM, facilitating timely electronic processing of claims by reducing requests for additional information.

ICD-10-CM also includes significant improvements over ICD-9-CM in coding primary care encounters, external causes of injury, mental disorders, neoplasms, and preventive health. The ICD-10-CM code set reflects advances in medicine and medical technology, as well as accommodates the capture of more detail on socioeconomic, ambulatory care conditions, problems related to lifestyle, and the results of screening tests. It also provides for more space to accommodate future expansions, laterality for specifying which organ or part of the body is involved as well as expanded distinctions for ambulatory and managed care encounters.

B. ICD-10-PCS Procedure Codes

CMS developed a procedure coding system, ICD-10-PCS. ICD-10-PCS has no direct relationship to the basic ICD-10 diagnostic classification, which does not include procedures, and has a totally different structure from ICD-10-CM. ICD-10-PCS is sufficiently detailed to describe complex medical procedures. This becomes increasingly important when assessing and tracking the quality of medical processes and outcomes, and compiling statistics that are valuable tools for research. ICD-10-PCS has unique, precise codes to differentiate body parts, surgical approaches, and devices used. It can be used to identify resource consumption differences and outcomes for different procedures, and describes precisely what is done to the patient. ICD-10-PCS codes have seven alphanumeric characters and group together services into approximately 30 procedures identified by a leading alpha character. There are 16 sections of tables that determine code selection, with each character having a specific meaning. (See section V of the August 22, 2008 proposed rule (73 FR 49802-49803) for a chart that compares ICD-9-CM, ICD-10-CM, and ICD-10-PCS codes.)

As explained in the August 22, 2008 proposed rule (73 FR 49801), to our knowledge, no SSO has developed, adopted, or modified a standard code set that is suitable for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions.

IV. Summary of Proposed Provisions and Analysis of and Responses to Public Comments

In the August 22, 2008 proposed rule (73 FR 49796), we solicited comments from stakeholders and other interested parties on the proposed adoption of ICD-10-CM and ICD-10-PCS code sets. We received 3,115 timely public submissions from all segments of the health care industry including providers, physician practices, hospitals, coders, standards development organizations, vendors, State Medicaid agencies, State agencies, corporations, tribal representatives, healthcare professional and industry trade associations, and disease-related advocacy groups.

Some comments were received timely, but were not relevant to the August 22, 2008 proposed rule and were not considered in our responses. Those comments referred to general Medicare program operations; a call for the development of a single payer health care system in the United States; general economic issues; a request for finalization of HIPAA standards that were not included in the August 22, 2008 proposed rule; a request to adopt coding guidelines for CPT codes; comments on another unrelated notice of proposed rulemaking; and other issues that are outside of the purview of the August 22, 2008 proposed rule. The relevant and timely submissions within the scope of the August 22, 2008 proposed rule that we received tended to provide multiple detailed comments on our proposals.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the economic impact analysis), and our responses to the comments are set forth below:

A. Adoption of ICD-10-CM and ICD-10-PCS as Medical Data Code Sets Under HIPAA

In § 162.1002(c)(2), we proposed to adopt ICD-10-CM (including the official guidelines) to replace ICD-9-CM Volumes 1 and 2 (including the official coding guidelines), for coding diseases; injuries; impairments; other health problems and their manifestations; and causes of injury, disease and impairment, or other health problems.

In § 162.1002(c)(3), we proposed to adopt ICD-10-PCS (including the official guidelines) to replace ICD-9-CM Volume 3 (including the official coding guidelines) for the following procedures or other actions taken for diseases, injuries, and impairments on hospital

inpatients reported by hospitals: prevention, diagnosis, treatment, and management.

Comment: Commenters overwhelmingly supported our proposal to adopt ICD-10-CM and ICD-10-PCS as code sets under HIPAA, replacing the ICD-9-CM Volumes 1 and 2, and the ICD-9-CM Volume 3 code sets, respectively, citing the benefits we described in the August 22, 2008 proposed rule. Some commenters pointed out that the United States, with its continued use of ICD-9-CM, is behind the rest of the world which has already migrated to ICD-10, and that ICD-9-CM's basic structure is flawed and outdated, and cannot accommodate new medical technology and terminology. Commenters agreed that ICD-9-CM Volume 3 is running out of space, and that this space limitation curtails the ability to capture accurate reimbursement and quality data for health care documentation. A few commenters noted that, as providers migrate toward the use of electronic health records (EHRs), use of the more robust ICD-10-CM and ICD-10-PCS codes will be necessary to support EHRs' more detailed information requirements. Another commenter noted that waiting to move to ICD-10-CM and ICD-10-PCS incurs its own costs as the underlying data used for patient care improvement, institutional quality reviews, medical research and reimbursement becomes increasingly unreliable.

Response: We are amending § 162.1002 to adopt ICD-10-CM and ICD-10-PCS as medical data code sets under HIPAA, replacing ICD-9-CM, Volumes 1 and 2, and ICD-9-CM Volume 3.

Comment: We also received a number of comments stating that we should not adopt ICD-10-CM and ICD-10-PCS as code sets under HIPAA. Several commenters said that the ICD-9-CM code set is adequate to meet current coding needs, making ICD-10-CM and ICD-10-PCS unnecessary. These commenters said that current ICD-9-CM codes do not have serious limitations, and perhaps simply need some modifications to alleviate any limitations that ICD-9-CM might have. A number of commenters said that we should not adopt ICD-10-CM and ICD-10-PCS because the cost associated with the transition from ICD-9-CM to ICD-10-CM and ICD-10-PCS would be a burden to industry. However, they did not offer specific alternative solutions.

Other commenters offered a number of different alternatives, including:

- Create additional space in ICD-9-CM through the annual elimination and

reassignment of codes that are no longer used.

- Modify the structure of ICD-9-CM to provide for the assignment of additional codes.

- Continue to assign new procedures to the two, previously unassigned overflow chapters of ICD-9-CM, chapters 00 and 17, and once those chapters are filled, no new codes should be created that cannot be assigned to the appropriate body system chapter.

- Adopt the American Medical Association's Physicians' Current Procedural Terminology (CPT) for coding inpatient hospital procedures.

- Wait and adopt the ICD-11 code set. Two commenters stated that by the time the United States has achieved proficiency using ICD-10-CM and ICD-10-PCS, the rest of the world will be using ICD-11, and our nation's coding reporting system will once again be incompatible with that of other countries.

- Decouple the coding of diseases at the point of patient care from the classification of diseases for secondary uses of medical record data by developing a U.S. Disease-Entity Coding System (USDECS) instead of adopting ICD-10-CM.

One commenter erroneously interpreted our proposed adoption of ICD-10-PCS as a proposal to replace CPT codes in the ambulatory setting. Another commenter said we should recognize that hospital outpatient departments are currently required to report using HCPCS and CPT codes, but that some hospitals have elected to code these hospital outpatient medical records using ICD-9-CM procedure codes.

Response: None of the suggested alternatives adequately address the shortcomings of ICD-9-CM that were identified and discussed in the August 22, 2008 proposed rule. The majority of commenters supported our analysis of these shortcomings. As we noted in the August 22, 2008 proposed rule (73 FR 49827), we do not believe that extending the life of ICD-9-CM by assigning codes to unrelated chapters or purging and reassigning codes that are no longer used is a long-term solution, and it would perpetuate confusion for coders and data users if hierarchy and code set structure were to continue to be set aside in the issuance of new codes. Gaining space in ICD-9-CM by annually purging codes that are not used is problematic because, while it creates space, this space may not necessarily be in the same chapters in which codes are needed. As no one asserted that this purging process would open up sufficient capacity to assign new codes

in the hierarchical sections in which the new codes ought to be placed, purging and reassigning might only lead to coder confusion and further contribute to the hierarchical instability of the code set. Moreover, such action would destroy the ability to perform longitudinal research.

Modifying the existing ICD-9-CM code sets by adding more digits and/or alpha characters was discussed as a possible alternative to adoption of the ICD-10-CM and ICD-10-PCS code sets at public meetings of the ICD-9-CM Coordination and Maintenance Committee; however, there appears to be little industry support for this alternative. The disruption resulting from adding a digit and/or alpha character to the ICD-9-CM code set, and then trying to both refine and modify approaches to assigning codes would result in nearly the same costs in infrastructure and systems changes as a transition to ICD-10-PCS, but with no significant improvement in the coding system.

In the August 22, 2008 proposed rule (73 FR 49804), we explained that we did not consider the CPT-4 coding system to be a viable alternative to ICD-10-CM and ICD-10-PCS code sets because CPT does not adequately capture facility-based, non-physician services, and commenters did not offer any new information to support that approach.

In the August 22, 2008 proposed rule, we did not propose the replacement of CPT with ICD-10-PCS in the ambulatory setting. In the August 17, 2000 final rule (65 FR 50312), we adopted the HCPCS and CPT codes as the official procedure coding systems for outpatient reporting. ICD-9-CM procedure codes are not a HIPAA standard for coding in these settings, and while some hospitals may elect to double code their outpatient records using both HCPCS and CPT, as well as ICD-9-CM procedure codes for internal purposes, this is not a requirement. We do not encourage this type of double coding, and do not believe that this voluntary practice impacts the analysis of whether or not ICD-10-PCS should be adopted.

We discussed waiting to adopt the ICD-11 code set in the August 22, 2008 proposed rule (73 FR 49805), noting that the World Health Organization (WHO) has only begun preliminary work on ICD-11. There are no firm timeframes established for completion of the ICD-11 developmental work, testing or release for use date. We are aware of reports that the WHO's alpha version of ICD-11 may be available for testing in 2010, with possible approval of ICD-11 for general worldwide use in 2014.

However, work cannot begin on developing the necessary U.S. clinical modification to the ICD-11 diagnosis codes or the ICD-11 companion procedure codes until ICD-11 is officially released. Development and testing of a clinical modification to ICD-11 to make it usable in the United States will take an estimated additional 5 to 6 years. We estimated that the earliest projected date to begin rulemaking for implementation of a U.S. clinical modification of ICD-11 would be the year 2020.

The suggestion that we wait and adopt ICD-11 instead of ICD-10-CM and ICD-10-PCS does not consider that the alpha-numeric structural format of ICD-11 is based on that of ICD-10, making a transition directly from ICD-9 to ICD-11 more complex and potentially more costly. Nor would waiting until we could adopt ICD-11 in place of the adopted standards address the more pressing problem of running out of space in ICD-9-CM Volume 3 to accommodate new procedure codes.

Finally, the development of a United States Disease-Entity Coding System (USDECS), which would involve developing a totally new classification system not based on any previous classification system platforms, would require even more time than implementing ICD-11, and would also hamper efforts to evaluate United States data in the context of other countries' experiences.

Comment: A few commenters stated that HHS needs to ensure that the use of ICD-10-CM and ICD-10-PCS code sets will not conflict with other federally recognized standards.

Response: We assume the commenter is referring to Secretariately recognized interoperability standards recommended by the Healthcare Information Technology Standards Panel (HITSP), a cooperative partnership between the public and private sectors formed to harmonize and integrate standards that will meet clinical and business needs for sharing information among organizations and systems. In some HITSP interoperability specifications, including those for Electronic Health Records, Laboratory Results Reporting and Biosurveillance, HITSP has defined or identified specific interoperability standards, including use of SNOMED-CT®, to support interoperability of systems. As discussed in the August 22, 2008 proposed rule (73 FR 49803), ICD-10-CM and ICD-10-PCS are classification coding systems while SNOMED-CT® is a clinically complex terminology standard. As we noted in the August 22, 2008 proposed rule, we do not believe

that SNOMED-CT® is a suitable standard for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. The numerous codes would be impractical to assign manually and are not suited to the secondary purposes for which classification systems like ICD-10 codes are used because of their size and considerable granularity, complex hierarchies, and lack of reporting rules. (See 73 FR 49803-49804). SNOMED-CT® is not a substitute for ICD-10 as a coding system, but, as further noted in the August 22, 2008 proposed rule, the benefits of using SNOMED-CT® increase if such use is linked to a classification system such as ICD-10-CM and ICD-10-PCS. Mapping would be used to link SNOMED-CT® to ICD-10 code sets. Plans are underway to develop these crosswalks, so a transition to ICD-10 code sets will ultimately facilitate realizing the benefits of using the specified interoperability standards including SNOMED-CT®. Moreover, it is the promulgation of regulations, and not the HITSP process, that dictates which standards are ultimately to be used for administrative transactions.

Comment: A number of commenters stated that quality performance measures currently used for programs such as the Physician Quality Reporting Initiative (PQRI) are based on ICD-9-CM diagnosis codes, and it is unclear how the change to ICD-10 would impact those programs.

Response: We anticipate that the use of ICD-10-CM, with its greater detail and granularity, will greatly enhance our capability to measure quality outcomes. We acknowledge that quality performance outcome measures are currently used for high-profile initiatives such as the hospital pay-for-reporting program. The greater detail and granularity of ICD-10-CM and ICD-10-PCS will also provide more precision for claims-based, value-based purchasing initiatives such as the hospital-acquired conditions (HAC) payment policy. Crosswalks that allow the industry to convert ICD-9-CM codes into ICD-10-CM and ICD-10-PCS codes (and vice versa) are already in existence. These crosswalks and others that are developed during the implementation period will allow the industry to convert payment systems, HAC payment policies, and quality measures to ICD-10. We note that, under this rule, ICD-10 codes will not be implemented as a HIPAA code set until 2013. Programs that offer incentives that are based on performance outcome measures that may be impacted by the changeover from ICD-9-CM to ICD-10-CM will

have sufficient time to plan for a smooth transition to ICD-10 coding. Our own such preparation will include ICD-10 updates to the quality measures as part of our routine regulatory process.

B. Compliance Date

In the August 22, 2008 proposed rule, we proposed October 1, 2011 as the compliance date for ICD-10-CM and ICD-10-PCS code sets for all HIPAA covered entities. To illustrate our implementation timeline for preliminary planning purposes, we also published in the proposed rule (73 FR 49807) a draft implementation timeline for both Version 5010 and ICD-10-CM and ICD-10-PCS.

Comment: While an overwhelming majority of commenters favored adoption of ICD-10-CM and ICD-10-PCS, they expressed many different positions regarding the compliance date. Most commenters disagreed with the proposed October 1, 2011 compliance date, stating that it did not provide adequate time for industry to train coders and complete systems changeovers and testing.

In general, commenters expressed particular concern about the industry's ability to implement both ICD-10 and the concurrently proposed X12 Version 5010 transactions standards (Version 5010) in the proposed timeframe. The commenters pointed out that this timeframe would jeopardize plans' ability to process claims and could therefore result in more unpaid or improperly paid claims. They also pointed out that this compliance date would provide less time for adopting ICD-10-CM and ICD-10-PCS than the actual amount of time it took industry to implement other HIPAA standards, including the National Provider Identifier. One commenter proposed incentive payments to HIPAA covered entities to help them achieve compliance given the short compliance timeframe.

NCVHS' September 26, 2007 recommendation on the implementation of Version 5010 and ICD-10 was frequently cited by commenters as being the benchmark against which they measured their own recommendations. Some commenters stated that we should further consider the NCVHS recommendation to the Secretary that there be a 2-year time gap between the finalization of the implementation of Version 5010, and compliance with ICD-10. A number of commenters interpreted the NCVHS recommendation as being that of a 3-year time gap, and cited that as their basis for supporting a 2013 or in some

instances, a 2014 compliance date for ICD-10.

In fulfillment of part of its HIPAA-mandated responsibilities, NCVHS submitted recommendations to HHS that suggested establishing two different levels of compliance for the implementation of ICD-10-CM and ICD-10-PCS code sets relative to compliance with Version 5010. "Level 1 compliance," as interpreted by NCVHS, would mean that the HIPAA covered entity could demonstrate that it could create and receive ICD-10-CM and ICD-10-PCS compliant transactions. "Level 2 compliance," as interpreted by NCVHS, would mean that HIPAA covered entities had completed end-to-end testing with all of their trading partners. NCVHS further recommended that no more than one implementation of a HIPAA transaction or coding standard be in Level 1 at any given time, which tacitly suggests that Level 2 testing for Version 5010 could, in NCVHS' estimation, reasonably take place concurrently with initial Level 1 activities associated with ICD-10 implementation.

As commenters noted, the NCVHS letter stated that "it is critical that the industry is afforded the opportunity to test and verify Version 5010 up to two years prior to the adoption of ICD-10." The letter's Recommendation 2.2 further states that "HHS should take under consideration testifier feedback indicating that for Version 5010, two years will be needed to achieve Level 1 compliance."

A small number of commenters supported the proposed October 1, 2011 implementation date. They believed that the date was achievable, and stressed that the benefits of ICD-10 are so significant that an aggressive implementation timetable was justified because it would make additional information available that would support health care transparency, and thereby benefit patients, and that further delays in implementation would result in increased implementation costs. Others simply stated that the time had come for the U.S. to catch up with the rest of the world in using ICD-10.

A smaller number of commenters supported an implementation date of October 1, 2012. They, too, cited the benefits of ICD-10, and argued that a one-year postponement of the proposed October 2011 date would provide sufficient time in which the industry could achieve compliance with ICD-10-CM and ICD-10-PCS. A few commenters explicitly noted that a 2012 implementation date would allow them adequate time to budget and plan for the changeover. Other commenters stated

that ICD-10 compliance should come no earlier than October 2012; and still others recommended an October 2012 compliance date if such a compliance date would allow for a 3-year implementation timetable for ICD-10 following the Version 5010 compliance date.

A number of commenters suggested a compliance date of October 2013, citing insufficient time in which to install and test ICD-10-CM and ICD-10-PCS within their claims processing and other related IT systems, the need for coder and provider education and outreach, and the time needed for implementation of previous HIPAA standards. These commenters stated that an October 2013 date would afford them with the minimum of 2 years after implementing Version 5010 that they said they needed in order to comply with ICD-10-CM and ICD-10-PCS. The compliance date must occur on October 1 of any given year in order to coincide with the effective date of the annual Medicare Inpatient Prospective Payment System (IPPS). A number of commenters supported a 2013 compliance date as more realistic than the proposed 2011 date, and urged that we move quickly to publish a final rule to adopt ICD-10-CM and ICD-10-PCS. Other commenters simply noted that 2013 was a reasonable date that would allow more time for effective implementation and training on the proper use of code sets. Commenters noted that this date should give HIPAA covered entities sufficient time to fully implement Version 5010 before moving on to ICD-10. A few other commenters noted that the compliance date for ICD-10 should not be any earlier than 2013.

The majority of commenters, including individual providers and industry associations, supported a compliance date of October 1, 2014 which they said could be less costly, allow more time for education, and would better ensure that the desired benefits of the ICD-10-CM and ICD-10-PCS code sets are achieved. The majority of submissions that supported a 2014 compliance date were form letters submitted by members representing the position of one industry professional association.

A few commenters suggested an implementation date of October 1, 2015 or beyond, once again citing their perceptions of the high cost of the transition to ICD-10-CM and ICD-10-PCS, and the need for extensive education and training.

Other commenters did not propose a specific compliance date, but rather indicated the need for 3 years after the Version 5010 compliance date. Other

commenters suggested that 95 percent of covered entities be successfully converted to Version 5010 prior to the start of ICD-10 implementation.

One commenter stated that the adoption of ICD-10-CM should be delayed until the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) has been released.

Response: We recognize that the compliance date issue is crucial to the successful implementation of ICD-10. We have assessed the comments carefully, balancing the benefits of earlier implementation against the potential risk of establishing a deadline that does not provide adequate time for successful implementation and thorough testing. We cannot consider a compliance date for ICD-10 without considering the dependencies between implementing Version 5010 and ICD-10. We recognize that any delay in attaining compliance with Version 5010 would negatively impact ICD-10 implementation and compliance. The lack of information on cost estimate impacts also supports a later ICD-10 compliance date to allow the industry to spread out any unanticipated costs over a longer period of time.

Pursuant to a regulation published in this same edition of the **Federal Register**, the Version 5010 compliance date has now been established as January 2012, to afford the industry an additional year, for a total of 3 years to achieve compliance with Version 5010.

From our review of the industry testimony presented to NCVHS and comments received on our August 22, 2008 proposed rule, it appears that 24 months (2 years) is the minimum amount of time that the industry needs to achieve compliance with ICD-10 once Version 5010 has moved into external (Level 2) testing.

We believe that the spirit and intent of the NCVHS letter recommends that the Secretary move the industry forward on the adoption and implementation of, and compliance with, Version 5010 and

the ICD-10-CM and ICD-10-PCS code sets. At the same time, NCVHS recognizes the wide-reaching impacts of the transition to ICD-10-CM and ICD-10-PCS, and in doing so, implies that any implementation plans and timetables should be structured as to be realistic for the industry as a whole.

