**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Parts 160 and 162**

**[CMS–0013–P]**

**RIN 0958–AN25**

# HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would modify two of the medical data code set standards adopted in the Transactions and Code Sets final rule published in the **Federal Register**. It would also implement certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Specifically, the proposed rule would modify the standard code sets for coding diagnoses and inpatient hospital procedures by concurrently adopting 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. These new codes would replace the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) Volumes 1 and 2, and the International Classification of Diseases, Ninth Revision, Clinical Modification (CM) Volume 3 for diagnosis and procedure codes, respectively.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 21, 2008.

**ADDRESSES:** In commenting, please refer to file code CMS–0013–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov,* accessed 8–12–08. Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0013–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0013–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–8016.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

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

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

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

**FOR FURTHER INFORMATION CONTACT:** Donna Pickett (301) 458–4434 for ICD–10–CM, Pat Brooks (410) 786–5318 for ICD–10–PCS, and Denise Buenning (410) 786–6711 for other questions.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov,* accessed 8–12–08. Follow the search instructions on that Web site to view public comments.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. To make an appointment to view the public comments, please call telephone number 1–800–743–3951.

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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 improved 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 consists of sections 1171 through 1179. 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 (the Secretary) to be developed, adopted, or modified by a standard setting organization (SSO), except in the special 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 Data Content Committees (DCCs) in the course of the development, adoption, or modification of the standard: the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (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 permits 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 following the effective date of the adoption of the modification. 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. We are proposing that the compliance date for the provisions of this proposed rule for all covered entities, including small health plans, would be October 1, 2011.

Please refer to the Transactions and Code Sets final rule (65 FR 50312), published in the **Federal Register** on August 17, 2000, and the Privacy Rule (65 FR 82462), published in the **Federal Register** on December 28, 2000, for further information about electronic data interchange and the statutory background.

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

The Transactions and Code Sets final rule appeared in the August 17, 2000 **Federal Register** (65 FR 50312). That 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 Transactions and Code Sets Modifications final rule, published on February 20, 2003 (68 FR 8381), modified the implementation specifications for several adopted transactions standards, among other provisions. (Please refer to the HIPAA Transactions and Code Sets final rule and HIPAA Transactions and Code Sets

Modifications 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 Transactions and Code Sets final rule, we also adopted a number of standard medical data 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 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 the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: prevention, diagnosis, treatment, and management.

ICD–9–CM Volumes 1 and 2, and 3 were already widely used in administrative transactions when we promulgated the Transactions and Code Sets rule. We decided that adopting these existing code sets would be less disruptive for covered entities than modified or new code sets. In the Transactions and Code Sets final rule (65 FR 50327), we discussed comments on using the ICD–10–CM and ICD–10–PCS code sets as future HIPAA standard medical data code sets. Some commenters praised the accuracy of the ICD–10–CM and ICD–10–PCS code sets, others raised concerns about the differences between the ICD–9–CM and ICD–10–CM and ICD–10–PCS code sets, including the increased level of detail in ICD–10–PCS. We responded that additional testing and revision were needed before adopting the ICD–10–CM and ICD–10–PCS code sets as a standard. (Please refer to the Transactions and Code Sets final rule for details of that discussion (65 FR 50327).)

In addition to standard transactions and code sets, the final rule adopted a procedure for maintaining existing standards, for adopting modifications to existing standards, and for adopting new standards. Our process in proposing the adoption of ICD–10–CM and ICD–10–PCS, to replace ICD–9–CM Volumes 1 and 2, and 3, follows that procedure. The following is a summary of the consultation requirements for the Secretary for the adoption of standards under sections 1172(b) through (f) of the Act:

For standards that have been developed, adopted, or modified by a standard setting organization, the SSO must consult with the following organizations in the course of such development, adoption, or modification:

- The National Uniform Billing Committee (NUBC).
- The National Uniform Claim Committee (NUCC).
- The Workgroup for Electronic Data Interchange (WEDI).
- The American Dental Association (ADA).

For any other standards, the Secretary is required to consult with these same organizations.

As part of the HIPAA modification and update process, the NCVHS holds hearings on proposed changes to HIPAA transaction and code set standards and makes recommendations to the Secretary as appropriate.

Under section 1174 of the Act, the Secretary must also ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets, and provide instructions on how data elements encoded before any modification may be converted or translated. As discussed in section VIII.A of this proposed rule, we will establish an ICD–10–CM/PCS Coordination and Maintenance Committee that is similar to the ICD–9–CM Coordination and Maintenance Committee. The ICD–10–CM/PCS Coordination and Maintenance Committee will be charged with routine maintenance, testing, enhancement, and the expansion of the ICD–10 code sets. In addition, the National Center for Health Statistics (NCHS) has recently completed a crosswalk that maps ICD–9–CM Volumes 1 and 2 to ICD–10–CM. CMS also has developed a crosswalk that maps ICD–9–CM Volume 3 to ICD–10–PCS. These crosswalks are available at *http://www.cms.hhs.gov/ICD10* (accessed 8–12–08) and *http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm,* (accessed 8–12–08). These crosswalks are revised in the fall of each year.