In establishing the ICD-10 compliance date, we have sought to select a date that achieves a balance between the industry's need to implement ICD-10 within a feasible amount of time, and our need to begin reaping the benefits of the use of these code sets; stop the hierarchical deterioration and other problems associated with the continued use of the ICD-9-CM code sets; align ourselves with the rest of the world's use of ICD-10 to achieve global health care data compatibility; plan and budget for the transition to ICD-10 appropriately; and mitigate the cost of further delays.

We believe that an October 1, 2013 ICD-10 compliance date achieves that balance, being 2 years later than our proposed October 2011 ICD-10 compliance date and providing a total of nearly 5 years from the publication of the Version 5010 final rule through final compliance with ICD-10. The 32 months from completion of Level 1 testing for Version 5010 in January 2011 (at which point Level 1 ICD-10 activities can begin) to the October 1, 2013 compliance date for ICD-10 should allow the industry ample time to effect systems changeovers and testing so as to become fully compliant with the ICD-10-CM and ICD-10-PCS code sets.

We note that those requesting compliance dates of 2014 and later did not suggest methods for mitigating the negative effects of delaying compliance, including the increased implementation costs which may result from the increase in the number and size of legacy systems that will need to be updated; delay in achieving the benefits identified in the August 22, 2008 proposed rule; and the impacts of continued degradation of the code sets.

We further note that many health plans supported a 2013 compliance date. Since the complexity of ICD-10 implementation will be much higher for health plans (because after health plans update systems to utilize ICD-10 codes, they will also have to develop claims processing edits based on those codes) than for individual providers and coders, we take the support of health plans for a 2013 compliance date as an indication of the reasonableness of this timeline.

It is also important to note that, while NCVHS recommended that Level 1 activities for Version 5010 and ICD-10 should not overlap, it is inevitable that, as covered entities embark on requirements analysis for Version 5010, they will identify ICD-10 issues as a natural offshoot of those efforts. Thus, even if entities choose not to begin full-scale ICD-10 implementation efforts until Version 5010 has reached Level 2 compliance, they will likely begin that phase with a preexisting knowledge base about ICD-10, and will also have identified lessons learned and best practices that will inform those later activities.

We also note that the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) is projected to be released in 2012 by the American Psychiatric Association (APA). CDC is working with APA to ensure that ICD-10-CM and DSM-V codes match, and that the timing of this projected release would conform with the commenter's request that the ICD-10 compliance date occur after the release of DSM-V.

We are adopting the ICD-10-CM and ICD-10-PCS as medical data code sets under HIPAA, replacing ICD-9-CM Volumes 1 and 2, and Volume 3, with a compliance date of October 1, 2013, and have updated the draft ICD-10/Version 5010 implementation timeline which previously appeared in the proposed rule (73 FR 49807) to read as follows:

TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.0 AND ICD-10

Version 5010/D.0	ICD-10
01/09: Publish final rule	01/09: Publish Final Rule
01/09: Begin Level 1 testing period activities (gap analysis, design, development, internal testing) for Versions 5010 and D.0.	
01/10: Begin internal testing for Versions 5010 and D.0.	
12/10: Achieve Level 1 compliance (Covered Entities have completed internal testing and can send and receive compliant transactions) for Versions 5010 and D.0.	
01/11: Begin Level 2 testing period activities (external testing with trading partners and move into production; dual processing mode) for Versions 5010 and D.0.	01/11: Begin initial compliance activities (gap analysis, design, development, internal testing).

TIMELINE FOR IMPLEMENTING VERSIONS 5010/D.0 AND ICD-10—Continued

Version 5010/D.0	ICD-10
01/12: Achieve Level 2 compliance; Compliance date for all covered entities. This is also the compliance date for Version 3.0 for all covered entities except small health plans*.	10/13: Compliance date for all covered entities.

Note: Level 1 and Level 2 compliance requirements only apply to Version 5010, NCPDP Telecommunication Standard Version D.0, and NCPDP Medicaid Subrogation Standard Version 3.0.

Comment: One commenter stated that the October 1 compliance date should be changed to better align with the health care industry's regularly scheduled annual system changeovers.

Response: The commenter did not reference specific system changeovers, suggest an alternative date, or specify the regularly scheduled system changes to which it refers, so we are unable to assess the validity of the comment. We received no other comments opposed to an October 1 date. The October 1 date was selected to ensure that the ICD-10 compliance date would coincide with the effective date of the Medicare IPPS update.

Comment: A number of commenters urged that the compliance date for the HIPAA health care claims attachment standard not coincide with the Level 1 implementation activities related to either Version 5010 or ICD-10.

Response: We will take this into consideration in establishing a compliance date in the health care claims attachment standard final rule.

C. Implementation Period

Comment: A minority of commenters disagreed with our proposal to establish a single compliance date for ICD-10. Some commenters suggested a variety of alternatives for phased-in or staggered implementation of the ICD-10-CM and ICD-10-PCS code sets in order to alleviate the impact of implementation. A number of these commenters suggested that we allow "dual processing": in other words, acceptance of either ICD-9 or ICD-10 code sets on any given claim for a specified period of time. They expressed concern about having a single date on which all covered entities would have to convert to ICD-10, and stressed the need for testing between trading partners to ensure that claims are properly processed. They also pointed out that covered entities would have to maintain dual processes in any case to process old claims.

Other commenters proposed that the ICD-10-CM diagnosis and ICD-10-PCS procedure codes be implemented at different times. A few commenters suggested adopting other nations'

approaches to implementing ICD-10 such as those used in Canada and Australia, specifically, staggered implementation of the new codes either by geographic region, by covered entity category, and/or allowing for a later implementation date for small entities.

Other commenters pointed out that diagnosis and procedure codes affect the amount of payment, and that dual processing (that is, the possibility that a claim for services provided on a given date being processed for reimbursement at two different rates based on two code sets) would add significant complexity.

Response: Implementation of ICD-10 will require significant business and technical changes for all covered entities.

We acknowledge that ICD-9-CM codes will continue to be used only for the period of time during which old claims (those with dates of service prior to October 1, 2013) continue through the payment cycle. We do not believe that this period during which covered entities will be maintaining the ability to work in two code systems is what commenters meant by "dual processing." Rather, we believe that commenters utilized the term "dual processing" to mean the provider's ability to use their own discretion in deciding whether to submit claims using ICD-9 or ICD-10 code sets after the October 1, 2013 compliance date. Such use of more than one code set for coding diagnoses or procedures, whether in a medical record or claim, would cause significant business process duplication. It could result in different information being shared about a patient because the ICD-10 code set is so much more robust than ICD-9, and the code for a given diagnosis/procedure does not necessarily match one code to one code between the code sets.

While HHS could elect to provide for some sort of "staggered" implementation dates, we have concluded that it would be in the health care industry's best interests if all entities were to comply with the ICD-10 code set standards at the same time to ensure the accuracy and timeliness of claims and transaction processing.

We agree with commenters that maintenance of two code sets for a significant span of time such that, on any specific date of service in that time frame one could submit, process and/or receive payment on a claim based on ICD-9-CM or the ICD-10-CM and ICD-10-PCS code sets would raise considerable logistical issues and add to the complexity of the ICD-10 code set implementation. One would need to employ/operate duplicate coding staffs and systems. For example, we understand that Medicare's systems will not allow the use of two different code sets for services provided on the same date, and we presume that other covered entities' systems were likewise not designed with such capacities. Even if such coding and processing capabilities were available, the biller would have to ensure that claims indicated the coding system under which they were generated, and the recipient would need to put measures in place to avoid processing on the wrong system. We believe that this would impose a very significant burden on plans and providers/suppliers. The availability and use of crosswalks, mappings and guidelines should assist entities in making the switchover from ICD-9 to ICD-10 code sets on October 1, 2013, without the need for the concurrent use of both code sets in claims processing, medical record and related systems with respect to claims for services provided on the same day. Furthermore, although the Act gives the Secretary the authority to extend the time for compliance for small health plans if the Secretary determines that it is appropriate, we believe that different compliance dates based on the size of a health plan would also be problematic, since a provider has no way of knowing if a health plan qualifies as a small health plan or not.

As stated in the August 22, 2008 proposed rule (73 FR 49806), a phased-in implementation of ICD-10 that allows for payment systems to accept both ICD-9 and ICD-10 codes for services rendered on the same day would constitute a significant burden on the industry. We continue to believe that, based on our previous HIPAA standards implementation experience

and in consideration of the complexities of the U.S. health care system's multi-payer system, allowing both code systems to be used and reported at the same time (i.e., for services/procedures performed on the same day) would create confusion in processing and interpreting coded data, and claims could likely be denied for services, or returned as errors if processing errors resulted in edits that indicated too many or too few digits. It would be more costly for the various health care payment systems used in the United States to accept and process claims with both ICD-9 and ICD-10 code sets. Providers would have to maintain both coding systems, and there would be significant system implications in trying to determine which coding system was being used to report the coded data.

Adopting diagnosis and procedure codes at different times would result in similar system problems, namely pairing an ICD-9 diagnosis code with an ICD-10 procedure code, or vice versa. For more examples of problems associated with maintaining the two coding systems concurrently, please refer to the August 22, 2008 proposed rule (73 FR 49806).

Allowing the industry to use ICD-10-CM and ICD-10-PCS codes voluntarily would also result in confusion. Systems would not be able to recognize whether the code was an error made in an ICD-9 code entry, or actually an ICD-10 code, again causing rejection errors.

We continue to believe it is in the industry's best interest, and that includes small health plans, to have a single compliance date for ICD-10-CM and ICD-10-PCS. This will reduce the burden on both providers and insurers who will be able to edit on a single new coding system for claims received for encounters and discharges occurring on or after October 1, 2013, instead of having to maintain two coding systems over an extended period of time. Providers and insurers would use ICD-9-CM edits and payment logic for claims relating to encounters and discharges occurring prior to the date of compliance, and the ICD-10-CM and ICD-10-PCS edits and payment logic for all claims relating to encounters and discharges occurring on or after the ICD-10 compliance date. They would not have the burden of selectively applying either the ICD-9-CM or ICD-10-CM edits and logic to claims before the compliance date, and as a result, we have not established dates for Level 1 and Level 2 testing compliance for ICD-10 implementation. We encourage all industry segments to be ready to test their systems with ICD-10 as soon as it is feasible. We believe that the October

1, 2013 compliance date will allow various payment systems to correctly edit the codes and make payments based on the payment and coding system in effect at that time, and is sufficiently far in the future to provide all sectors of the industry adequate time to implement the code sets.

As described in section XI.D of the August 22, 2008 proposed rule (73 FR 49827), a number of phase-in compliance options for ICD-10-CM and ICD-10-PCS were considered and rejected because of the nature of the U.S. multi-payer system. Phased-in ICD-10-CM and ICD-10-PCS compliance based on staggered dates set by geography over extended periods of time would require plans (especially national plans), and possibly multi-state chain or national providers/suppliers or health care entities that were vertically integrated, to maintain and operate both ICD-9 and ICD-10 coding systems for an extended period of time. The time frame during which covered entities will need to learn and use the new ICD-10 codes, while at the same time continuing to work with the old ICD-9 codes, should be minimized because during this period there is an increase in the chance of errors in payments, and such confusion and uncertainty in the provider/supplier community could result in undesirable delays in processing claims that should be avoided to the extent possible. We believe that maintaining dual systems concurrently for an extended period of time would impose a very significant burden on plans and providers/suppliers. In the August 22, 2008 proposed rule (73 FR 49827), we also referenced the Canadian and Australian experience with their geographic phased-in ICD-10 implementation approach, and the problems they reported that were inherent in that approach. We have received no new information on other countries' experience with the implementation of their respective version of ICD-10 that would lead us to reverse our initial conclusion that a phased-in approach based on geographic boundaries is not in the best interests of the industry. Therefore, in consideration of the many problems inherent with these phased-in and/or staggered implementation alternatives, we are adopting October 1, 2013 as the compliance date for the ICD-10-CM and ICD-10-PCS medical data code sets.

D. Date of Admission Versus Date of Discharge Coding

Comment: We proposed to follow the current practice of implementing new code set versions effective with the date

of service, which for purposes of inpatient facilities means the medical codes in effect at the time of patient discharge. For example, if a patient is admitted in September and the patient is discharged on or after the October 1 compliance date, the hospital would have to assign the codes in effect on October 1. Several commenters requested that inpatient hospital facilities use the version of the codes in effect at the date of admission instead of the date of discharge because this would benefit inpatient facilities that use interim billing. They proposed that hospitals that did not use interim billing could continue to use the date of discharge for determining the version of ICD code sets to be used for coding.

Response: It has been a long standing practice for inpatient facilities to use the version of ICD codes in effect on the date of discharge. Most hospitals do not code their records for billing purposes until the patient is discharged. Much information is gathered through the process of inpatient treatment. Tests are performed, surgeries may be completed, and additional diagnoses may be assigned. Therefore, the documentation is more complete by the time a patient is discharged. At this point the hospital coder assigns the codes that are in effect on the date of discharge. All of our national inpatient data is based on this practice. We do not agree that changing this practice would be of benefit to hospitals, and maintain that the opposite would be true, and is counter to the implementation of a single, consistent ICD-10 implementation date. Furthermore, using the date of admission for some types of claims coding, and date of discharge for other types of claims coding would also greatly disrupt national data and create problems in analyzing what has, until this point in time, been a consistent approach to coding medical records. Hospitals engaged in interim billing will not see any change from their current practices. They will continue to use the code set in effect for services occurring prior to October 1, 2013 and will use the next year's update (in this case, ICD-10-CM and ICD-10-PCS for 2013) for services occurring on or after October 1, 2013.

Therefore, we will not change the current practice followed by inpatient facilities of coding based on the date of discharge.

E. Coding Guidelines

Comment: Several commenters expressed the need for ICD-10 coding guidelines to be developed and maintained. Some commenters incorrectly pointed out that guidelines

were not available, while others were aware of the ICD-10 guidelines that are posted on the CMS and CDC Web sites. Commenters expressed concern that the ICD-10-CM guidelines on CDC's Web page were created in 2003, and stated that they are "draft" guidelines that have not been updated. Commenters further indicated that this lack of finalized coding guidelines will make it difficult for software and systems vendors to develop ICD-10 products and for covered entities to begin training staff. Commenters also stated that there should be a single, authoritative source for ICD-10 coding guidelines to avoid variations in the interpretation and use of the codes. These commenters questioned whether the implementation of ICD-10 should be delayed until such time as the guidelines can be updated.

Response: We agree that it is important to have an official set of ICD-10 coding guidelines, and that they be properly maintained. CMS, CDC, AHA and AHIMA joined forces some time ago under a long-standing memorandum of understanding to develop and approve the guidelines for ICD-9-CM code set coding and reporting. These "Cooperating Parties" conduct annual reviews of these guidelines and develop new guidelines as needed, considering stakeholder input obtained through public meetings of the ICD-9-CM Coordination and Maintenance Committee, and through input submitted from AHA and AHIMA members. Only those guidelines approved by the Cooperating Parties are official and posted to CDC and CMS Web sites, and this has proven to be an effective approach to guideline development and maintenance. The Cooperating Parties will finalize a 2009 version of the Official ICD-10-CM coding guidelines, which will be posted to CDC's Web site in January 2009. Updated coding guidelines for ICD-10-PCS are included in the Reference Manual already posted to CMS' Web site at http://www.cms.hhs.gov/ICD10/Downloads/pcs_refman.pdf. Given the imminent availability of updated coding guidelines, we do not believe that it would be appropriate to further delay the adoption of the ICD-10 code sets pending the issuance of the updated guidelines.

F. ICD-10 Mappings and Crosswalks

Comment: Many commenters emphasized the importance of reliable crosswalks between ICD-9-CM and ICD-10-CM and ICD-10-PCS. Some commenters incorrectly stated that there were no crosswalks available between ICD-9-CM and ICD-10-CM and ICD-10-PCS diagnosis and procedure codes

and pointed out the importance of such crosswalks for implementation. Other commenters stated that they would require "additional bi-directional mapping developed by a single authoritative national source prior to implementation," to prevent loss of data integrity. Commenters expressed concern about possible crosswalk and mapping errors, the lack of a crosswalk between ICD-10-CM and the ICD-10 code set for international data comparability, and about the ability of available crosswalks to serve as a useful tool in data conversion. Some commenters stated there should be an extension of the timeline for ICD-10 compliance due to the limited availability and utility of the existing crosswalks. Several commenters recommended that HHS inform industry stakeholders how often these mappings will be updated and how they will be maintained. One commenter asked whether companies may develop their own proprietary mapping systems and if this could impact the compliance dates. We also received a comment that, if ICD-10 is implemented, we should provide a crosswalk between the Ambulatory Payment Classification (APC) groups and the Medicare Severity—Diagnosis Related Groups (MS-DRGs).

Response: We agree that crosswalks between ICD-9-CM and ICD-10-CM and ICD-10-PCS will be critical. Section 1174(b)(2)(B)(ii) of the Act states that if a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

In anticipation of that possible need if/when ICD-10 code sets were to be adopted, authoritative, detailed bi-directional (that is, they can be used to translate from the old code to the new, or from the new to the old) crosswalks, or mappings, which we refer to as General Equivalency Mappings (GEMs), have been developed between ICD-9-CM Volumes 1 and 2 and ICD-10-CM and the ICD-9-CM Volume 3 and ICD-10-PCS. These mappings were developed with stakeholder input into their creation and maintenance, and discussed at public meetings of the ICD-9 Coordination and Maintenance Committee.

CDC developed one such bi-directional mapping between ICD-9-CM diagnosis codes and ICD-10-CM. This mapping, and an accompanying guide explaining how to use the mapping, are available on CDC's Web page at <http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm>, as well as the CMS Web page at http://www.cms.hhs.gov/ICD10/02_ICD-10-PCS.asp.

CMS developed bi-directional mappings between ICD-9-CM Volume 3 and ICD-10-PCS, along with an accompanying guide explaining how to use the 2008 mappings, which are posted to the CMS Web page at http://www.cms.hhs.gov/ICD10/01m_2009_ICD-10-PCS.asp#TopOfPage.

CDC's mapping was highly successful as a clinical equivalent was reported to be possible in all but 0.6 percent of ICD-10-CM codes. In those 0.6 percent of ICD-10-CM codes, a new diagnosis concept was introduced into ICD-10-CM that was not previously found in ICD-9-CM. Therefore, in 0.6 percent of the ICD-10-CM codes, there were no similar codes in ICD-9-CM to which the ICD-10-CM code could be mapped, and this is clearly indicated in the GEM mappings. However, there are general equivalence mappings for over 99 percent of all ICD-10-CM codes and for 100 percent of the ICD-10-PCS codes. The ICD-9-CM Coordination and Maintenance Committee reported on the use of the GEM mapping in converting the MS-DRGs from ICD-9-CM to ICD-10-CM codes. A complete report of this activity is included in the September 24-25, 2008 ICD-9-CM Coordination and Maintenance Committee meeting summary which can be found at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage.

The use of the GEM mappings to convert the MS-DRGs from ICD-9-CM to ICD-10 codes demonstrates that the GEM mappings are extremely accurate and useful. The GEM mappings were able to convert 95 percent of the ICD-9-CM diagnosis codes in the digestive part of the MS-DRGs to the appropriate ICD-10-CM and ICD-10-PCS codes. For these digestive system MS-DRGs, the GEM mappings automatically converted 99 percent of the ICD-9-CM digestive system diagnoses codes and 91 percent of the ICD-10-PCS procedure codes to the appropriate digestive system ICD-10 codes. Five percent required some additional analysis, and we believe that future experience will increase that rate of conversion. We trust that these will be of great assistance to the industry in converting payment, quality and other types of systems from ICD-9-CM to

ICD-10-CM and ICD-10-PCS and vice versa.

There may be value in annually revising these bidirectional mappings to allow for conversions between ICD-9-CM codes and the ICD-10-CM and ICD-10-PCS codes as the ICD-10 code sets are updated annually after their adoption. The ICD-9-CM Coordination and Maintenance Committee is the public forum used to discuss updates to ICD-9-CM and it will be used to discuss updates to the ICD-10 coding system, as well as the mapping between the systems. As previously discussed, this Committee will be re-named the ICD-10 Coordination and Maintenance Committee once ICD-10 is implemented. The Committee will continue to discuss issues such as mappings to the prior coding system, ICD-9-CM. The Committee will discuss the need to continue updating these mappings for a minimum of 3 years after the ICD-10-CM and ICD-10-PCS final compliance date. Should the industry recommend that this period be extended by several years, then we would anticipate that the mappings will continue to be updated through the auspices of the Committee, and will seek input from industry stakeholders through the Committee as to whether these mappings are beneficial to industry, and whether mappings to ICD-9-CM should be updated for an additional period of time.

CMS also has developed a reimbursement mapping that can be used to update payment systems that gives the ICD-10-CM code that best matches the previously used ICD-9-CM code. This reimbursement mapping will allow other payers to more quickly determine how they want to classify a particular ICD-10 code within their payment system. Should payers want to consider refinements to their payment systems based on the additional detail provided by ICD-10, they may do so. The complete ICD-10-CM and ICD-10-PCS GEMs may also assist in those cases where additional information is needed, which is not found in the more streamlined reimbursement mapping. For details of the discussion of the reimbursement mappings at the ICD-9-CM Coordination and Maintenance Committee, please access the CMS Web site at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage.

CMS will post to this same Web site the reimbursement mapping file along with the 2009 versions of the GEMs and the 2009 version of ICD-10-PCS by the end of 2009. CDC will be posting the 2009 version of the ICD-10-CM GEMs to their Web site at <http://www.cdc.gov/>

[nchs/about/otheract/icd9/icd10cm.htm](http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm) by the end of 2009.

CMS will use mappings to convert the Medicare-Severity Diagnosis Related Groups (MS-DRGs) from ICD-9-CM to ICD-10-CM and ICD-10-PCS. MS-DRGs are used by Medicare to determine hospital payments under the Inpatient Prospective Payment System (IPPS). This conversion was discussed at the September 24, 2008 ICD-9-CM Coordination and Maintenance Committee meeting. This presentation can be found at: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp#TopOfPage. We expect that CMS will have converted all MS-DRGs to ICD-10 by October 2009, and will share those results with payers and providers at a future ICD-9-CM Coordinating and Maintenance Committee meeting. The adoption of the final ICD-10 version of MS-DRGs will be subject to rulemaking. We encourage anyone who has particular concerns about possible errors in the crosswalks and/or mappings to share them with CMS and CDC through the ICD-9-CM Coordination and Maintenance Committee so that mappings can be updated as we move forward toward implementation.

We disagree that we should develop a crosswalk between APCs and MS-DRGs when ICD-10 is implemented. We do not have a crosswalk between the current APCs, which are based on CPT codes, and MS-DRGs, which are based on ICD-9-CM codes. The IPPS, which relies on MS-DRGs, and the hospital outpatient prospective payment system (OPPS), which relies on APCs, were developed to reimburse providers in different settings, are maintained separately, and undergo separate formal rulemaking each year.

Finally, CDC fully intends to produce a crosswalk between ICD-10 and ICD-10-CM, addressing the need for international data comparability, and this crosswalk will be completed and made available one year prior to the ICD-10 compliance date. CDC already uses ICD-10 to report cause of death, and it is anticipated that this crosswalk will be of great interest to those engaged in international data reporting.

Any additional tools will certainly assist in the implementation of ICD-10, and both CMS and CDC will continue to make improvements and refinements to their publicly available mappings and post them for others to use. Other vendors may develop products to assist in analyzing codes or converting data, but we do not see any reason why the availability of such products, whether proprietary or non-proprietary, would

have any bearing on the determination of a final compliance date for ICD-10-CM and ICD-10-PCS.

G. ICD-10 Education and Outreach

Comment: Many commenters stated that the proposed October 2011 ICD-10 compliance date would not allow for proper industry education and outreach and that the tight timeline would constitute a major burden to the industry. Commenters expect that certified coders would need detailed education in order to identify the proper codes for accurate billing. Some commenters said regular physician office staff would need to become certified coders, and current certified coders would need to get recertified, incurring a costly exam fee.

Many commenters recommended that significant education and outreach for ICD-10 would be needed, and they suggested a number of strategies, including the need for national associations to collaborate on education efforts; a need for a consistent set of messages and/or materials from a national authoritative source; recognition that different audiences/entities (for example, inpatient hospital coders) may need different levels of training; that in-person training should supplement Internet training and printed documents; and that CMS should provide funding for ICD-10 training for State Medicaid program staff.

Response: As stated in the August 22, 2008 proposed rule (73 FR 49807), with the publication of this final rule, we will begin to proactively conduct outreach and education activities which include, but are not limited to, roundtable conference calls with industry stakeholders, development of FAQs, fact sheets, and other supporting education and outreach materials for industry partner dissemination. We also anticipate that there will be extensive industry-sponsored educational opportunities through various stakeholder associations. As part of our education and outreach efforts, we will work closely with industry stakeholders to make subject matter experts available to them, and to expeditiously help stakeholders disseminate relevant information at the national, regional and local level that will be useful to them in educating their respective members.

Comment: One commenter expressed the belief that implementing ICD-10 will exacerbate the current shortage of clinical coders. Other commenters stated that we did not account for the impact to formal training programs for degree and national certificates that will need to be updated or redeveloped.

Response: We have received no indication from industry and/or technical school representatives that the changeover from ICD-9 to ICD-10 codes might contribute to the existing shortage of clinical coders and, in fact, increased marketplace demand for coders as a result of the adoption of ICD-10-CM and ICD-10-PCS may lead to more enrollment in coding curriculums. School representatives have indicated their readiness to adapt to any needed ICD-10 curriculum changes and anticipate that they will be able to produce "ICD-10 ready" clinical coders upon graduation from their respective institutions. We anticipate that educational venues offering coding courses are already familiar with making annual updates to curriculums to reflect yearly code set revisions. The final compliance date of October 1, 2013 should afford educational institutions ample time to change their curriculums, seek out appropriate educational materials and related resources, and graduate ICD-10 competent coders.

Some hospitals may require coders to have a certification from a national professional association. While desirable, this does not appear to be a requirement for coders working in physician offices or other ambulatory settings. We understand that many certified coders must meet annual continuing educational requirements or authorities to maintain their certifications. As we have no coding certification requirements or authorities, we recommend that those concerned with future certification standards contact the applicable professional organizations.

We agree with commenters that it is important that consistent and accurate ICD-10-CM and ICD-10-PCS materials are developed to assist with national training and education. We also agree that it is important that educational training be a collaborative effort among all interested stakeholders. We will continue to collaborate with other stakeholder organizations on outreach and education on the transition from ICD-9 to ICD-10, taking into consideration the contextual and timing needs of different industry segments, including hospitals, providers, coders, etc., in a way that will ensure all affected entities have the resources needed to properly code.

Both AHA and AHIMA will take lead roles in developing additional, more detailed technical training materials for coders. AHA also plans to continue their training support activities by updating their education materials to ICD-10 and will change the name of their publication to Coding Clinic for

ICD-10. AHA has announced that it will begin to include ICD-10 information in its Coding Clinic in advance of the actual ICD-10-CM and ICD-10-PCS implementation date.

CMS has been working collaboratively with the Cooperating Parties to develop additional ICD-10 educational materials which will be posted at: http://www.cms.hhs.gov/ICD10/05_Educational_Resources.asp#TopOfPage.

H. Testing

Comment: A minority of commenters stated that ICD-10-CM and ICD-10-PCS need more testing prior to implementation. Some commenters recommended pilot testing, with one of those commenters stating that pilot testing should take place before the issuance of a final rule, on the assumption that information gained through pilot testing could be used to inform the development of a final rule. A few commenters stated that more internal and external training would be needed beyond that which we described in the August 22, 2008 proposed rule. Another commenter said that additional time—between six months to a year—should be added to the final Version 5010 compliance date to allow for testing.

Response: Any pilot testing of ICD-10-CM and ICD-10-PCS would demonstrate its integration into business processes and/or systems, and not the appropriateness of its adoption as a HIPAA standard through the notice and comment rulemaking process. Furthermore, were pilot testing to demonstrate a need for additional codes, etc., these changes could be handled through the code set maintenance process, without the need for further rulemaking to accomplish such changes. Therefore, we see no reason to pilot test ICD-10-CM and ICD-10-PCS before issuing a final rule.

In the development of the August 22, 2008 proposed rule (73 FR 49807) draft timetable, we accounted for testing with both internal and external partners as part of the generally accepted industry implementation process for the implementation of these medical data code sets as adopted HIPAA standards. This follows similar implementation plans undertaken for previously adopted and implemented HIPAA standards. Such testing is a way to determine whether, once systems changeovers are in place, transactions using the ICD-10-CM and ICD-10-PCS code sets would be successfully and accurately processed within a HIPAA covered entity's own systems, as well as whether that entity can successfully transmit such information from its own

system to a trading partner. We welcome the opportunity to work with industry on any voluntary testing of the workflows, productivity, and other practical considerations of the changeover from ICD-9-CM to ICD-10-CM in the ambulatory setting that could result in the development of "lessons learned" that might be disseminated to assist this industry segment with a smooth transition to ICD-10.

With regard to testing the utility of the ICD-10-CM and ICD-10-PCS code sets themselves, we refer to the results of the AHA-AHIMA ICD-10-CM field testing reported to NCVHS on September 23, 2003, involving 6,177 medical records coded by credentialed coding professionals. A copy of this report can be found at <http://www.ncvhs.hhs.gov/030923ag.htm>.

We believe that there has been successful, independent field testing of the utility and functionality of ICD-10-CM and ICD-10-PCS, and that no additional testing of this nature is necessary.

I. ICD-10 Code Set Development and Utility

Comment: Several commenters stated that countries such as Canada and Australia have not developed such extensive clinical modifications to medical code sets compared to those used in the U.S. because their versions of the ICD-10 code sets are not used in ambulatory settings. Commenters recommended that a process be undertaken to streamline and/or significantly reduce the number of ICD-10 codes to make adoption easier.

Response: Unlike the United States, other countries do not use ICD-10 codes for reimbursement purposes. The level of detail in the United States' clinical modification version of the ICD-10 code set has resulted in an increased number of codes, and is commensurate with the complexities of our multi-payer health care system. The United States' clinical modifications have been derived in part with the input of clinical specialty groups that have requested this level of specificity. If the United States is moving toward an electronic healthcare system and increasingly using codes for quality purposes, there is a need to capture more precise information, not less. ICD-10-CM and ICD-10-PCS will greatly support these efforts.

The Canadian health care system and the United States health care system are very different. Canada does not have the same data needs as the United States. The Canadian version of ICD-10, called ICD-10-CA, has been implemented in hospitals, hospital-based ambulatory care centers, day surgery centers and

high-cost clinics (for example, dialysis and cancer clinics). National ambulatory care reporting has not been fully implemented in Canada, but some provinces have already expanded the use of ICD-10-CA beyond hospital-based ambulatory care. ICD-9-CM was never implemented in physician offices in Canada because each province had its own billing system, but the provinces now fully intend to do so, and are moving in that direction.

Each country uses its respective version of ICD-10 for its own purpose, but common threads from other countries' ICD-10 implementation experiences, such as systems changeovers, business process issues and the timing of their conversions to ICD-10, can help inform our ICD-10 implementation experience in the United States. An increased number of codes does not necessarily result in increased complexity in using the coding system. Though training would be required in order to make full use of the increased number and granularity of the codes, greater specificity can mean the correct code is easier to determine because there is less ambiguity. Not all HIPAA covered entities will use all of the ICD-10-CM and ICD-10-PCS codes. Similar to the way a dictionary is utilized, ICD-10-CM and ICD-10-PCS make available a full spectrum of codes, and entities will selectively use only those codes that are germane to their specific clinical area of practice or healthcare operations.

We are also aware that, in many instances in the ICD-10-CM code set, the 7th character is repetitive in nature. Taking this into account, the remainder of the core codes amount to far fewer new codes to learn. Therefore, we do not believe that reducing the number of ICD-10-CM and ICD-10-PCS codes to make adoption easier is warranted, nor do we believe that the code sets' size is a justification for not implementing ICD-10-CM and ICD-10-PCS in a timely manner.

Comment: Some commenters stated that the ability to demonstrate laterality already exists through modifiers available for use with ICD-9-CM that allow the capture of duplicate claims.

Response: In the August 22, 2008 proposed rule (73 FR 49801), we defined laterality as the ability to specify which organ or part of the body is involved when the location could be on the right, left or bilateral. The advantage of ICD-10-CM over ICD-9-CM code sets is that ICD-10-CM accounts for laterality in the code set coding itself. ICD-9-CM only allows for laterality indicators through means of an extra modifier. These modifiers can only

be used on outpatient claims to further describe the HCPCS codes, which are used for reporting physician and ambulatory procedures. HCPCS codes will continue to be used for reporting physician and ambulatory procedures. Current claim forms and systems do not allow for modifiers on the diagnosis codes in any setting or for procedures in the inpatient setting. This problem is corrected with both the ICD-10-CM and ICD-10-PCS codes. This improved ability to convey laterality can reduce duplicate payments and/or claims, and better inform research on conditions that may affect only one area of the body; for example, a stroke.

We believe that the laterality inherent in ICD-10-CM provides another reason to adopt ICD-10-CM and ICD-10-PCS code sets as HIPAA standards.

Comment: Several commenters stated that there is a discrepancy between the number of ICD-10-CM diagnosis codes stated in the August 22, 2008 proposed rule, and other previous citations. A commenter asked if the ICD-9-CM 13,000 diagnosis codes and 3,000 procedure codes referred to in the August 22, 2008 proposed rule are those that are currently in use or include potential space for use in the future.

Response: The June 2003 version of ICD-10-CM contained 120,000 codes. That figure was used in both CMS and other industry presentations because that was the number of codes in ICD-10-CM at that time. A draft of the ICD-10-CM code set was posted to CDC's Web site and CDC solicited comments on how to update and/or revise the coding system. Based on those submitted comments, CDC made revisions to ICD-10-CM that led to a reduction in the total number of ICD-10-CM codes for use in the clinical modification developed for use in the United States. A similar, annual process has been undertaken for ICD-10-PCS, resulting in changes to the number of ICD-10-PCS codes as well.

The ICD-9-CM 13,000 diagnosis codes and 3,000 procedure codes referenced in the August 22, 2008 proposed rule (73 FR 49802), represent those codes that are currently in use. These codes are updated each year by the ICD-9 Coordination and Maintenance Committee and, therefore, the number of codes changes annually. For FY 2009, there are 14,025 ICD-9-CM diagnosis codes and 3,824 ICD-9-CM procedure codes in use.

Comment: Commenters stated that the annual ICD-9-CM code set updates should cease one year prior to the implementation of ICD-10. Also, they stated that such a "freeze" on code set updates would allow for instructional

and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place just immediately before the compliance date, necessitating additional updates and/or purchases.

Response: The ICD-9-CM Coordination and Maintenance Committee has jurisdiction over any action impacting the code sets. Therefore, the issue of consideration of a moratorium on updates to the ICD-9-CM, ICD-10-CM and ICD-10-PCS code sets in anticipation of adoption of ICD-10-CM and ICD-10-PCS will be addressed through the Committee at a future public meeting.

Comment: One commenter noted that, while ICD-10-CM will incorporate needed specificity and clinical information as compared to the ICD-9-CM code set, the ICD-10-CM diagnosis code set in general does not include "function diagnosis," the performance deficit for which an occupational therapy intervention is provided. The commenter strongly urged CMS to include in the ICD-10-CM code set a method of coding the functional impairments of patients requiring rehabilitation services, add specific functional diagnoses to ICD-10-CM codes, or adopt the use of the International Classification of Functioning, Disability and Health (ICF).

Another commenter stated that ICD-10-CM codes do not address the need to stratify the level of severity of traumatic brain injuries.

Response: We agree with the commenter that ICD-10-CM, like ICD-9-CM, does not include concepts that relate to difficulties with activities of daily living, functional impairments, and disability. Those concepts are found in the ICF, published by the World Health Organization. The wide scale incorporation of ICF concepts, with structural and definitional differences, into ICD-10-CM would be inappropriate. The WHO acknowledged this when developing ICF as a separate and distinct classification within the WHO Family of International Classifications. While we agree that ICF has great ability to more accurately and completely describe functioning and disability concepts, its adoption as a HIPAA code set is beyond the scope of this final rule.

The issue of coding of traumatic brain injury was discussed at the September 24-25, 2008 meeting of the ICD-9-CM Coordination and Maintenance Committee. It was stated at that time that the Committee would address any changes to be made to ICD-9-CM for traumatic brain injuries, and

those changes would also be incorporated into ICD-10-CM as necessary.

V. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the August 22, 2008 proposed rule. Those provisions of this final rule that differ from the August 22, 2008 proposed rule are discussed as follows.

In § 162.1002(b), we have revised the year “2011” to read “2013” in this regulation.

In § 162.1002(c), we have revised the year “2011” to read “2013” in this regulation.

In § 162.1002(c)(3), we have removed the term “Classification” and replaced it with “Coding” in this regulation.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 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.

Section 162.1002 of 45 CFR explains the implementation and continued use of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding for the period on and after October 1, 2013. The burden associated with the implementation and continued use of ICD-10-CM and ICD-10-PCS is the time and effort required to update information systems for use with updated HIPAA transaction and code set standards. Specifically, the entities must comply with the ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards, which accommodate the use of the ICD-10-CM and ICD-10-PCS code set. The burden

associated with meeting the ICD-10-CM and ICD-10-PCS code set standards is not discussed in this final rule; however, the burden associated with these standards is accounted for in the Version 5010 final rule, CMS-0009-F, published elsewhere in this **Federal Register**. The inclusion of other standards referenced in the Version 5010 final rule, namely the National Council of Prescription Drug Programs (NCPDP) Telecommunications Standard Version D.0, and the NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0, has no impact on that analysis' ability to address the PRA burden of ICD-10-CM and ICD-10-PCS.

The burden associated with meeting the Version 4010 standards is contained in the following affected sections: § 162.1102, § 162.1202, § 162.1301, § 162.1302, § 162.1401, § 162.1402, § 162.1501, § 162.1502, § 162.1602, § 162.1702, and § 162.1802. The affected sections are currently approved under OCN 0938-0866 with an expiration date of July 31, 2011; however, the Version 5010 final rule provides for the revision of the requirements contained in the aforementioned affected sections to update the adopted HIPAA transaction standard to Version 5010. As OCN 0938-0866 was issued for the current version of this HIPAA standard, we have submitted to OMB a revised version of information collection request (OCN 0938-0866) for its review and approval of the information collection requirements associated with the implementation of the Version 5010 standards, and ultimately, the implementation of ICD-10-CM and ICD-10-PCS. Included as part of the revised Information Collection Requirement (ICR) are detailed instructions on the implementation of ICD-10-CM and ICD-10-PCS. These information collection requirements are not effective until approved by OMB.

VII. Regulatory Impact Analysis (RIA) Statement of Need

The objective of this regulatory impact analysis (RIA) is to summarize the costs and benefits of moving from ICD-9-CM to ICD-10-CM and ICD-10-PCS code sets in the context of the current health care environment.

The following are the three key issues that we believe necessitate the need to update from ICD-9-CM to ICD-10-CM and ICD-10-PCS:

- ICD-9-CM is out of date and running out of space for new codes.
- ICD-10 is the international standard to report and monitor diseases and mortality, making it important for the

U.S. to adopt ICD-10 classifications for reporting and surveillance.

- ICD codes are core elements of many HIT systems, making the conversion to ICD-10 necessary to fully realize benefits of HIT adoption.

For a more detailed discussion of the limitations of ICD-9-CM, please refer to section III.B in the preamble of the August 22, 2008 proposed rule (73 FR 49799). As noted in the August 22, 2008 proposed rule, no other viable alternatives to adopting ICD-10 were identified. The costs and benefits for moving from ICD-9-CM to ICD-10-CM and ICD-10-PCS were assessed within the requirements of the Executive Orders and Acts cited in the regulatory impact analysis.

A. Overall Impact

We examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104-121), section 1102(b) of the Social Security Act, sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258 and Executive Order 13422, which modifies the list of criteria used for regulatory review) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We consider this to be a major rule, as it will have an impact of over \$100 million on the economy. Accordingly, we have prepared an RIA.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess the anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditures of \$100 million in 1995 dollars (updated annually for inflation) in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector. That threshold level is currently approximately \$130 million.

Based on our analysis, we anticipate that the private sector would incur costs exceeding \$130 million per year beginning 3 years after the publication of the final rule, and ending 3 years after implementation. Our analysis indicates that the States' share of ICD-10 implementation costs would not exceed \$130 million over a 1-year period. In addition, local or tribal governments will not experience costs exceeding \$130 million over a 1-year period. We base our assessment on the fact that we received no comments from local governments indicating cost impacts exceeding \$130 million over a 1-year period in response to the August 22, 2008 proposed rule, and the Indian Health Service (IHS) estimate of costs to tribal governments totaling \$12.3 million as detailed in Table 1 of this final rule.

In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered three alternatives that are referenced in the preamble of this final rule, HHS has concluded that the provisions in this final rule are the most cost-effective alternative for implementing HHS's statutory objective of administrative simplification.

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. Executive Order 13132 requires the opportunity for meaningful and timely input by State and local officials in the development of rules that have Federalism implications. HHS consulted with appropriate local, State and Federal agencies, including tribal authorities and Native American groups, as well as private organizations. These private organizations included, among others, WEDI, NUCB, NUCC, and the ADA in accordance with section 1178(c)(3) of the Act.

In order to validate the fiscal and operational impact of this rule on State Medicaid agencies, current data on costs for States to implement a new code set would be necessary. We reference in the preamble of this final rule industry studies that were conducted by both Nolan and RAND that provide some insight into this information for States.

HHS has examined the effects of provisions in this final rule as well as the opportunities for input by the States. The Federalism implications of this final rule are consistent with the provisions of the Administrative Simplification subtitle of HIPAA by which HHS is required by the Congress

to promulgate standards for the interchange of certain health care information through electronic means. Under section 1178(a)(1) of the Act, these standards generally preempt contrary State law.

The States were invited to submit comment on this section and all sections of the August 22, 2008 proposed rule.

The objective of this regulatory impact analysis is to summarize the costs and benefits of moving from ICD-9-CM to ICD-10-CM and ICD-10-PCS code sets in the context of the current health care environment.

We received numerous comments on our analysis of the costs and benefits of transitioning from ICD-9 to ICD-10. In the August 22, 2008 proposed rule (73 FR 49830), we solicited additional data that would help us determine more accurately the impact of ICD-10 implementation on the various categories of entities affected by the proposed rule. We solicited, but did not receive, comments regarding certain assumptions upon which we based our impact analysis in the August 22, 2008 proposed rule, including the inflation factor we applied to our assumed costs, and the growth factor we applied to our assumed benefits. We also did not receive comments regarding the number of, or specific impacts to, third party administrators or design firms that may need to update their systems or business processes to accommodate the ICD-10 code set. In those cases where we did not alter our assumptions from those made in the August 22, 2008 proposed rule, the relevant tables are referenced but not reprinted in this final rule. Detailed summary tables are provided herein with all of the costs and benefits recalculated to reflect changes that were made in response to comments.

Although many commenters stated that we overstated the benefits of transitioning from ICD-9 to ICD-10, they provided no data or information to substantiate their assertions or to refute our benefits analysis; therefore, this RIA continues to rely on the benefit assumptions outlined in the proposed rule's RIA.

Many commenters stated that we underestimated the costs of transitioning from ICD-9 to ICD-10.

In some instances, commenters included the cost of transition to Version 5010 in their discussion of the costs for transitioning to ICD-10. In those instances, we were unable to separate Version 5010 implementation costs from ICD-10 implementation costs. In other instances, they provided Version 5010 implementation costs, but not ICD-10 implementation costs.

Regardless, in the majority of cases, commenters did not provide data or information to substantiate their cost estimates or to refute our cost estimates and regulatory impact analysis. Where new information was provided that allowed us to improve our cost estimates, we have outlined our rationale for the changes in the following narrative and summary tables.

1. Use of the Rand Report

Comment: A few commenters stated that the RAND report should not have been used as the basis for the impact analysis in the August 22, 2008 proposed rule because they asserted that the RAND report underestimates ICD-10's systems impacts and the labor-intensive nature of implementation activities. One commenter suggested that the Nolan report, and not the RAND report, was the more accurate study, and suggested that it should have been used as the primary source of data for the August 22, 2008 proposed rule's impact analysis.

Response: The 2004 RAND and Nolan reports are considered by the industry to be the benchmark studies for the transition from ICD-9-CM to ICD-10, and both have been cited by other reports as the basis for their ICD-10 cost assumptions. In the proposed rule (74 FR 49811), we detailed the differences between RAND and Nolan's data sources, assumptions and cost estimates on a wide variety of elements, including training, productivity, system changes, contract renegotiations and benefits. Each report considers some factors that the other does not, uses different data gathered from a variety of sources at different times, and cites some data that are not substantiated. The HHS intra-agency workgroup analyzed both reports prior to developing its own assumptions and conclusions, which served as the basis for the proposed rule's analysis.

2. Estimated Costs—General

Comment: Many commenters expressed their general perceptions regarding the costs of implementing ICD-10-CM and ICD-10-PCS. Some commenters stated that they thought it was simply too expensive for industry to implement ICD-10-CM and ICD-10-PCS in the current economic climate. Several commenters suggested that more analysis of the costs is needed, and recommended a variety of mechanisms, including a provider office/hospital panel. Others expressed the need to monitor and publicly report on the costs, benefits, and industry readiness through an independent party such as NCVHS.

Response: The estimates we developed for the August 22, 2008 proposed rule were based upon extensive analysis of publicly available data by an HHS intra-agency workgroup representing many areas of expertise. While the provisions and analysis offered in the August 22, 2008 proposed rule represented the best available information, we solicited input on our assumptions, and anticipated that commenters would provide any additional available data that was available that would enable us to refine our estimates of the impacts associated with the implementation of ICD-10-CM and ICD-10-PCS. While we did receive input regarding specific assumptions, most commenters did not substantiate their assertions that we underestimated costs and overstated benefits with data that we could use to produce more accurate estimates. In the cases where commenters provided updated, substantiated data, we have discussed the new information and revised our estimates accordingly.

We agree with commenters that NCVHS is an appropriate public body through which to solicit and share industry information on costs and implementation of, and compliance with, electronic transactions and code sets. We trust that it will continue to be a valuable resource to HHS and the industry as these code sets and other HIPAA standards are implemented.

3. Training—Number of Coders

Comment: A number of commenters disagreed with our estimate of the number of inpatient, full-time coders. In the August 22, 2008 proposed rule, we estimated that there are 50,000 full-time, inpatient coders based on AHIMA membership, and 179,230 part time coders, based on NAIC data as shown on Table 7 of the August 22, 2008 proposed rule (73 FR 49815). We assumed that full-time coders likely work in the hospital setting, and therefore would require training on both ICD-10-CM and ICD-10-PCS. We further assumed that part time coders likely work in the ambulatory setting, and therefore would require training only on ICD-10-CM. Commenters representing two national coder associations disagreed with the estimate that there are only 50,000 full-time inpatient coders in the United States. Five members of a national coder association commented that it is likely that the total number of coders nationwide is approximately 150,000, of which 100,000 are certified coders. However, they did not substantiate their assertion, nor distinguish between the number of full-time inpatient and part-time outpatient coders in this 150,000

figure. The other national coder association stated that they did not have a more accurate estimate of the number of full-time inpatient hospital coders, but simply wanted to note that, in their opinion, the basis of the number of full-time, inpatient coders used for our estimates in the proposed rule was flawed. This commenter stated that our assumption that part-time coders work in ambulatory settings, and that full-time coders work in hospitals was inaccurate because there are many full-time coders who practice in outpatient settings. They also recognized that estimating the number of coders in the U.S. is very difficult, and that current statistics for occupational classifications may not permit a fully accurate estimate of the number of coders, or the settings in which they work. Several commenters stated that there are other clinical specialty organizations that certify their members as coders and that those coders should also be included in our estimates.

A few commenters suggested that all coders would need additional physiology and anatomy training in order to use the ICD-10 code sets.

Response: In the proposed rule (73 FR 49815), we discussed our estimate of the number of full-time, inpatient coders. The Nolan study estimated approximately 142,170 coders, but did not differentiate between hospital coders (inpatient) and coders working in ambulatory settings, and also did not provide the source for these data. Assuming that full-time, inpatient coders were employed primarily by hospitals and that these individuals would be represented by AHIMA's 50,000 membership, we used that number in calculating the number of full-time, inpatient coders who would require training on both ICD-10-CM and ICD-10-PCS.

In the August 22, 2008 proposed rule (73 FR 49815), we also estimated, based on NAIC codes from the 2005 Statistics of U.S. Businesses, that there are approximately 179,267 part-time coders. This was based on our assumption that, for every 20 employees in an ambulatory setting, there would be one part-time coder. We calculated the estimated number of part-time coders in outpatient ambulatory practices with 20 to 499 employees. This total of part-time coders, 179,267, plus the aforementioned 50,000 full-time, inpatient coders, accounted for a total estimated coder universe of 229,267 coders who would require ICD-10-CM and/or ICD-10-PCS training.

We also do not believe that coders will need additional training in anatomy and physiology in order to use ICD-10

codes. Most, if not all, coders already possess basic knowledge of anatomy and physiology either through formal training or through on-the-job experience.

We understand that many hospitals require their coders to be certified through an examination program and annual continuing medical coding education offered by their professional associations and other educational entities. If we were to assume, as some national coder association members commented, that there are an estimated 100,000 certified coders, that they all are employed by hospitals, and that there are 5,700 hospitals in the United States, we would conclude that there are approximately 26 certified coders per hospital. We cannot confirm that all hospitals require their coders to be certified, and believe that the average of 26 certified coders per hospital is likely too high and would skew our analysis of these estimated costs.

We acknowledge that while there may be more than 50,000 inpatient coders, the 150,000 total coder estimate offered by some coder association commenters does not distinguish between how many of those may be inpatient coders versus outpatient coders. We also do not know how many other clinical specialty certified coders may exist. We do agree with both the commenters' and the RAND report's contention that, because inpatient coders must also learn ICD-10-PCS in addition to ICD-10-CM, we need to account for their increased training costs and productivity losses, and therefore, we must attempt to assign a value to the number of inpatient coders if we are to establish valid cost estimates.

Therefore, we will retain our estimate of 229,267 coders in total from the proposed rule. However, we will increase our estimate of hospital coders from 50,000 to 60,000 coders. This shift decreases the number of outpatient coders as shown in the proposed rule by 10,000, to 169,267, but still accounts for a total number of 229,267 coders. The basis for these revised assumptions is derived from our research of the U.S. Bureau of Labor Statistics (BLS) data. The BLS data show that, in the category "Medical Records and Health Information Technicians", which includes many coders, 60,000 of the individuals accounted for in this category are employed by hospitals. We acknowledge concerns that current statistics for occupational classifications may be inaccurate, but absent other substantiated data, we must rely on the information that is currently available and use our best judgment in arriving at a conclusion based on that data.

We note that our estimate of 229,267 coders in total is higher than the estimates from the Nolan report and commenters. We considered reducing our estimate accordingly, but decided to retain the higher number to assure we have adequately addressed this cost.

4. Number of Coder Training Hours/ Costs

Comment: In the August 22, 2008 proposed rule (FR 73 49815), we had estimated that, based on RAND data, approximately 50,000 inpatient coders who would need to learn both ICD-10-CM and ICD-10-PCS would require about 40 hours of training. We also estimated that ambulatory coders who would need to learn only ICD-10-CM would need only about 8 hours of training. We calculated the cost of ICD-10 code set training for inpatient coders at \$2,750 per coder, assuming \$550 in training costs and \$2,200 in lost productivity, for a total of \$137.51 million. For the proposed rule's 179,000 coders in the ambulatory setting, we estimated a cost of \$110 in training costs and \$440 each for lost work time, for a total of \$98.5 million.

Many commenters offered widely varying estimates as to the amount of time required, and associated costs, for coding training. A few commenters stated that the training time for coders outlined in the proposed rule appeared to be reasonable. Another commenter stated that we overstated training costs, and that "train the trainer" programs could be effectively used to train coding leaders who would then disseminate information to other colleagues, replacing the costs already being incurred by hospitals to keep up with changes in ICD-9-CM.

One commenter stated that an experienced coder would need as little as 5 hours of ICD-10 training. The majority of commenters estimated that it would take more than 40 hours of training, and more likely between 40 to 60 hours for coders to train in ICD-10. Still another commenter estimated that it would take between 60 to 80 hours of ICD-10 training for a coder in an ambulatory setting. Another commenter stated that coders must attend anywhere from 10 to 30 hours of training annually to earn continuing education credits to maintain their professional credentials, and that this time and expense would offset any ICD-10 training time and expense projections.

Commenters stated that coder training costs ranged from \$150 per coder to over \$96,000 to train a health plan's coding staff. One commenter stated that our estimated training cost of \$31 per hour per coder was too low, and can vary

greatly depending on geographic region. One commenter stated that we did not account for coder training-related travel. Another commenter stated that our estimate of \$550 per coder for a week of training is low by industry standards, but that the return on investment justifies any training expense.

Response: Commenters' estimates of the amount of time needed for coder training, based on whether they worked full-time in inpatient settings or part-time in ambulatory settings, varied greatly. Estimates for coder training involve five distinct areas of consideration: The training methodology; the clinical specialty; the number of inpatient and outpatient coders; the number of hours for coder training; and the cost per hour of training.

ICD-10 code set training will likely be offered by both commercial entities and/or industry associations or other interested stakeholders, and training can take many forms—self-directed internet or intranet, webinars, video conferences, correspondence courses, seminars, technical school and community college courses, seminars, etc. The longer and more detailed the training and the setting (for example, in person versus on-line training), the greater the impact on the cost of training. However, more "convenient" training, such as that offered on-line or through webinar, may also charge attendees a premium price for training based on the convenience of on-line or webinar programs. As one commenter noted, the use of a "train the trainer" approach to training would greatly reduce training costs for a larger organization that employs a number of coders and/or personnel who perform coding functions and require ICD-10 code set training. Also, training may or may not require travel and as such, there is no way to estimate travel expenses as a result of attending training for ICD-10 coding.

We recognize that perhaps as many as 100,000 coders may be certified, and already spend from 10 to 30 hours a year attending training for which they receive continuing education credits to maintain their certifications. These costs would likely already be accounted for as part of that ongoing educational process, but again, we have no way of knowing if these certified coders work in inpatient and/or outpatient settings. Absent such data, an attempt on our part to assign numbers of certified coders to one setting versus another would likely be inaccurate.

We have carefully considered the comments received, and we generally believe that some adjustments to our estimates for the number of hours and

costs of ICD-10 training for coders may be necessary.

Based on industry feedback regarding the need for more time than the 40 hours of training we estimated for inpatient coders to learn both ICD-10-CM and IC-10-PCS, we will increase our estimate of the number of hours of training that inpatient coders will need to learn ICD-10-CM and ICD-10-PCS from 40 hours to 50 hours, well within the commenters' suggested range of as little as 5 hours of training, to a maximum of 80 hours. As discussed above, we have estimated that there are 60,000 inpatient coders who would require these 50 hours of training. To account for geographic variations in costs, we will increase our training costs only, by 15 percent, to a cost of \$3,218.75 per coder, including \$2,500 for lost productivity (based on the increased number of training hours) and \$718.75 in training costs, for a total of \$212.06 million, annualized at 3 percent and 7 percent, as reflected in Table 4.

Based on similar feedback from the industry expressing concern about the complexity of ICD-10-CM due to its size and structural changes, and coder unfamiliarity, we also will increase from 8 to 10 hours the time that outpatient coders will need for ICD-10-CM training, and calculate that 169,267 outpatient coders will require 10 hours of ICD-10-CM training at a cost per coder of \$644 (\$500 in lost productivity due to the increase in hours, and \$143.75 in training, the latter of which includes a 15 percent increase in estimated training costs from the August 22, 2008 proposed rule), or a total of \$119.69 million, annualized at 3 percent and 7 percent, as shown in Table 4.

We considered reducing the estimates in recognition of the fact that almost half of the total number of coders are likely to receive some ICD-10 training as part of their continuing education requirements for maintaining certification. However, we elected to retain the higher number to ensure that we have adequately addressed this cost.

5. Physician Training

Comment: In the August 22, 2008 proposed rule, we estimated, based on RAND's assumption, that ten percent of all physicians, or about 150,000, would seek ICD-10 code set training. We made the assumption that this training would take up to 4 hours, instead of RAND's estimate of 8 hours, at a cost per hour of \$137. Many commenters stated that we underestimated the number of physicians that would need training on the ICD-10 code sets, and the amount of time that training would take. Some professional associations stated that all

physicians will need ICD-10 code set training. A few commenters, citing an industry-sponsored report on ICD-10 costs for physician practices, estimated 12 hours of ICD-10 code set training would be required for physicians.

In contrast, another national professional coder association referenced their own study, showing that almost half of the respondents reported that none of the physicians in their offices performed coding, and of those physicians who did, they performed coding on only a small portion of the ICD-9-CM code set. Other commenters confirmed that many physicians do not code themselves, but rather rely on billers or other staff, or use superbills for coding. However, several commenters stated that, at a minimum, all physicians will need to be aware of the basic guidelines and construct of the ICD-10 code set, or "awareness training", provided through existing physician continuing education and hospital-sponsored in-service training.

Response: In the August 22, 2008 proposed rule (73 FR 49809), we discussed the differences between the RAND and Nolan report assumptions relative to ICD-10 code set training for physicians. We also discussed our rationale for our decision to base our estimates on 4 hours versus RAND's 8 hours for physician ICD-10 training, because we assumed that the majority of physicians used superbills and would not require 8 hours of training.

There appears to be a wide variance of opinions across all industry segments as to how many physicians would need and/or want ICD-10 code set training, and the length of that training. As discussed in the coder training section of this impact analysis, we believe that there are many factors that may influence this estimate, including geographic region; clinical specialty; size of practice; and available resources (superbills, electronic medical records, etc.)

We agree that physicians will want training on ICD-10 code sets, but it is clear from commenters that the RAND estimate of only 10 percent of physicians wanting ICD-10 code set training may be too low. In an effort to better estimate the costs of ICD-10 training for physicians, while acknowledging commenters who stated that not all physicians will need training due to use of superbills, staff and other coding mechanisms, we will accept the Nolan study estimate of 754,000 physicians seeking a midpoint of 8 hours of ICD-10 training, at a cost of \$157.55 per hour (reflecting a 15 percent increase over the per hour cost

estimate of \$137.00 per hour used in the August 22, 2008 proposed rule), or \$1,043.14 million, annualized at 3 percent and 7 percent as shown in Table 4. We also will assume that the remainder of physicians will either not seek ICD-10 code set training, or will need less intensive "awareness training" which we anticipate will be available through continuing medical education opportunities of which they likely would have availed themselves absent the transition from ICD-9 to ICD-10.

6. Training for Auxiliary Staff

Comment: In the August 22, 2008 proposed rule (73 FR 49816), we estimated that, based on RAND data, there were some 250,000 code users. We assume that, of these 250,000, only 150,000 work directly with codes and would require 8 hours of training for an total training cost of approximately \$250 (\$31.25 per hour \times 8 hours). Some commenters mentioned that we did not account for other staff that may need training other than coders and physicians. Commenters stated that many health care settings, especially small physician practices, do not employ professional coders, but rather office staff who, along with other duties, provide the coding needed for claim submission and reimbursement purposes.

Commenters cited billing/administrative staff; clinicians and non-physicians; clinical support staff, analytical and IT professionals; coding specialists; labs; and ancillary staff as those additional staff who will require training on the new codes. One commenter estimated that for a health plan/payer, staff training could amount to \$96,156, not counting the cost of reference materials or training costs from outside sources.

One commenter mentioned that code users can also include those who use the codes for medical decisions and that they will need extensive training on the new codes. Another commenter stated that the category of "code users" represents individuals with a wide variety of roles and responsibilities, so the level of training needed would depend on how and to what extent the individual health professional use coded data and potentially how the training is delivered. One commenter disagreed with the number of code users that we outline in the proposed rule, estimating that there are only 20,000 code users, but did not substantiate the source of their information.

Response: In the August 22, 2008 proposed rule (73 FR 49815), we used RAND data to define code users as

people outside of health care facilities—researchers, epidemiologists, consultants, auditors, claims adjudicator, etc. Users could also include people within health care facilities in areas such as senior management, clinicians, quality improvement, utilization management, accounting, business office, clinical departments, data analysis, performance improvement, corporate compliance, data quality, etc. Additionally AHIMA defines a user of coded data as anyone who needs to have some level of understanding of the coding system, because they review coded data, rely on reports that contain coded data, etc., but are not people who actually assign codes. These could include the additional staff that will require training as cited above.

In the August 22, 2008 proposed rule (73 FR 49816), we estimated that there are approximately 250,000 code users, most likely employed by payers but that, based on RAND data, only about 60 percent, or 150,000, would require ICD-10 code set training for the purpose of actually assigning and/or interpreting codes. We believe that, given all the categories of coders, both professional and non-professional, physicians, other clinicians, auxiliary staff and the code users definitions as shown above, we have adequately accounted for a broad universe of potential code users and we maintain our original assumption of the number and costs of training for code users.

As stated in the August 22, 2008 proposed rule (73 FR 49814), we based our estimates on 2004 dollars because we used RAND study figures based on 2004 dollars. For purposes of this analysis, we are updating the value to 2007 dollars to be consistent with the updates to our benefits analysis by applying the increases in the Consumer Price Index (CPI-U) from 2004 to 2007. For the costs estimates, we divide the CPI-U annual index for 2007 (the most recent data available) by 2004's index to determine the adjustment factor in which to apply to each cost estimate. This adjustment factor equals approximately 1.098. Since the cost estimates for implementing ICD-10 are not tied to medical services, we feel that the CPI-U is reasonable to use for adjusting these 2004 costs for inflation. We are adjusting our estimate for code user training costs that were based on RAND data from the estimate shown in the August 22, 2008 proposed rule update to 2007 dollars for a revised total of \$41.18 million over 4 years, annualized at 3 percent and 7 percent, as shown in Table 4.

7. Productivity Losses

Comment: In the August 22, 2008 proposed rule (73 FR 49814), we acknowledged that, while RAND did not consider the cost of cash flow interruptions as a result of the adoption of ICD-10-CM and ICD-10-PCS, we agreed with the Nolan study that the implementation of the new code sets may cause serious cash flow problems for providers, and assumed that payers would develop temporary payment policies to mitigate this risk.

Many commenters agreed that, with the introduction of ICD-10, for a period of time, we may see an increase in returned or rejected claims which may cause physician practices and/or hospitals to spend more time fixing billing problems. Many commenters mentioned that ICD-10 will cause an increase of improperly paid claims and denied and/or rejected claims, which will require additional audit work and investigation to find and fix problems.

One commenter stated we underestimated the projected claim rejection rate in the August 22, 2008 proposed rule, and that they experienced a higher (20 to 30 percent) rejection rate when implementing the NPI. Commenters disagreed with our statement in the August 22, 2008 proposed rule (73 FR 49814) that it was the plans' practice to advance periodic interim payments (PIPs) to providers who might be affected by a claims processing slowdown. A few commenters, citing an industry-sponsored report on ICD-10 costs, stated that significant changes in reimbursement patterns according to severity of diagnosis (which are determined based on ICD-10-CM codes) will disrupt provider cash flows, and estimated the cost of cash flow disruption per physician practice to be between \$19,500 and \$650,000.

Commenters stated that CMS should monitor and publish claim rejection rates, issue clear and flexible Medicare advance payment guidelines and mitigation strategies if provider cash flow is adversely affected, and consider interim Medicare payments to hospitals if payments are disrupted.

Response: In the August 22, 2008 proposed rule (FR 73 49817), we accounted for the fact that the implementation of the new code sets is expected to produce a temporary increase in coding errors on the part of physicians, resulting in rejected and/or returned claims. We used Medicare returned claims data for FYs 2004 through 2006, and identified a spike pattern in Medicare returned claims 3 to 6 months following introduction of

annual ICD-9 code updates. We noted that we anticipated that the percent of returned claims following the ICD-10 implementation could be more than double the previous years' increase, and that returned claims may peak at around 6-10 percent of pre-implementation levels. We estimated a cost range from between \$274 million to \$1,100 million. We believe that our assumptions, based on three years' worth of Medicare returned claims data, more closely reflects returned claims experience, and therefore is more accurate than reliance on NPI experience, which was likely caused by plans' inability to link incoming NPIs with legacy identifiers.

We also reject the notion that significant changes in reimbursement patterns based on severity of diagnosis will disrupt provider cash flows. We do not anticipate that there will be any immediate changes to reimbursements with the initial implementation of ICD-10-CM. Data drives changes in reimbursements, and this data likely will not be available for quite some time after the implementation of ICD-10-CM, and thus reimbursement changes will be accomplished on an incremental basis.

States have prompt payment laws that require that penalties be assessed against health plans who do not issue payments for properly submitted claims in a timely manner, and Medicare is also subject to similar requirements. Therefore, it is in the best interests of all plans to pay promptly to avoid these penalties. Moreover, the October 2013 compliance date for ICD-10 provides ample time for plans to prepare and test their payment systems to allow for an orderly transition.

As stated in the proposed rule (73 FR 49817), the implementation of the new code sets is expected to produce a temporary increase of physician coding errors. We received many concurrences with this assumption but no additional or substantiated data to counter our quantitative analysis at this time. Therefore, we maintain our estimate based on our original costs, as stated in the August 22, 2008 proposed rule.

Comment: One commenter disagreed with our analysis of coding productivity in the August 22, 2008 proposed rule (73 FR 49817) because they stated that the use of preprinted forms or touch-screens does not constitute coding. One commenter also took issue with our estimate that productivity losses during the first six months of ICD-10-CM implementation will be reversed, stating instead that it will be a long-term productivity loss. One commenter mentioned that the August 2008 proposed rule suggests an outpatient productivity rate of 3,525 claims per

hour and that this is 100 times greater than what is customary in some specialties and more than 10 times what is performed in the most highly automated computer assisted coding operation.

Other commenters disagreed with our assumption that the average time to code an outpatient claim could take one-hundredth of the time for a hospital inpatient claim. Commenters stated that physician offices would suffer productivity losses because ICD-10-CM training would take physicians away from patient care, looking up new codes will take more time, it will take longer to process notes and billings, and practice workflows in general will be disrupted.

Response: In the August 22, 2008 proposed rule (73 FR 49816), we acknowledged that coders' productivity will be directly affected because of the need to learn new codes and definitions, and undoubtedly some claims will require resubmission to payers as both providers and payers adjust to the new codes. For outpatient productivity losses, we assume the average time to code an outpatient claim could take one-hundredth of the time for a hospital inpatient claim, taking into account the wide variety of outpatient settings and coding forms. Although commenters disagreed with this assumption, they did not substantiate their comments with data that contradicted our assumptions or analysis.

As stated in the August 22, 2008 proposed rule (73 FR 49816), many physicians use, and will continue to use super-bills, which reduces the coding time. We disagree with the commenter who stated that the use of superbills or touch screens does not constitute coding. Coding is the assignment of a code to a specific clinical condition or procedure; the mechanisms used to do this, whether electronic or manual, may differ, but codes are still assigned. We considered the variety of settings in which coding is done and noted that most only focus on one or two medical conditions (which would likely be clearly identified for the coders by the physician) in our analysis in the August 22, 2008 proposed rule.

We are adjusting our cost estimate for outpatient productivity losses from the estimate shown in the August 22, 2008 proposed rule to account to update to 2007 dollars, for a revised total of \$9.40 million in 2014, the year after ICD-10 implementation, and this annualized cost at 3 percent and 7 percent is reflected in Table 4.

Comment: A few commenters questioned our estimate of an additional 1.7 minutes to code an inpatient claim

in the first month of ICD-10-CM and ICD-10-PCS compliance, and the associated productivity losses. None of the commenters stated whether they deemed that estimate to be too high or too low.

Response: In the August 22, 2008 proposed rule (73 FR 49816), we estimated an additional 1.7 minutes to code an inpatient claim that includes an inpatient procedure in the first month of ICD-10-CM and ICD-10-PCS compliance. This estimate was based upon analysis reported in the RAND report. According to RAND, ICD-10-PCS was tested by two clinical data-abstracting centers. One center found that ICD-10-PCS which is used in inpatient settings, generated more codes and that each record, on average, took longer to code than did ICD-9-CM (3.6 minutes versus 1.9 minutes, or a difference of 1.7 minutes). We applied this 1.7 minute loss to 1.8 million inpatient claims requiring procedures coding per month (20,000,000 claims per year divided by 12 months) at \$50 per hour, or \$1.41 per claim, resulting in a productivity loss of \$2.7 million in the first month. After accounting for a monthly increase in productivity of \$450,000, and subtracting this from each month's lost productivity, we arrived at a total inpatient productivity loss of \$8.90 million in 2014, the year after ICD-10 implementation.

None of the commenters indicated whether this estimate was too low or too high. Therefore, we maintain our assumptions and our productivity loss estimates as outlined in the proposed rule. We are adjusting our estimate for inpatient productivity losses from that shown in the August 22, 2008 proposed rule to update to 2007 dollars, for a revised estimate of \$9.77 million in inpatient coder productivity losses, and annualized at 3 percent and 7 percent, as shown in Table 4.

Comment: Some commenters stated that the August 22, 2008 proposed rule did not adequately account for the cost of updates to the CMS-1500 claim form and superbills. One commenter noted that, while 50 percent of all physician practices use superbills, the conversion to the larger ICD-10-CM code set will make superbills cumbersome and impractical. A few commenters stated that the \$55 superbill revision cost cited in the proposed rule was too low. Another commenter stated that it took more than 2 hours to convert a sample family practice superbill from ICD-9 to ICD-10, resulting in an unusable 9-page document. Another commenter stated that superbill conversion could take up to 6 hours, with an additional 4-6 hours for physician review, costs of \$500 to

\$1,000 for editing and new batch printing, and additional costs for disposal of outdated superbills. A few commenters, citing an industry-sponsored report on ICD-10 costs, estimated the expense for revising superbills to be from between \$2,985 for a small physician practice, to \$99,500 for a large practice.

Response: Commenters erroneously interpreted our reference to superbill costs in the August 22, 2008 proposed rule (73 FR 49817). In that proposed rule, we estimated that the total cost of lost productivity (time) for a coder to convert a practice's superbill would be only about 2 hours' time or approximately \$55, not the entire cost of reprinting a supply of superbills. The 2003 field study conducted by the American Health Information Management Association (AHIMA) and the American Hospital Association (AHA) demonstrated that a superbill can be converted to ICD-10-CM in a few hours, and that they are no larger than existing superbills. Superbills generally do not list all of the specific codes relevant to a particular condition but if this was the case, the existing ICD-9-CM superbills would also be pages long.

The reprinting of superbills is an annual expense incurred by providers. For example, one form manufacturer might charge a provider anywhere from \$100 for 2,500 1-part, white bond superbills, to \$600 for 10,000, 3-part carbonless superbills. We also know that one major medical center incurred an annual cost of approximately \$93,000 for their reprinting of superbills. However, because ICD-9-CM code sets are updated annually, providers and hospitals would likely still incur revision and reprinting, as well as disposal costs for unusable superbills as an annual cost of doing business whether or not there was a changeover from the ICD-9-CM code sets to the ICD-10-CM and ICD-10-PCS code sets.

With respect to the CMS-1500 claim form, the National Uniform Claim Committee (NUCC) which maintains this claim form, already expanded the field for reporting diagnosis codes to accommodate the ICD-10 format in their August 2005 revision of the claim form. It is therefore ready for ICD-10 use with no additional cost.

Therefore, because we maintain that there will not be any substantive additional costs for reprinting of superbills, and none for the CMS-1500 claim forms resulting from the transition to ICD-10, we will not make any revisions to our impact analysis based on superbill and/or 1500 claim form costs. However, we are adjusting our cost estimate to update to 2007 dollars,

for a revised cost of \$12.08 million in 2014, the year after ICD-10 implementation, annualized at 3 percent and 7 percent as shown in Table 4.

Comment: The industry's perceived need for increased medical documentation was not addressed in the proposed rule because we did not consider it to be a relevant cost. We received several comments that the use of ICD-10-CM and ICD-10-PCS would cause physicians to order unnecessary medical tests to provide more precise diagnoses or require more documentation to the medical record, wasting medical resources, and greatly increasing provider costs. Commenters stated that one must use the most precise ICD-10 code every time to achieve the full benefits of ICD-10. Another commenter stated that local claims determination adjudication rules require claims coded with "unspecified" codes to be rejected.

Response: We agree that ICD-10-CM and ICD-10-PCS offer significantly greater detail and specificity reflecting the nature of a patient's medical condition. We also agree that there are substantial benefits to be derived from the greater detail of ICD-10-CM when a coder selects the most accurate code based on the available documentation. This is true whether one is using ICD-9-CM codes or ICD-10-CM codes. If one cannot assign a precise code, it is because the medical record documentation is not available or because a clear diagnosis has not been made and in that case, a more general, non-specific code would be selected. Such codes are available in both ICD-9 and ICD-10. However, we disagree that physicians will be pressured to perform unnecessary medical tests or include additional medical documentation because they are using ICD-10-CM and ICD-10-PCS code sets.

Physicians adhere to standards of care which, according to the AMA, "is a duty determined by a given set of circumstances that present in a particular patient, with a specific condition, at a definite time and place." These standards of care include full documentation which, according to the American Academy of Family Physicians (AAFP), "includes fully describing the patient's medical history, physical findings, (the physician's) diagnosis, the treatment plan and care rendered." Physicians select codes that reflect the information that they have available to them through patient history, physical findings and clinically appropriate testing, which they have documented in the patient's medical record based on the aforementioned standards of care. Patient care and

treatment are not pre-determined by diagnostic coding; in fact, diagnostic coding is determined from best practice patient care. A poorly documented medical record can be problematic for a number of reasons, but such deficient medical records are an issue of and by themselves, and not contingent upon whether the code assigned is an ICD-9-CM or an ICD-10-CM code.

Improved medical documentation is not predicated on the change from ICD-9-CM to ICD-10-CM. Rather, improved medical documentation is being driven by initiatives such as quality measurement reporting, value-based purchasing and patient safety.

We view any potential improvements in medical record documentation as a positive outcome of the move to ICD-10-CM and ICD-10-PCS. With better and more accurate data, patient care can only be improved.

For some services, such as a particular drug or surgical procedure, there may be a National Coverage Decision (NCD) or a Local Coverage Decision (LCD) that requires the reporting of a list of specific diagnosis codes. These coverage decisions sometimes include unspecified codes but oftentimes they do not. In a handful of cases, the coverage decision will list several specific diagnosis codes needed in order to make payments, and physicians are aware of the services or surgeries to which they apply. Under MS-DRGs, sometimes a lower payment results from reporting an unspecified code. An unspecified code will still result in a payment, but it might be a lower payment. The number of such cases will not necessarily increase as a result of the adoption of ICD-10.

8. System Changes—Provider/Vendor

Comment: Commenters stated they would incur costs to implement ICD-10-CM, including updating and/or replacing software and hardware. Commenters disagreed with our assumption in the proposed rule that vendors might provide their clients with updated ICD-10-compatible software at little to no charge. One commenter stated that some vendors charge upwards of \$10,000 for similar software updates.

Response: In the August 22, 2008 proposed rule (73 FR 49818), we assumed that large provider groups, chain providers and institutions, such as large hospitals, are most likely to require changes to their billing systems, patient record systems, reporting systems and associated system interfaces. We also noted that the new codes may also require the redesign of standard and special reports.

Additionally, small providers, who rely on superbills, as well as their home-grown systems for capturing patient information and claims submission, may only need to update their systems to accommodate the length of the new code fields. Costs of updating provider systems will depend on the degree of system integration; the need for outside technical assistance; and the number of systems and system interfaces that must be updated. Physician practices (and all providers) should begin looking at their use of ICD-9-CM and use the transition to ICD-10 as an opportunity to consider changes that will improve their processes and workflows.

Although commenters do not agree that vendor-supplied software will be provided to providers free-of-charge, we maintain that, for small providers that are PC-based or have client-server systems, the provider may not bear any immediate costs for the software upgrades. Practice management systems will need to be revised to accommodate ICD-10 codes, but this change will take place as a part of the migration to the Version 5010 standards, and these costs have been accounted for in that impact analysis.

Although we recognize that providers' systems will require updating, we did not receive substantial information or data during the August 22, 2008 proposed rule's public comment period that would lead us to revise our cost analysis in this area. We are adjusting our cost estimate as shown in the August 22, 2008 proposed rule to update to 2007 dollars, for a revised cost of \$150.64 million over 4 years, annualized at 3 percent and 7 percent as shown in Table 4.

Comment: In the August 22, 2008 proposed rule (73 FR 49805), we cited a November 2002 joint letter to NCVHS from the AHA, Federation of American Hospitals (FAH) and Advamed supporting the implementation of ICD-10-CM and ICD-10-PCS as national standards. We also noted in the proposed rule (73 FR 49818) that large institutions such as hospitals will need to transition their systems to both ICD-10-CM and ICD-10-PCS, at a cost ranging from \$55 million to \$220 million. One commenter stated that few hospitals were aware of the impending transition to ICD-10, and have not developed the multi-disciplinary teams necessary for a successful transition. Other hospital commenters noted that they use a combination of purchased software and in-house applications, and both will require modifications for ICD-10 code sets for functions such as code assignment, medical records abstraction, claims submission, and other financial

functions, at a heavy financial burden to them. However, they did not contest our systems cost estimates. One commenter noted that this large transition will require at minimum two hospital budget cycles in order to properly plan and allocate resources.

Response: Hospital commenters did not submit any new data that substantiated their assertions and would predispose us to revising our large provider group cost projections, so we will continue to rely on our estimate as outlined in the August 22, 2008 proposed rule. Given the change of the ICD-10 compliance date to October 2013, we anticipate that hospitals will have ample budget cycle time during which to plan for their systems implementation of ICD-10-CM and ICD-10-PCS. Moreover, the conversion of billing systems to accommodate ICD-10 codes will take place as part of the migration to the Version 5010 standards, and these billing system conversion costs have been accounted for in that impact analysis.

Comment: We stated in the August 22, 2008 proposed rule (73 FR 49818) that, while many providers who use vendor-supplied software may be able to defer the costs of software upgrades, the vendor industry may have to bear, at least initially, the costs of such upgrades. Using RAND's analysis, based on interviews conducted with industry experts, we estimated cost of system changes for software vendors of transitioning to ICD-10 to include the wide range of information and billing systems and the configurations of provider systems. Commenters stated we underestimated or did not account for all vendor software and systems revision costs. These include patient accounting, practice management and billing systems; encoders and grouper software; contract management and reimbursement modeling programs; quality measurement systems; software components of emergency departments, and ambulatory and physician office systems that must be revised to accommodate the use of the ICD-10 code sets. Commenters also stated that systems used to model or calculate acuity, staffing needs, patient risk and patient care; decision support systems and content; presentation of clinical content for support of plans of care; and selection criteria within electronic medical records would be impacted by the use of ICD-10 code sets. Commenters stated that specifications for data file extracts, reporting programs and external interfaces, analytic software that performs business analysis or that provides decision support analytics for financial and clinical

management; and business rules guided by patient condition or procedure would also need to be revised for ICD-10 use. Commenters estimated an average of 24 months for product development, and that vendor product release cycles, typically between 18 to 36 months, do not usually match regulatory compliance dates and the transition to ICD-10 may negatively impact these cycles.

Response: While some commenters provided additional examples of vendor systems that will need to be updated for the transition to ICD-10, they did not provide us with any costs associated with those systems. We are unable to determine at this point if those additional systems can be applied to all vendors since vendors deal with many types and sizes of providers and provider organizations.

We agree with commenters that there will be impacts to vendor systems, and that it may be difficult to initially account for all system changes because of the varying needs of individual providers.

We again point out that a portion of these costs will take place as part of the migration to the Version 5010 standards and these system costs have been accounted for in that impact analysis. However, based on the comments we received which stated that the proposed rule did not account for all of the vendor systems that will need to be updated to accommodate the new code set, we have increased our estimate of software vendor systems by 20 percent. Subsequently, we have increased our software vendor system costs from the previous \$96.05 million to \$115.29 million over a 4-year period, annualized at 3 percent and 7 percent as shown in Table 4.

9. System Changes—Plans

Comment: In the August 22, 2008 proposed rule (73 FR 49818), we acknowledged that revisions to payer systems may be one of the largest ICD-10 cost categories, at approximately \$164.64 million, with a range of \$110 million to a \$274 million cost, based on data from the RAND report. We also acknowledged that not all payer system changes may have been identified in our impact analysis. Commenters stated that payer business process impacts resulting from implementation of ICD-10-CM and ICD-10-PCS would include, among others, impacts to medical policy; benefit design and coding; vendor management; data reporting; disease and case management; trend analysis and quality assurance. Commenters noted that edits will need to be updated to accommodate ICD-10's

impact on auto-adjudication systems. One commenter cited a 2000 industry white paper that stated for each 100 hours spent on programming, payers must spend an additional 30–35 hours preparing specifications, conducting analysis and design sessions, performing testing and conducting other implementation-related activities. Another commercial payer estimated 8,000 programming hours for their transition from ICD-9 to ICD-10, not including specification changes or testing, while another plan estimated that it would cost between \$3.00 and \$5.80 per plan member to cover the cost of ICD-10 implementation. One commenter stated that integrating the expanded ICD-10 code sets into their business systems would be difficult, while another stated that detailed information on how reimbursement programs will be affected should be made available to payers at least one year before ICD-10-CM and ICD-10-PCS implementation so that payers can plan for training, financial analysis and modeling.

Response: Commenters did not provide substantiated data that would allow us to update our payer system cost estimates at this time.

We agree with commenters that there will be an impact to payer systems, and that it may be difficult to initially pinpoint all of the system changes because of the pervasive use of ICD-9 codes within payer systems. As part of our internal analysis of CMS payment systems that currently use ICD-9 code set data and would likely use ICD-10 code set data, we conducted interviews with all CMS components and identified no less than 20 systems across 30 business processes/areas that potentially would be impacted. As an example of the internal investigative process CMS undertook as part of our ongoing ICD-10 planning and analysis, CMS has shared this information with the industry through its summary report at <http://www.cms.hhs.gov/TransactionCodeSetsStands/Downloads/AHIMASummary.pdf>. We expect that once payers initiate similar ICD-10 planning and analysis activities, they will identify both known and heretofore unknown impacts to their payer systems, and can better evaluate them in terms of minimal, medium, and high impacts relative to cost and risk.

As discussed in the August 22, 2008 proposed rule (73 FR 49800), there are multiple ways for entities to integrate the ICD-10 code sets into their business settings. As the codes are incorporated into systems and processes, some providers, plans, and vendors may decide to populate the new codes

throughout their entire system all at once, or translate the codes on a flow basis as they are used. Integration of the codes in many cases will be determined by the extent to which the available granularity is needed in transactions.

For purposes of this analysis, we acknowledge that the estimated payer systems costs may exceed those identified in the August 22, 2008 proposed rule. Recognizing that these payer system costs may be difficult to ascertain, and considering the comments submitted that expressed concern regarding underestimation of payer system costs, we have increased our estimate of payer systems costs by 20 percent based on comments which stated that the August 22, 2008 proposed rule did not account for all of the systems that will need to be updated to accommodate the new code set. We believe that a 20 percent increase in our estimate of payer system costs will recognize these potential unaccounted system costs and better estimate ICD-10 implementation costs. Therefore, we have increased our payer system costs from the previous \$164.64 million to \$197.64 million over 4 years, annualized at 3 percent and 7 percent as shown in Table 4.

As information becomes available from industry, we anticipate that it will be shared through advisory bodies such as NCVHS, and other industry communication vehicles such as association Web sites, newsletters, open door forums, conferences, etc. As information on the impact of ICD-10 transition to CMS programs becomes available, CMS plans to share information through official CMS communication vehicles as appropriate, for purposes of informing the industry's ICD-10 implementation planning.

10. System Changes—Government

Comment: In the August 22, 2008 proposed rule (73 FR 49819), we discussed potential costs to State Medicaid programs associated with the transition from ICD-9 to ICD-10. We noted the limitations of our analysis, and we estimated that it would cost approximately \$102 million or about \$2 million per State to transition their systems to ICD-10-CM and ICD-10-PCS. The majority of comments focused on costs of ICD-10-CM and ICD-10-PCS implementation to State Medicaid programs. A number of commenters stated that the August 22, 2008 proposed rule did not fully account for the impact of ICD-10-CM and ICD-10-PCS on State Medicaid programs. In light of those additional unaccounted for costs, some State Medicaid agencies stated that they would not be ready to

accept the new ICD-10 code sets by the proposed October 2011 compliance date, resulting in rejected claims, claims paid inappropriately, and an increase in adjustments and re-billing. Of the comments received regarding the ICD-10-CM and ICD-10-PCS conversion costs for State Medicaid agencies, none were able to offer any data to support their assertions that these conversion costs were underestimated in the August 22, 2008 proposed rule. Another commenter stated that Medicaid paper claim forms will need to be reprinted for ICD-10 codes. Four States stated that the transition to ICD-10 will increase their Medicaid Management Information Systems (MMIS) replacement costs, and that these updates could be jeopardized if their system transition from ICD-9 to ICD-10 is made too quickly. They noted that changes to MMIS, as well as legacy systems, may force them to initially run dual systems. One State Medicaid agency recommended a provision that would waive implementation of the ICD-10 code sets in any legacy system scheduled for replacement.

One commenter stated the August 22, 2008 proposed rule did not account for system conversions and training required for public programs outside of Medicaid, including the use of ICD-10 in public health reporting and surveillance systems. The commenter stated that implementation of ICD-10 would result in legacy system migration costs, and changes to longitudinal analysis for downstream data users, including State employee health plans, some social service programs, State health care, and university research and training programs. While the commenter noted these impacts, they did not provide any data that would cause us to further revise our analysis at this time. Tribal government representatives expressed concern about their costs associated with the implementation of ICD-10-CM and ICD-10-PCS, asking that the ICD-10 compliance date be moved forward to October 2013 to allow them time to achieve compliance.

A few commenters stated that we did not consult with local governments on the impacts that might result from the transition from ICD-9-CM to ICD-10-CM as required by Executive Order 13132.

Response: We agree with commenters that ICD-10 Medicaid cost estimates were understated because they were based on a very limited State survey. We anticipated that State Medicaid agencies would respond with more accurate and complete data, but they were unable to do so, with some citing current State budget uncertainties.

The ICD-10 compliance date of October 1, 2013 addresses State Medicaid agencies' concerns about not being able to be ready to accept claims with the new ICD-10 code set by the proposed October 1, 2011 date. State Medicaid agencies can approach the transition from ICD-9-CM to ICD-10-CM and ICD-10-PCS either through installation of a new MMIS system (of which 18 States are currently in various stages of procurement) that would already accommodate the ICD-10-CM and ICD-10-PCS codes; or through remediation of their current systems. Either way, States are reimbursed by the Federal government for 90 percent of the cost of ICD-10-CM and ICD-10-PCS modification to the State's Medicaid system design, development, installation or enhancement, leaving 10 percent as the state's share of the expense.

This updated information, and discussions with Medicaid subject matter experts regarding our experience with similar Medicaid implementations with the States (Y2K and NPI, for example) leads us to revise our estimates of the States' Medicaid program cost of ICD-10 implementation from \$102 million, to a range of between \$200 million to \$400 million. Taking the midpoint of that range, or \$300,000,000, we estimate that the average ICD-10 cost per State Medicaid program, at their 10 percent cost share, to be \$588,235, for a State Medicaid program cost of \$30 million. We estimate the remaining 90 percent cost share to the Federal Medicaid program as an average of \$5.294 million per State, or a Federal Medicaid share of \$270 million. Therefore, based on this new information, we have increased by \$270 million the Federal government's share of the Medicaid system cost estimates, and revised the State's 10 percent cost share to \$30 million, with costs annualized at 3 percent and 7 percent, respectively, as shown in Table 1.

At some Tribal programs, Medicare and Medicaid collections represent half of the operating budget of the facility and any delay or decrease in collections as a result of the transition from ICD-9-CM to ICD-10-CM will have an impact on Tribal programs' ability to provide services. The Indian Health Service (IHS) has jurisdiction over Tribal health care programs and provides the Tribes with necessary system upgrades to their Resource and Patient Management Systems (RPMS). IHS will need to invest in systems changes for all 60 RPMS software packages, integrate ICD-10-CM and ICD-10-PCS codes into their reports, train staff on new codes, and test data transmissions with payers. IHS was one of the first Federal agencies to recognize the impact of ICD-10 on their support of Tribal health services, and has taken these expenses into consideration in their estimate of their ICD-10 costs, of which the latest data were included in the proposed rule at 73 FR 49819.

HHS actively participated in NCVHS' public and open process for soliciting input on ICD-10. In the August 22, 2008 proposed rule (73 FR 49799), we discussed the number of NCVHS hearings on ICD-10, and the wide array of testifiers and comment submitters, including public health representatives. The Public Health Data Standards Consortium (PHDSC), which includes local and county health departments among their members, as well as the National Association of City and County Health Officials (NACCHO) were invited to testify. Their issues were addressed by the National Association of Health Data Organizations (a not-for-profit organization that addresses the collection, analysis, dissemination, public availability, and use of health data) which testified strongly in favor of moving to ICD-10 code set. The PHDSC and the U.S. Joint Public Health Informatics Task Force, which includes NACCHO, both submitted positive comments on our proposed rule, calling for implementation of ICD-10 by no later than October 2012. NCVHS considered all of this input, and made recommendations to adopt ICD-10-CM and ICD-10-PCS to the Secretary. These recommendations were all taken into consideration by HHS as it developed this rule.

TABLE 1—GOVERNMENT COSTS \$ MILLION

Change	Government agency	Cost annualized 3%, 7%	
		3.00%	7.00%
Systems/Software Modifications and Updates:			

TABLE 1—GOVERNMENT COSTS \$ MILLION—Continued

Change	Government agency	Cost annualized 3%, 7%	
		3.00%	7.00%
	CMS	\$31.41	\$41.17
	IHS	0.67	0.88
	VA	1.60	2.09
Subtotal	33.68	44.14
Training:			
	CMS	0.80	1.04
	IHS	0.11	0.14
	VA	3.94	5.16
Subtotal	4.84	6.35
Planning:			
	CMS	0.34	0.44
	IHS	0.25	0.33
	VA	0.21	0.27
Subtotal	0.80	1.04
Other (contractor provider inquiries)	1.06	1.38
State Medicaid Agencies	2.51	3.29
Total	42.89	56.21

Comment: A commenter stated that we should consider suspending Medicare Administrative Contractor (MAC) and RAC auditing for at least 12 months following the ICD-10 compliance date. One commenter stated that during the transition from ICD-9 to ICD-10, provider coding errors should not be used as a basis for prosecution under the False Claims Act. Another commenter noted that CMS should not unfairly penalize providers if the agency adopts a prospective budget neutrality adjustment (BNA).

Response: These comments relate specifically to ICD-10-CM and ICD-10-PCS implementation issues that will impact the Medicare program. We will take these comments under consideration, and inform the industry and other interested stakeholders through normal CMS communication channels of any decisions made relative to these issues as we plan for the transition from ICD-9-CM to ICD-10-CM and ICD-10-PCS.

11. Impact on Clinical Laboratories

Comment: A few commenters stated that neither the proposed rule nor the RAND and Nolan ICD-10 reports addressed the impacts of ICD-10 adoption on clinical laboratories. Commenters stated that clinical laboratories submit a large volume of small claims and rely on providers to submit correct codes but that obtaining missing codes, following up on and/or correcting invalid codes submitted by providers is a large administrative burden. Commenters stated that, by using ICD-10 codes, providers will be

more likely to submit incorrect codes or will fail to submit them at all. Commenters also mentioned that pathologists will have to be trained in how they document the diagnoses they submit in their pathology reports, which would require an increase in medical documentation.

One commenter stated that, although they perceived an impact of the adoption of ICD-10 on clinical laboratories, the 60-day public comment period was not enough time for them to gather substantive data on that impact.

One commenter suggested that clinical labs be exempt from the requirement to adopt ICD-10-CM or at least not be required to utilize the highest degree of specificity in diagnosis coding when submitting claims.

According to some commenters, clinical laboratory systems that will be impacted include: Order entry; laboratory billing, reporting, and data warehousing; and programs, screens, reports, requisitions, forms (printed and electronic), interfaces, contracts and policy manuals. Additionally, commenters stated that use of ICD-10-CM will require more highly qualified and more expensive specialists to translate physicians' narratives into the appropriate ICD-10-CM coding. Commenters also stated that clinical labs will be responsible for educating providers as to the proper submission of diagnosis codes as well as conducting business rule development, programming, testing and implementation for hundreds of internal software programs, remapping hundreds of external interfaces as well as

conducting end-to-end testing with trading partners.

An industry-sponsored report on ICD-10-CM and ICD-10-PCS costs acknowledged that ICD-10 would have an impact on clinical laboratories, but provided no substantiated data in support of that statement. The report does mention that one large national laboratory has estimated its up-front cost of implementing ICD-10-CM to be about \$40 million, including IT and education costs. However it does not provide how that cost was derived, and we are unable to assess the basis for this estimate or the extent to which it may include costs already included in our assumptions.

Response: We addressed the impact of the adoption of ICD-10-CM on clinical laboratories in two areas, part-time coders and laboratories as small entities, and used the public information available to us at the time of the development of the August 22, 2008 proposed rule as a basis for our assumptions and our cost/benefit analysis. In the August 22, 2008 proposed rule (73 FR 49815), we acknowledged in Table 7 ("Ambulatory Entities Assumed To Employ Part-Time Coders Based on the 2005 Statistics of U.S. Businesses") that 6,080 coders were likely employed by medical and diagnostic laboratories (designated as North American Industry Classification System or NAICS code 6215), and included them in our estimate of the costs of coder training. We assumed that these 6,080 coders would have training costs per coder of \$550, for an estimated cost of \$3.344 million.

In the August 22, 2008 proposed rule (73 FR 49828), we also noted that approximately 92 percent of medical laboratories are assumed to be small entities, with annual receipts below \$9 million, and considered them in our analysis of the impact on small entities. In Table 9 (“Estimated Impact of ICD-10 Transition Cost on Inpatient and Outpatient Providers and Suppliers, Adjusted for Inflation”), we had included NAICS code 6215, which was erroneously labeled “Medical Diagnostic and Imaging Services” but is actually “Medical and Diagnostic Laboratories”, for which we allocated a portion of provider systems costs based on a percent of laboratory revenues. In the August 22, 2008 proposed rule, we estimated this cost to be \$5 million, for a combined cost of \$8.344 million (\$3.344 million based upon 6,080 laboratory coders in Table 7 in the August 22, 2008 proposed rule at \$550 per coder + \$5 million from Table 9 in the August 22, 2008 proposed rule). The August 22, 2008 proposed rule’s Table 9 data for medical and diagnostic laboratories is updated in this final rule from \$5 million to \$13.14 million to account for the increase in costs, and is reflected in Table 2 and our Table 6 cost summary (which includes annualized costs at 3 percent and 7 percent), both of which appear in this final rule. This accounts for provider follow-up productivity losses as described by the commenters. Although commenters provided a great deal of qualitative information as to the impact of the ICD-10-CM transition on the clinical laboratory industry, and again, we acknowledge that it will be impacted, we did not receive any quantitative data from commenters to support a revision of our analysis of the quantitative impact of the adoption of ICD-10-CM on clinical laboratories.

Clinical laboratories cannot be exempted from the requirement to adopt ICD-10-CM. All HIPAA covered entities need to be ICD-10-ready at the same time to not disrupt claims payment and processing. Since clinical laboratories utilize ICD codes for reimbursement and submit claims to various payers, it is imperative that they implement ICD-10 at the same time as the rest of the health care industry. As to one commenter’s suggestion that laboratories not use the highest degree of specificity in diagnosis coding when submitting claims, the use of the ICD-10 codes do not drive the clinical care, as previously discussed in this RIA. Laboratories should continue to code based on the information at hand, or supplied by the provider or

based on the clinical test being conducted.

As we previously indicated in our discussion on medical documentation in this final rule, we also disagree with commenters who stated that pathologists would need additional training to provide correct diagnosis as a result of using ICD-10 codes. While laboratories will be responsible for working with providers to ensure proper programming and testing, these are activities that they would undertake on an ongoing basis with any new provider clients. The implementation of ICD-10 in hundreds of internal software programs, and the remapping hundreds of external interfaces as well as end-to-end testing with trading partners are similar processes that all HIPAA covered entities will be undertaking as they implement ICD-10, and are part of the generally accepted ICD-10 system implementation process. Other than the cost estimates for coder training and productivity losses, absent other quantitative data from clinical laboratories on costs, we cannot at this time project any more specific cost estimate relative to clinical laboratories’ transition from ICD-9-CM to ICD-10-CM and ICD-10-PCS.

12. Impact on Pharmacies

Comment: Some commenters stated that the ICD-10 proposed rule did not account for the impact that the transition to ICD-10-CM and ICD-10-PCS would have on the pharmacy industry. One commenter stated that the adoption of the National Council of Prescription Drug Plans’ Telecommunications Standard Version D.0, and increased adoption of e-prescribing, will cause an increase in diagnosis code use required by payers.

A few commenters stated that between 40 and 50 percent of prescription claim volume is associated with prescription refills. Some commenters recommended that there be a one year staggered transition period for pharmacies to implement ICD-10-CM so that authorized prescription medication refill orders can complete the reorder cycle uninterrupted. A commenter stated that for refills, pharmacies will not be able to use an ICD-9 to ICD-10 crosswalk because of the lack of one-to-one relationships but will have to contact physicians to obtain the ICD-10-CM code the prescriber has assigned to the patient. Another commenter stated that all prescription refills written prior to the compliance date for ICD-10-CM should be exempted from having to use the ICD-10-CM codes. Commenters also stated that ICD-9-CM codes are used by

pharmacy benefit managers (PBMs) for disease management reporting, and for client reporting, benchmarking, and patient stratification. Commenters stated that ICD-10-CM would impact the pharmacy industry for training, systems and business process revisions, manual review of systems, outreach to providers, consumer education, cost of manual provider contact, and other considerations. Conversely, two other commenters stated that ICD-9 codes are not heavily used in pharmacies, and that impact would be minimal. None of the commenters were able to provide substantiated data to support their qualitative impact claims.

Response: NCVHS held multiple hearings and solicited comments from all industry segments regarding the potential impacts of ICD-10-CM on their respective business processes and systems. During the ongoing NCVHS process, representatives of the pharmacy industry did not indicate that the transition from ICD-9-CM to ICD-10-CM codes would be problematic and, therefore, we did not identify pharmacies as an impacted industry segment in the August 22, 2008 proposed rule’s regulatory impact analysis. We now understand that ICD-9-CM codes are currently used in pharmacy settings when the patient’s drug benefit plan may require a diagnosis code for purposes of prior authorization. However, the pharmacist does not assign this diagnosis code; it must be obtained by the pharmacist from the prescriber, just as it would if ICD-9-CM codes were still in use. The adoption of NCPDP Telecommunications Standard Version D.0 was overwhelmingly favored by the pharmacy industry for its ability to better support Medicare Part D requirements. We do not anticipate that the use of NCPDP Telecommunication Standard Version D.0 or the ICD-10-CM code sets in pharmacy settings will cause an increase in the requirement to use codes to report supplies/services in e-prescribing transactions and that, in fact, the use of such standards will enhance retail pharmacy transactions through their greater specificity, reducing pharmacy call-backs to physicians, and improving the efficiency of pharmacy claims submissions and accurate payments. As with other coding situations, ICD-9-CM codes will continue to be used up to and until the October 1, 2013 compliance date, at which time ICD-10-CM and ICD-10-PCS code sets will be required.

With regard to ongoing prescription refills that are written prior to, and refilled after the October 1, 2013 compliance date, we anticipate that

pharmacies will be able to use the reimbursement mappings posted to the CMS Web site to translate ICD-9-CM codes into ICD-10-CM. These mappings provide a one-to-one match of the closest ICD-9-CM to ICD-10-CM and ICD-10-PCS codes for reimbursement purposes. We also anticipate that, given the new compliance date of October 2013, this will afford the pharmacy industry ample additional time to identify and fix any outstanding refill issues.

Although commenters provided qualitative information as to the impact of the ICD-10 transition on the pharmacy industry, we did not receive any data that would allow us to offer any refined estimates of quantitative impacts to the pharmacy industry.

13. Contract Renegotiation

Comment: A number of commenters stated that the cost of contract renegotiations was not addressed in the proposed rule, and that once contracts are opened to accommodate the ICD-10 transition, many providers will want to review their negotiated rates based on revised fee schedules. Other commenters stated that it is more cost effective for payers and providers to renegotiate contracts in conjunction with their renewal dates, whereas off-cycle negotiations demand additional resources, analysis and time, which would be required under the transition to ICD-10.

A commenter mentioned that for an entire network of hospital contracts, 25 to 30 percent may be up for renewal in any given year. Another commenter stated many high-volume providers have multi-year agreements with negotiations taking months, and reimbursement terms can be the most time-consuming part of the process. Other commenters mentioned that extensive pricing analysis will be required prior to entering contract renegotiations. One commenter stated it will be difficult to price contracts because unknown provider billing patterns will create financial uncertainty for providers and payers.

Other commenters mentioned that the new coding system will cause differences in the classification of provider services and the reporting of utilization patterns. Provider contracts will require modification to account for subsequent reimbursement changes to achieve budget neutrality.

Response: In the August 22, 2008 proposed rule (73 FR 49814), we discussed the different approaches taken by RAND and Nolan with regard to the cost of contract renegotiations. RAND stated that periodic contract

renegotiations are the norm in the health care payer industry, with 1-year and 3-year contract cycles being quite common. RAND assumed that the conversion to ICD-10-CM and ICD-10-PCS would introduce more issues to negotiation, but would be far less likely to spur negotiations when there otherwise would have been none.

Nolan assumed that, because ICD-10-CM and ICD-10-PCS represents changes in the underlying diagnostic and procedural coding, many if not all contracts based on code definitions and their associated reimbursement rates will require development, negotiation, review and ultimately agreement. Nolan assumed this will be a costly and time-consuming process shared by payers and providers alike. The number of contracts Nolan used for their analysis—5 to 20 per entity—is much smaller than the millions of contracts the industry has estimated because Nolan assumed that many contracts for physicians and provider groups would be standardized and would be negotiated by contracting staff rather than by physicians themselves. Nolan did not provide any separate estimates for the costs of contract renegotiation to health plans, assuming that these costs would be included in the health plans' overall costs of ICD-10-CM and ICD-10-PCS implementation.

As discussed in the August 22, 2008 proposed rule (73 FR 49814), we did not account for the costs of contract renegotiations because we shared RAND's assumption that providers and payers must regularly renegotiate contracts in response to new policies. Contracts are renegotiated to revise the terms of the contract, usually in response to changes in policy that affect rates of reimbursement, and as we have already noted, we do not anticipate that the ICD-10-CM and ICD-10-PCS data that would constitute the basis for changes in reimbursement will be available until some time after the initial implementation of ICD-10-CM.

Therefore, we believe that any cost of renegotiating contracts will be spread out over time, be undertaken at the time of the regularly scheduled contract renewal, and should be accounted for as a cost of doing business.

14. Impact on Electronic Medical Records

Comment: In the August 22, 2008 proposed rule (73 FR 49829), we discussed the impact of ICD-10 on electronic medical record (EMR) systems. Many commenters stated that the EMRs systems will be too costly to reprogram for ICD-10 code sets, but offered no examples of what those costs

might be. However, one commenter estimated that only 4 percent of physicians have an extensive, fully functioning EMR system, and only 13 percent have a basic EMR system. Commenters stated the complexity of system changeovers will delay EMR adoption, put stress on practice operations and increase costs. One industry group stated that, unlike other systems, not all ICD-10 hardware and software changes for EMRs will be accommodated by the Version 5010 upgrade of vendor applications.

Response: We agree that there will be costs associated with reprogramming electronic medical record systems to accommodate the use of ICD-10. However, as both commenters and the proposed rule noted, the rate of adoption of EMRs among providers is currently very low, and the transition to ICD-10-CM and ICD-10-PCS would affect only those providers who now employ EMRs. As those providers have already made their initial investment in their EMR system and are enjoying the benefits associated with its use, we expect that they will make the necessary upgrades to allow continued use of their system. For those providers who anticipate purchasing EMR systems, they should verify with their vendors that the systems they are considering can accommodate ICD-10-CM and ICD-10-PCS codes. We also anticipate that providers who need to migrate their EMR systems to ICD-10 will work closely with their vendors to ensure successful transitions. We also agree that, for clinical and administrative functions within EMR systems that are not integrated into other systems that use Version 5010, separate hardware and/or software costs may be incurred. However, absent data from vendors and providers, we cannot at this time project any specific cost estimates relative to ICD-10 transition and EMRs.

15. General Benefits

Comment: Overall, most commenters agreed with the benefit categories outlined in the August 22, 2008 proposed rule (73 FR 49821). Some commenters stated that, although these benefits will eventually be seen from the ICD-10 transition, their size was overestimated by the August 22, 2008 proposed rule. However, no substantiated data was provided by these commenters that would provide quantifiable information to counter our assumptions or convince us to change our analysis at this time.

While many commenters agreed with the benefits outlined in the proposed rule, they also suggested other benefits that could be realized through the

transition to ICD-10. Commenters stated that these other benefits included improvement in medical knowledge and technology; the ability to substantiate the medical necessity of diagnostic and therapeutic services; the ability to demonstrate the efficacy of using technology for particular clinical conditions; and the ability to identify complications and adverse effects through the use of technology. Another commenter specifically mentioned that ICD-10-CM also permits the identification of individual fetuses in multiple gestation pregnancies which will make it possible for the first time to link a coded condition to a specific fetus.

One commenter stated that while the discussion of the benefit of "more accurate payments for new procedures" in the proposed rule seems to focus on Medicare payments, the benefit would apply to other payers and health plans as well.

Conversely, some commenters questioned the benefits of ICD-10. A few commenters questioned whether covered entities would really achieve more accurate payments, fewer rejected claims and fewer improper claims. Some commenters expressed doubt as to whether physician practices specifically would achieve many of the stated ICD-10 benefits. Others noted that conversion to ICD-10 would make almost 30 years of longitudinal U.S. morbidity data derived from ICD-9 virtually useless and it would be difficult to draw conclusions about trends in ICD-9 or ICD-10 translated data when aggregate comparisons assume that all hospitals are coding consistently. It was also noted that information or benchmarks were not available from previous HIPAA implementations that could validate or disprove the projected benefit assumptions.

Some commenters stated that many of the projected benefits refer to improvements in the procedure code classification system (ICD-10-PCS) and are not directly tied to ICD-10-CM adoption.

Response: As outlined in the August 22, 2008 proposed rule, we were conservative in our estimate of benefits. In many instances, we claimed only a small percentage of our calculated full benefit, and in a number of areas where we did not have quantifiable benefit data, we declined to claim any benefit whatsoever. We agree with commenters who stated that we did not account for all the benefits that could potentially be realized through the use of ICD-10-CM and ICD-10-PCS. If benefits were overestimated, as some commenters

asserted, those assertions did not indicate how or to what degree we may have overestimated benefits, nor did they provide information that we could use to revise our benefits estimates.

In the proposed rule, for the benefit growth factor pre-implementation, we use the growth in national health care expenditures for years 2005-2007, with year 2007 having an estimated growth rate of 1.212. For the growth projections for years 2012 and beyond, we use the compounded growth in the U.S. population which is projected to grow at 0.008 per year.

In this final analysis we use the same approach, but rather than 2004 as the base year for the analysis, we now use expenditures from 2007 as the base year of the analysis. We then apply the 1.212 growth rate adjustment to the 100 percent benefit value for each respective benefit listed in Table 5, and use the resulting number to pro-rate the phase-in amounts based upon the identified phase-in percentage assigned for the first year in which the benefits first appear. Going forward from the year in which the regulation is implemented, we applied the population growth factor compounded by the number of years from the implementation year of the regulation (2014). We now estimate benefits at \$4,539.63 million over 15 years, and annualized at 3 percent and 7 percent, as reflected in Table 7, compared with \$3,950.74 million over 15 years in the August 22, 2008 proposed rule. Since the benefits estimates are now based in 2007 dollars, we updated the cost numbers to 2007 dollar for comparability.

16. Education and Outreach

Comment: Commenters stated that while there should be a set of basic ICD-10-CM and ICD-10-PCS training materials with consistent messages, education should be designed for different learning levels and audiences. Other commenters suggested the development of a detailed provider education and outreach plan with emphasis on small physician practices and software vendors; increasing the number of Medicare customer service representatives and creating a separate toll free hotline for ICD-10 questions; hosting regularly scheduled regional calls with rural providers, independent clinical laboratories, key stakeholders, physicians, and State and regional medical societies; designating a central point person to guide ICD-10-CM and ICD-10-PCS implementation and ensure consistency of materials; and development of a public access Web site for ICD-10 interpretation and guidance.

Commenters also stated that academic medical centers and teaching hospitals will be impacted by ICD-10-CM and ICD-10-PCS and should be targeted for more intense educational outreach. Commenters recommended that CMS should fund ICD-10 education and outreach programs, and pursue both paid and earned ICD-10 educational advertising.

Response: In the August 22, 2008 proposed rule (73 FR 49807), we detailed our intention to provide ICD-10 education and outreach to a wide variety of health care entities, including Medicare contractors; Fiscal Intermediaries, Carriers, and Medicare Administrative Contractors; hospitals; physicians; other providers; and other stakeholders. We stated that we will develop and make publicly available a host of tools, including extensive "Frequently Asked Questions" documents which will be updated as new questions and/or information arise; fact sheets; and other supporting education and outreach materials for partner dissemination. Other potential impacted groups will be targeted, and activities will be developed, based on this stakeholder input. We acknowledge that different health care professionals and entities will have different information needs, and we are beginning to address this need through educational materials posted to <http://www.cms.hhs.gov/MedLearn> and <http://www.cms.hhs.gov/ICD10/> Web sites. All materials go through extensive reviews from a number of subject matter experts prior to dissemination to the public to assure accuracy and consistency. Our free, ongoing series of roundtable and open door forum discussions tailored to specific audiences such as ESRD providers, rural providers, hospitals, etc. also address a full spectrum of stakeholder segments and concerns, including ICD-10, on a regularly scheduled basis.

Many stakeholders, through the August 22, 2008 proposed rule's public comment process, expressed their willingness to assist in disseminating information to their respective constituencies, and we will take advantage of those offers of assistance, working closely with industry in this regard.

17. Impacts on Training Programs

Comment: A commenter stated that the August 22, 2008 proposed rule did not address possible coder shortages and the need to re-certify coders. The commenter noted that implementing ICD-10 will exacerbate the current shortage of clinical coders, and did not account for the impact on formal

training programs for degree and national certificates that will need to be updated or redeveloped. Some commenters stated regular physician office staff would need to become certified coders, and current coders will need to recertify, incurring a costly exam fee. Commenters noted that ICD-10-CM and ICD-10-PCS are too technical to teach in a short amount of time. Other commenters stated that the October 2011 proposed compliance date did not allow enough time for publishers to update and revise medical coding and billing program texts and curriculum; and allow institutions to purchase, install and test the new IT systems needed to train medical coders.

Response: We have received no indication from industry, and have no reason to believe, that the changeover from ICD-9-CM to ICD-10-CM and ICD-10-PCS codes might contribute to the existing shortage of clinical coders. In fact, increased marketplace demand for coders as a result of adoption of ICD-10-CM and ICD-10-PCS may lead to more enrollment in coding curriculums and, in turn, the graduation of more and better qualified coders. Industry trade and technical school representatives have indicated their readiness to adapt to any needed curriculum changes as a result of the adoption of ICD-10, and anticipate that they will be able to produce "ICD-10 ready" clinical coders upon graduation from their respective institutions. As ICD-9-CM codes are currently updated annually, we anticipate that educational venues offering courses in coding would be familiar with making changes in curriculum to reflect these revisions. The final compliance date of October 1, 2013 should afford educational institutions sufficient time to change their instructional coding curriculums, and seek out and obtain appropriate educational materials and related resources.

Some hospitals may require their coders to be certified by certifying bodies such as the various national professional associations, and while desirable in the ambulatory setting, this does not appear to be a requirement for coders working in physician offices or other ambulatory settings. Coders must maintain annual continuing educational requirements to maintain their certifications. As CMS has no coding certification requirements, we refer those concerned with future certification standards to contact their applicable professional organizations.

18. Impact on Other HIT Initiatives

Comment: In the August 22, 2008 proposed rule (73 FR 49805-49806), we

detailed known health information technology (HIT) initiatives and their relation to ICD-10 adoption and timing. Commenters stated that there are too many other HIT initiatives that they are being asked to embrace, creating too much competition for scant resources and time, but did not offer any substantiated data concerning potential costs associated with these other initiatives. Commenters noted that the Medicare Improvements for Patients and Providers Act (MIPPA) legislation creates e-prescribing incentives at the same time as the proposed October 2011 ICD-10 implementation date. A few health plans stated that there are multiple statewide requirements that also place demands on their available resources that would otherwise be diverted to ICD-10 implementation, but did not indicate costs associated with these requirements. Some commenters asked that the final rule for claims attachments be delayed until after the compliance date for ICD-10-CM and ICD-10-PCS.

Response: Of the 11 initiatives listed in the August 22, 2008 proposed rule, 7 of them had compliance deadlines which have already passed. These included HITSP interoperability specifications for use cases; the NPI compliance date; publication of CCHIT criteria for inpatient electronic health record products; publication of CCHIT criteria for certifying health information technology networks and systems; the NPI compliance date for small health plans; and a second set of e-prescribing final standards under Medicare Part D and adoption of the NPI for electronic prescribing transactions. Of the remaining 4 initiatives, 2 relate to compliance dates associated with the adoption of Version 5010, NCPDP Telecommunications Standard D.0, and NCPDP Medicaid Subrogation Standard 3.0, both of which are now projected for January 2012 (the Medicaid Subrogation Standard for small health plans only is projected for January 2013). The two remaining initiatives, the compliance date in the proposed rule for a new HIPAA standard for the healthcare claims attachment standard, and the proposed compliance date for the claims attachment transaction for small health plans, were scheduled for 2011 and 2012, respectively. We acknowledged in the August 22, 2008 proposed rule that implementing ICD-10 codes sets will require significant effort on the part of covered entities and their vendors, and took other HIT initiatives into consideration in establishing our proposed ICD-10 compliance date to sequence compliance in a manner that

would allow covered entities to concentrate their efforts on ICD-10 implementation during the relevant period. For more information on ICD-10's relation to and impact on other HIT initiatives, see the discussion in the August 22, 2008 proposed rule (73 FR 49805).

We believe that with the new ICD-10 compliance date of October 1, 2013, there will be ample time—an additional two years from the proposed October 1, 2011 compliance date, and a year from the MIPPA 2012 e-prescribing deadline—for providers to prepare for the changeover from ICD-9 to ICD-10.

We have stated publicly, and reiterate once again, that we will not consider implementing a new HIPAA standard for claims attachment transactions until after the compliance date for ICD-10.

With regard to commenters' assertions that there are multiple State requirements that will compete with implementation of ICD-10, we believe that these requirements are not new, but constitute updates to existing State requirements that would need to be accomplished whether or not ICD-10 was implemented, and for which entities affected by these requirements are already prepared. The later compliance date of October 1, 2013 should allow ample time for HIPAA-covered entities to implement ICD-10 while meeting any applicable State requirements, and should allow for planning of future health information technology initiatives to assure there is no overlap of HIPAA standards implementations.

19. Impact on Other Entities

Comment: Commenters noted that other non-HIPAA covered entities would be impacted by the change from ICD-9 to ICD-10. They cited worker's compensation programs, which would need to update their systems that support EDI transactions, as well as the Version 5010 of the 837 transaction standard for institutional claims and/or encounters. Commenters noted that life insurers will have to enter new diagnosis codes/conditions into their underwriting decisions. Commenters stated that all reports sent from third party administrators to employer sponsors of group health plans will need to be translated into ICD-10 for longitudinal analysis to track financial and health care quality performance. A commenter stated that the OASIS data set for home health care, the inpatient rehabilitation patient assessment instrument (IRF-PAI) and the post-acute care payment reform demonstration project plan will all need to account for the cost of transitioning to ICD-10 code

sets within their respective instruments. Commenters also stated that durable medical equipment (DME) providers would be impacted because they are required to submit diagnosis codes when billing DME supplies and Medicare Part B covered services.

Response: In the August 22, 2008 proposed rule (73 FR 49805), we addressed the adoption of ICD-10-CM and ICD-10-PCS as medical data code sets under HIPAA and, therefore, did not specifically address the potential impacts of ICD-10 adoption on non-HIPAA entities.

Neither RAND nor Nolan addresses impacts of ICD-10 on non-HIPAA entities. On page 2 of the October 2003 Nolan study on ICD-10 implementation (http://www.renolan.com/healthcare/icd10study_1003.pdf), it notes that the study “excludes many providers such as nursing homes, clinical labs and durable medical equipment vendors. Similarly, a large number of payer organizations have been excluded such as third party administrators, clearinghouses, and many small and medium insurers. These providers and payer entities were excluded because they were unable to develop initial cost estimates needed in the study.” We believe that, as with Nolan’s observations in their 2003 report, this is still the case. We heard from a handful of commenters who stated that the adoption of ICD-10 will have a ripple effect on life insurers, worker’s compensation programs, third party administrators and similar entities, but they did not offer any quantitative data that could be used to refine the impact analysis calculation of their costs associated with the adoption of ICD-10. According to our analysis of 2005 data from the National Academy of Social Insurance’s report on benefits, coverage and costs of worker’s compensation programs, more than \$26.2 billion in medical benefits were paid out in 2005, at an employer cost of \$88.8 billion, but the administrative costs associated with worker’s compensation programs are not available from this source.

From a benefits perspective, we do know that Chapter 20 of ICD-10, “External Causes of Morbidity (V01–Y98),” provides for the classification of environmental events and external circumstances as the cause of injury, and other adverse effects. These codes are more precise and describe a wider range of causes of injuries, which should be quite helpful to worker’s compensation programs in determining the exact cause of an injury.

With regard to OASIS, IRF–PAI and the post-acute care payment reform demonstration project, the business

process and systems impacts of ICD-9-CM, and subsequently ICD-10-CM and ICD-10-PCS, on these and similar instruments have already been identified. The costs associated with the implementation of ICD-10 relative to these instruments will be accounted for through CMS’s ongoing ICD-1CM and ICD-10-PCS internal planning and analysis activities and will be shared with the industry once these costs have been projected.

We acknowledge that many uncertainties exist regarding the transition to ICD-10-CM and ICD-10-PCS, and that the costs and benefits associated with the transition as outlined in this final rule may not fully capture all of the impacts to the industry. In order to account for this uncertainty, we included low, high and primary estimates of the costs and benefits of transitioning to ICD-10-CM and ICD-10-PCS. These estimates may also include some uncertainty in that the costs and benefits may be higher or lower than even our low and high estimates.

Some examples of uncertainty include the acknowledgment that our estimates for physician training may not accurately reflect the number of physicians who may require or request training on ICD-10-CM and ICD-10-PCS, because we received conflicting estimates from stakeholders during the ICD-10-CM and ICD-10-PCS proposed rule comment period. Additionally, some industry studies have determined that productivity losses will be time-limited, while others have opined that productivity losses may be continuous.

We also recognize that the ICD-10-CM and ICD-10-PCS proposed rule did not account for all of the systems that may be impacted by the ICD-10-CM and ICD-10-PCS transition. Due to the complexity of the U.S. health care system, it is very difficult to determine the number and all the types of systems that will need to be updated for ICD-10-CM and ICD-10-PCS use. However, we anticipate that, upon publication of this final rule, the industry will begin its requirements gathering, development and planning activities for the ICD-10-CM and ICD-10-PCS transition. We also acknowledge that the ICD-10-CM and ICD-10-PCS benefits estimates may include some uncertainty. We did not receive many comments on the benefits estimates that were provided in the August 22, 2008 proposed rule. However, we fully anticipate that once the ICD-10-CM and ICD-10-PCS code sets are implemented, and the industry becomes more familiar and comfortable with their use, benefits may be easier to measure.

B. Regulatory Flexibility Analysis

1. Final Regulatory Flexibility Analysis

Section 604 of the Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a final rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit status or by qualifying as small businesses under the Small Business Administration’s (SBA’s) size standards (having revenues of \$7.0 million to \$34.5 million in any 1 year). For details, see the SBA’s Web site at http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf (refer to Sector 62).

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 604 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.

As stated in the August 22, 2008 proposed rule (73 FR 49828), we determined that about 200 nonprofit health care organizations that offer 213 health plans are considered small entities under the RFA because of their non-profit status, and that 97 percent of all physicians’ practices and clinics also qualify as small entities under the RFA.

In the August 22, 2008 proposed rule (73 FR 49819), we showed the distribution of the transition costs to the ICD-10 codes for providers, suppliers, payers and software and system design firms. For calculating the impact on small entities, entities were grouped by the North American Industry Classification System (NAICS) and were presented at the firm level. The NAICS figures were adjusted based on the medical inflation factor we applied to all costs. Data were collected primarily by inpatient and outpatient categories. To allocate the transition costs, we used an available base which served as a proxy to the sub-groupings of inpatient and outpatient providers and suppliers. For the task of allocating the transition costs, we used the revenue-receipts reported in the Services Annual Survey and the National Health Expenditure Accounts, published by the U.S. Census Bureau. We grouped providers and

suppliers by inpatient and outpatient groups reflecting the level at which the data was available. In Column 3, we presented the revenue-receipts for each type of provider-supplier, insurance carrier-third party administrator, and computer design firm expected to bear transition costs. Column 4 showed the percent of the two groups' revenue-receipts each provider-supplier type comprised of the group's total. In Column 5, we applied the percentages to the total ICD-10 transition costs for each provider-supplier type.

ICD-10-CM and ICD-10-PCS transition costs per entity are calculated based on overall costs. As discussed in this final rule, we have revised our August 22, 2008 proposed rule estimates for ICD-10-CM and ICD-10-PCS training, productivity loss, and systems changes based on industry comments received during the proposed rule's comment period. We also have revised the data shown in the August 22, 2008 proposed rule's Table 9 (73 FR 49820) to account for inflation. We applied our revised costs to the number of firms and total revenue/receipts for each provider-

supplier type depicted in Table 2 below in order to more accurately reflect the increase in the distribution of costs across industry segments.

Table 2 ICD-10-CM and ICD-10-PCS costs for these provider-supplier types now reflect a cost of \$1,878.68 million, versus \$1,087.70 million in the August 22, 2008 proposed rule's Table 9 (73 FR 49420). We also have now correctly designated NAICS Code 6512 as "Medical and Diagnostic Laboratories" to reflect inclusion of laboratory data in our regulatory impact analysis.

TABLE 2—ESTIMATED IMPACT OF ICD-10 TRANSITION COST ON INPATIENT AND OUTPATIENT PROVIDERS AND SUPPLIERS [Adjusted for Inflation]

NAICS	Provider/supplier type	Firms	Revenue/receipts (\$ millions)	Percent of revenue receipts	ICD-10 costs (\$ millions)	Percent ICD-10 costs of revenue receipts
622	Hospitals (General Medical and Surgical, Psychiatric and Drug and Alcohol Treatment, Other Specialty).	4,409	653,033	81.45	254.14	0.03
623	Nursing Facilities (Nursing care facilities, Residential mental retardation, mental health and substance abuse facilities, Residential mental retardation facilities, Residential mental health and substance abuse facilities, Community care facilities for the elderly, Continuing care retirement communities).	22,867	148,716	18.55	57.88	0.03
Subtotal		27,276	801,749	100	312.02	0.03
6211	Office of Physicians (firms)	189,542	330,889	61.60	1,171.92	0.03
6214	Outpatient Care Centers (Family Planning Centers, Outpatient Mental Health and Drug Abuse Centers, Other Outpatient Health Centers, HMO Medical Centers, Kidney Dialysis Centers, Free-standing Ambulatory Surgical and Emergency Centers, All Other Outpatient Care Centers).	13,624	73,966	13.80	26.09	0.03
6215	Medical and Diagnostic Laboratories	7,811	37,253	6.93	13.14	0.03
6216	Home Health Services	14,512	47,007	8.75	16.58	0.03
6219	Other Ambulatory Care Services (Ambulance and Other).	5,872	24,593	4.58	8.67	0.03
N/A	Durable Medical Equipment	404,293	23,709	4.41	8.36	0.03
Subtotal		635,654	537,417	100	1,244.76	0.03
524114, 524292	Health Insurance Carriers and Third Party Administrators ⁴ .	4,578	723,412	100	197.60	0.01
5415	Computer System Design and Related Services	97,556	200,695	100	115.30	0.01
Subtotal		102,134	924,107		312.90	0.01
Total		765,064	2,263,273		1,878.68	

Table notes: Data for this table comes from the Statistics of U.S. Businesses 2005 tables for firms and establishments presented by employee size, and from the Bureau of the Census Services Annual Survey for 2006 that provides annual receipt-revenues by NAICS. Both data sets are available from <http://www.census.gov/econ/www/index.html>. Data on the number of Durable Medical Equipment suppliers comes from the 2007b CMS Data Compendium http://cms/hhs.gov/DataCompendium/17_2007_Data_Compndium.asp#TopOfPage.

Revenue data comes from the National Health Expenditures tables, 1960-2006, http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage. All accessed on 8-12-08. Firms data come from http://www.census.gov/svsd/www/services/sas/sas_data/sas54.htm, accessed 8-12-08. Revenue and receipts for each industry sector and sub-sector come from the Census Bureau Services Annual Survey for 2006 at B29. Revenue/receipt data for NAICS codes 6211-6219, 622 and 623 come from tables 8.1-8.10. Data for codes 5415 come from tables 6.1-6.21. Revenue/receipts are used to allocate ICD-10 implementation costs. Revenue/receipts were sub-totaled by ambulatory provider plus DME suppliers (NAICS 62111-6219) and inpatient providers (NAICS 622, 623) and the percent of the sub-totaled revenue/receipts for the provider/supplier was computed and applied to the total ICD-10 implementation costs for each of two sub-totaled groupings. ICD-10 costs for ambulatory provider do not include the cost of system changes. Some costs, however, are included with inpatient system changes since large multi-campus, integrated health care facilities are likely to include their ambulatory care facilities in the cost of upgrading their information systems.

Practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual revenues of less than \$6.5 million are considered to be small entities. We estimated that 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are also small entities under the RFA.

We also accounted for the impact of ICD-10 adoption on small insurance carriers, third party administrators and system design and related service firms. We first determined the number of entities that meet the SBA size standard.

For insurance carriers and third party administrators, the SBA size standard is annual receipts of \$6.5 million. For system design and related services firms, the SBA size standard is annual receipts of \$23 million.

The Statistics of U.S. Businesses data (<http://www.census.gov/econ/www.index.html>) used in the August 22, 2008 proposed rule at 73 FR 49820 shows 97,556 system design and related services firms (NAICS code 5415), providing software services, data processors, computer facilities management services, computer system design services, custom programming

services as well as other computer-related services. Table 3 below outlines the impact of ICD-10-CM and ICD-10-PCS on payers and computer design and related services. We have updated these data to reflect our cost revisions and include them in our calculations of our cost summary which appears in Table 6 of this final rule. We believe that our analysis supports the conclusion that implementation of ICD-10-CM and ICD-10-PCS will not impose a significant economic burden on payers and computer design and related services firms.

TABLE 3—IMPACT ON PAYERS AND COMPUTER DESIGN AND RELATED SERVICES

NAICS	Payers and system design and related services	Firms	Small entities	Revenue/receipt (\$ millions)	Small entity receipts (in millions \$)	% Small entity receipts of total receipts	Total ICD-10 costs (in millions \$)	Annual small entity share of ICD-10 costs (in millions \$)	% Small entity implementation cost/revenue-receipts
524114, 524292 5415	Health Insurance Carriers and Third Party Administrators	4,578	3,449	723,412	18,309	2.53	197.60	1.2	0.01
	Computer Systems Design and Related Services	97,556	96,948	200,695	107,048	53.34	115.3	15.4	0.01

Because most medical providers are either non-profit or meet the SBA's size requirements for "small entities" for purpose of regulatory impact analyses, we generally consider all health care providers and suppliers to be small entities. Table 9 in the August 22, 2008 proposed rule and the associated discussion (73 FR 49820) showed that the transition to ICD-10-CM and ICD-10-PCS will not have a significant impact on a substantial number of small health care entities.

To come to this conclusion, as stated in the August 22, 2008 proposed rule, we estimated that small insurance carriers and third party administrators would have an ICD-10 implementation cost of \$4 million, or approximately \$1 million per year, for the four years that they would incur implementation costs.

A similar exercise for system design and related computer services firms yielded a cost of \$51.5 million over 4 years, or \$12.9 million per year. We stated that it is possible that we could be including more firms than will actually be implementing the codes.

In the August 22, 2008 proposed rule, to test our analysis, we assumed that burden would equal 3 percent of small entity revenue. This is based on HHS' May 2003 guidance on proper consideration of small entities in rule making (<http://www.hhs.gov/execsec/smallbus.pdf.pdf>) that states that if a rule imposes a burden equal to or greater than 3 percent of a firm's revenues, it is significant. We assumed small business market share would remain constant at 53 percent of the

overall business market for their NAIC classification, and that the \$12.9 million costs described above would be equally distributed among the small entities. In describing our calculation we stated that we took 3 percent of the total cost and computed the number of small entities for which the cost of implementing the ICD-10-CM and ICD-10-PCS codes would be a significant burden. This description of the calculation was in error. What we did was to calculate the revenue amount, of which the small entity share of the ICD-10-CM and ICD-10-PCS implementation costs would equal 3 percent. That is, we divided \$12.9 million by 3 percent to yield \$430 million. Then, dividing the number of small entities into the total small entity share of revenues yields an average revenue amount per small entity of \$1.104 million. Finally, dividing the \$430 million by the average revenue per small entity of \$1.104 million yields the number of small entities of 389. This number represented the maximum number of small entities, if only that many participated in the ICD-10-CM and ICD-10-PCS implementation, for which the costs would be a significant burden.

Based on our revised estimate of costs for ICD-10 implementation, computer systems design and related services' cost share has been increased from \$12.9 million to \$15.4 million, the revenue level for which the costs would equal 3 percent is increased to \$513 million. Again, dividing the average small entity revenue amount of \$1.104 million into the \$513 million yields the number of

small entities (465) for which the ICD-10-CM and ICD-10-PCS implementation would become a significant burden if only that number of entities took part.

From this analysis we now estimate that if 465 or fewer small firms provide computer systems design and related services, the burden of ICD-10-CM and ICD-10-PCS implementation on them could be significant.

We also developed a scenario for a typical community hospital with 100 beds, 4,000 annual discharges and gross revenues of \$200 million (see 73 FR 49830 for the details on how we calculated this implementation cost). We assumed that the hospital would experience a productivity loss in the first 6 months after implementation (based on the AHA/AHIMA 2003 ICD-10 field study and other countries' ICD-10 implementation experiences), totaling \$1,233. We applied a similar methodology to determine outpatient productivity losses, using RAND's estimate that it would take 1/100 of the time it takes to code an inpatient claim to code an outpatient claim because outpatient claims do not require the use of the ICD-10-PCS code set. We applied 0.17 extra minutes per claim, at a labor charge of \$50 an hour, and a cost per claim of \$0.014. For the first month, the productivity loss for inpatient coding is \$15.28, with a total 6-month productivity loss of \$53. For systems changes and software upgrades, based on comments that claimed our system implementation costs were too low, we increased the costs to implement the

required changes from \$300,000 to \$1,000,000. For the sake of presenting a "worse case" scenario, we assume all implementation costs will be incurred or expensed within a 1-year period. This contrasts with our assumption as outlined in this final rule's RIA where we expect the costs to be incurred over a 4-year period. Along with training and productivity losses, the cost for a typical community hospital to implement the ICD-10 code sets will be \$1,003,986. To determine the percent of the hospital's revenue diverted to funding its ICD-10 conversion, we divided the hospital's revenues of \$200 million by the cost to convert their systems to use the ICD-10 code sets to obtain a result of 0.50 percent.

As previously discussed in this final rule, we considered alternatives for small entities to adopting the ICD-10-CM and ICD-10-PCS code sets. These included assigning new ICD-9-CM diagnosis and procedure codes where needed using the remaining unassigned codes and ignoring the hierarchy of the ICD-9-CM code set; using CPT-4 for coding hospital inpatient procedures; and skipping ICD-10 and waiting until ICD-11 is ready for use in the United States and adopting ICD-11 at that time. We also considered phasing in the implementation of the new codes by geographic region or by large versus small entities. Another option was for small entities to maintain dual coding systems for a period of time; or to delay implementation for small entities. All of these options were reviewed and rejected for the reasons discussed in the August 22, 2008 proposed rule at 73 FR 49826.

2. Response to Comments on Small Entities

Comment: For purposes of our analysis pursuant to the RFA, nonprofit organizations are generally considered small entities; however, individuals and states are not included in the definition of a small entity. Because most medical providers are either nonprofit or meet the SBA's size standard for small businesses for purposes of regulatory analysis, we treat all medical providers as small entities.

Many commenters representing small physician practices and healthcare-related associations stated that the cost of implementing ICD-10-CM as early as October 2011, shortly after the NPI implementation, might bankrupt small physician practices. Some commenters disputed our cost estimates for small entities as being too low, but none offered quantitative data on the impact of ICD-10 on their small practices. Commenters generally made vague

references to anticipated costs due to delayed reimbursements, lost productivity and costs of training, and outlays for software and hardware, and asked that the compliance date be pushed back. Some commenters stated that they will have difficulty integrating ICD-10 codes into their systems and business functions.

One commenter stated that the number of ICD-10 codes makes printing the code set in book form prohibitive, and that because of this, small providers will be forced to purchase electronic systems and software. Some commenters from small practices stated that they do not have electronic systems to support ICD-10, and cannot afford to hire additional staff or re-train existing staff in ICD-10 coding. A few small practices stated that they will need additional time in which to become compliant with the new code sets, while others disagreed, and stated that allowing small practices to continue to use ICD-9 while other industry segments use ICD-10 code sets would cause serious claims processing and reimbursement problems.

Response: As detailed in the August 22, 2008 proposed rule (73 FR 49808), the Regulatory Flexibility Act (RFA) requires agencies to analyze options for the regulatory relief of small entities. As previously explained, our analysis presumed that all medical providers were small entities. While we did not estimate that the cost of ICD-10 implementation per small physician practice would be substantial, we did acknowledge that, given the large number of affected entities, the aggregate total cost to the industry as a whole could be substantial.

Of those commenters identifying themselves as small practices, all but one did not dispute the need to move to ICD-10, but stated the timing of our proposed October 2011 compliance date was problematic because small practices do not have the financial and/or other resources (staff, technology, etc.) to quickly make the move from ICD-9-CM to ICD-10-CM. As the compliance date has been moved to October 2013, we anticipate that this will afford small practices the time they need to spread any costs associated with the implementation of ICD-10 in their practices over a longer period of time.

As discussed previously in this final rule, there are multiple ways for small entities to integrate the ICD-10 code sets into their business settings, either populating the new codes throughout their entire system all at once, or integrating the codes on a flow basis as they are used.

Additionally, any small practices may continue to submit paper claims, using preprinted forms that include all of the appropriate codes required for use in such practices. In most instances, practitioners in small practices may assign the diagnosis themselves and may include the ICD-10 code on the paper billing form. The use of the ICD-10 code sets is not predicated on the use of electronic hardware and software. The ICD-10 code set has already been produced in a book version of ICD-10-CM that measures only 2 inches in depth; the book version of ICD-10-PCS measures 1 inch in depth. Vendors have indicated that they are in the process of developing both paper-based and software products for purchase once ICD-10 is implemented. For those small practices that have already migrated to electronic systems and wish to purchase software, a CD of the ICD-10 code set will be made available through the U.S. Government Printing Office (GPO). The ICD-9-CM CD, also sold through the GPO, has been priced at less than \$30 for many years, and we expect an ICD-10-CM CD, when available, to be comparably priced. We do not believe this purchase price to be burdensome to small providers.

Also, as previously noted in this final rule, the ICD-10-PCS code set is available at no charge on the CMS Web site at http://www.cms.hhs.gov/ICD10/02_ICD-10-PCS.asp#TopOfPage. The ICD-10-CM code set is also available free of charge on the NCHS Web site at <http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm>. Both of these Web sites also feature the previously referenced tools such as crosswalks and guidelines for downloading at no charge.

As previously discussed in this impact analysis, we believe that there will be a plethora of training opportunities through the Internet, in-services, hospital-based training, association educational programs, medical and medical specialty associations, etc., and that the marketplace will make the appropriate ICD-10 training available to small providers in the most efficient manner possible, recognizing that solo practitioners and their staffs cannot afford extensive amounts of time away from their offices to partake in training.

Finally, as previously discussed in this final rule, we agree with commenters who stated a phased-in approach to ICD-10 implementation to allow more time for small entities to transition to ICD-10 is not feasible because the use of dual coding systems would result in burdensome costs to industry, confusion as to which code set

was being used in claims submission, and which payers are capable of accepting the new codes. The result would be massive claims processing delays and lagging reimbursements to providers.

3. Conclusion

We did not receive any data or information to substantiate arguments that our impact analysis of the potential effects of ICD-10 implementation on small entities was flawed. We, therefore, maintain our small entity ICD-10

impact assumptions based on the Regulatory Flexibility Analysis section of the proposed rule at 73 FR 49827. Based on the foregoing analysis, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

TABLE 4—SUMMARY OF ESTIMATED COSTS IN \$ MILLIONS ANNUALIZED 3%, 7%

		Low		High		Primary	
		3.00%	7.00%	3.00%	7.00%	3.00%	7.00%
Training:	Inpatient Coders	\$8.88	\$11.64	\$35.53	\$46.57	\$17.76	\$23.28
	Outpatient Coders	5.01	6.57	20.05	26.28	10.03	13.14
	Code Users	2.26	2.96	4.61	6.04	3.45	4.52
	Physicians	43.69	57.27	235.07	308.11	87.38	114.53
Productivity Losses:	Inpatient	0.00	0.00	4.61	6.04	0.82	1.07
	Outpatient	0.00	0.00	4.61	6.04	0.79	1.03
	Physician Practices	0.46	0.60	2.26	2.96	1.01	1.33
	Improper and returned claims	22.95	30.08	92.14	120.77	45.53	59.67
Systems Changes:	Providers	4.61	6.04	18.43	24.15	12.62	16.54
	Software Vendors	4.83	6.33	19.31	25.32	9.66	12.66
	Payers	8.28	10.85	33.11	43.40	16.56	21.70
	Government Systems	21.44	28.11	85.77	112.42	42.89	56.21

TABLE 5—SUMMARY OF ESTIMATED BENEFITS IN \$ MILLIONS ANNUALIZED 3%, 7%

	Low estimate		High estimate		Primary estimate	
	3%	7%	3%	7%	3%	7%
More accurate payments for new procedures	\$49.77	\$65.24	\$199.09	\$260.95	\$99.54	\$130.47
Fewer rejected claims	48.88	64.07	195.51	256.26	97.76	128.13
Fewer improper claims	24.44	32.03	97.75	128.12	48.87	64.06
Better understanding of new procedures	41.32	54.15	165.26	216.61	82.63	108.31
Improved disease management	25.73	33.73	102.93	134.91	51.46	67.45

Table 6: Annual estimated costs over 15 years for ICD-10 (in \$ millions) discounted 3%, 7%

Year		2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Present Value (3%)	Present Value (7%)
Training	Inpatient Coders	0	0	31.81	159.04	21.21	0	0	0	0	0	0	0	0	0	0	\$188.71	\$162.42
	Outpatient Coders (ambulatory)	0	0	11.97	95.75	11.97	0	0	0	0	0	0	0	0	0	0	\$106.35	\$91.35
	Code Users	0	0	4.12	32.94	4.12	0	0	0	0	0	0	0	0	0	0	\$36.59	\$31.43
	Physicians	0	0	104.31	834.52	104.31	0	0	0	0	0	0	0	0	0	0	\$926.90	\$796.17
	Subtotal	\$0.00	\$0.00	\$152.21	\$1,122.25	\$141.61	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1,258.55
Productivity Losses	Coders—Inpatient	0	0	0	9.77	0	0	0	0	0	0	0	0	0	0	0	\$8.68	\$7.45
	Coders—Outpatient	0	0	0	9.4	0	0	0	0	0	0	0	0	0	0	0	\$8.35	\$7.17
	Physician Practices	0	0	0	12.08	0	0	0	0	0	0	0	0	0	0	0	\$10.73	\$9.22
	Improper and returned claims	0	0	0	0	329.4	164.7	49.41	0	0	0	0	0	0	0	0	\$462.25	\$375.37
	Subtotal	\$0.00	\$0.00	\$0.00	\$31.25	\$329.40	\$164.70	\$49.41	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$490.02
System changes	Providers	22.6	45.19	75.32	7.53	0	0	0	0	0	0	0	0	0	0	0	\$140.16	\$127.82
	Software Vendors	17.29	34.59	57.65	5.76	0	0	0	0	0	0	0	0	0	0	0	\$107.27	\$97.82
	Payers	29.65	59.29	98.82	9.88	0	0	0	0	0	0	0	0	0	0	0	\$183.89	\$167.70
	Government	76.79	153.59	255.98	25.6	0	0	0	0	0	0	0	0	0	0	0	\$476.33	\$434.40
	Subtotal	\$146.33	\$292.66	\$487.77	\$48.77	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$907.64
Total Cost (in \$millions)	\$146.33	\$292.66	\$639.98	\$1,202.27	\$471.01	\$164.70	\$49.41	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2,656.21	\$2,308.34

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TABLE 7—ANNUAL ESTIMATED BENEFITS OVER 15 YEARS FOR ICD-10 (IN \$ MILLIONS) DISCOUNTED 3%, 7%

Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	Present value (3%)	Present value (7%)
More-accurate payment for new procedures	0	0	0	0	21.88	58.41	72.89	85.12	97.46	109.93	122.55	135.34	148.32	161.51	174.94	\$854.27	\$564.25
Fewer rejected claims	0	0	0	0	30.42	60.89	97.51	121.59	122.08	122.17	122.27	122.37	122.47	122.57	122.66	854.29	577.50
Fewer improper claims	0	0	0	0	15.22	30.44	48.75	60.79	61.03	61.08	61.13	61.18	61.23	61.28	61.33	427.12	288.73
Better understanding of new procedures	0	0	0	0	29.18	77.88	97.19	97.5	97.58	97.66	97.74	97.81	97.89	97.97	98.05	727.42	496.71
Improved disease management	0	0	0	0	9.92	19.86	52.99	66.08	66.34	66.4	66.45	66.5	66.56	66.61	66.66	447.49	300.31
Total Benefits (in millions)	\$0.00	\$0.00	\$0.00	\$0.00	\$106.62	\$247.48	\$369.33	\$431.08	\$444.49	\$457.24	\$470.14	\$483.20	\$496.47	\$509.94	\$523.64	\$3,310.58	\$2,227.51

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2011 TO FY 2025
[in millions]

Category	Primary estimate (millions)	Low estimate (millions)	High estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized monetized benefits:				
7% Discount	\$244.6	\$90.0	\$269.4	RIA
3% Discount	\$277.3	\$102.2	\$305.4	RIA
Qualitative (unquantified) benefits	Improved biosurveillance and global disease management.	RIA
COSTS:				
Annualized monetized costs:				
7% Discount	\$253.4	\$59.7	\$278.8	RIA
3% Discount	\$222.5	\$51.9	\$24.8	RIA
Qualitative (unquantified) costs	None	None	None	
Transfers:				
Annualized monetized transfers: "on budget"	N/A	N/A	N/A	
From whom to whom?	N/A	N/A	N/A	
Annualized monetized transfers: "off-budget"	N/A	N/A	N/A	
From whom to whom?	N/A	N/A	N/A	

List of Subjects in 45 CFR Part 162

Administrative practice and procedures, Electronic transactions, Health facilities, Health Insurance,

Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in this preamble, the Department of Health and Human Services amends 45 CFR part 162 as follows:

PART 162—ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 162 is amended to read as follows:

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 105 of Pub. L. 110–233, 122 Stat. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)).

■ 2. Section 162.1002 is amended by revising paragraph (b) introductory text and adding paragraph (c) to read as follows.

§ 162.1002 Medical data code sets.

* * * * *

(b) For the period on and after October 16, 2003 through September 30, 2013:

* * * * *

(c) For the period on and after October 1, 2013:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

- (i) Diseases.
- (ii) Injuries.
- (iii) Impairments.
- (iv) Other health problems and their manifestations.
- (v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS

Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

- (i) Prevention.
- (ii) Diagnosis.
- (iii) Treatment.
- (iv) Management.

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

Dated: December 11, 2008.

Michael O. Leavitt,
Secretary.

[FR Doc. E9–743 Filed 1–15–09; 8:45 am]

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