## II. ICD–9–CM

The International Classification of Diseases (ICD) is developed and maintained by the World Health Organization (WHO). Originally designed to classify causes of death (mortality), the scope of the ICD has expanded to include non-fatal diseases (morbidity). The application of the classification to morbidity has expanded as the code set has been revised. Nonetheless, the United States and other countries continue to find it necessary to develop clinical modifications of the ICD to meet the needs of their respective health care systems that include administrative and clinical protocols, and require more detail and specificity for reporting health care.

When the Medicare hospital Inpatient Prospective Payment System (IPPS) was implemented in 1983, ICD–9–CM was used as the basic input for assigning the diagnosis-related groups (DRGs). All diagnostic and procedural information was captured using ICD–9–CM.

### *A. ICD–9–CM Volumes 1 and 2 (Diagnoses)*

NCHS houses the WHO Collaborating Center for the Family of International Classifications for North America (United States and Canada), and has responsibility for the implementation of the ICD. NCHS produced a clinical modification to WHO's ICD–9 by adding more specificity to its diagnosis codes (ICD–9–CM Volumes 1 and 2). ICD–9–CM maps to ICD to facilitate comparison of mortality and morbidity statistics. ICD–9–CM was adopted in the United States in 1979 for morbidity applications, and was adopted as a HIPAA standard 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. 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.

### *B. ICD–9–CM Volume 3 (Procedures)*

Inpatient hospital services procedures are currently coded using ICD–9–CM Volume 3. The WHO's ICD does not include procedure codes. ICD–9–CM procedure codes are three to four digits long. The code set was adopted as a HIPAA standard in 2000 for reporting inpatient hospital procedures. Current Procedural Terminology, 4th Edition (CPT–4) and Health Care Common Procedure Coding System (HCPCS) are used to code all other procedures. The ICD–9–CM procedure code set is organized into chapters by body system, and CMS maintains the ICD–9–CM procedure codes.

### *C. Maintaining/Updating ICD–9–CM (Volumes 1 and 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 a forum for receiving public comments on proposed code revisions, deletions, and additions. The Committee is co-chaired by the NCHS and CMS; NCHS maintains ICD–9–CM Diagnosis Codes (Volumes 1 and 2), and CMS maintains ICD–9–CM Procedure Codes (Volume 3).

Although the ICD–9–CM Coordination and Maintenance Committee is a Federal committee, suggestions for updates come from both the public and private sectors. Interested parties may submit recommendations for updates (that is, adding new codes, deleting codes, and editing descriptive material related to existing codes) at least 2 months before a scheduled meeting. Proposals for a new code must include a description of the code being requested and rationale for why the new code is needed. Supporting references and literature may also be submitted.

This Federal committee meets in March and September. Decisions on code title revisions are made by March for inclusion in the annual IPPS proposed rule. Updates on codes, payments, and reporting systems are finalized after the previous fall meeting and may become effective October 1 of the same year.

Section 503(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) included a requirement for updating ICD–9–CM codes twice a year, instead of a single update on October 1 of each year. Section 503(a) of the MMA, which amended section 1886(d)(5)(K) of the Act, states that the ''Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the fiscal year that begins after such date.'' By adding codes for a new technology at an earlier date, CMS can recognize the new technology more quickly for purposes of payment under the IPPS.

While section 503(a) of the MMA does not require the Secretary to adjust the DRG classification and payments until the subsequent fiscal year, the DRG software and other systems must be updated to recognize and accept the new codes, and providers must update their systems mid-year to capture the new codes. Hospitals must obtain coding book updates and coding software updates and make other system changes to capture and report the new codes.

Proposals for new and revised codes, summaries of meetings, information about deadlines for comment, scheduled dates for the next meeting, deadlines for receipt of maintenance proposals, and mailing and e-mail addresses are posted to the CMS Web site at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes,* accessed 8–12–08, and the NCHS Web site *http://www.cdc.gov/nchs/icd9.htm,* accessed 8–12–08. Additionally, CMS and NCHS publish a complete addendum describing details of all changes to ICD–9–CM. It is publicized on their Web sites in May of each year. Many commenters on the proposed Transactions and Code Sets proposed rule commended this open process (65 FR 50343–50344).

## III. Limitations of ICD–9–CM

### *A. Background*

In 1997, the NCVHS began to study the issues related to known shortcomings of ICD–9–CM and to assess the need to transition to ICD–10 (or an alternative code set), including the impact of such a transition. The NCVHS has conducted more than 8 days of hearings since 1997. Oral and written testimony was provided by more than 80 public and private sector groups representing the health care industry, Federal and State governments, the public health and research communities, health plans, and health care providers. In addition, the NCVHS commissioned a RAND Corporation study on the potential costs and benefits of transitioning to ICD–10–CM and ICD–10–PCS. From the testimony received and the RAND study findings, NCVHS concluded that ICD–10–CM and ICD–10–PCS should be adopted as a HIPAA standard to replace the current standard, ICD–9–CM Volumes 1 and 2, and 3. In a letter to the Secretary dated November 5, 2003, NCVHS recommended that HHS initiate the regulatory process for the concurrent adoption of ICD–10–CM and ICD–10–PCS. The NCVHS letter (*http://www.ncvhs.hhs.gov/031105lt.htm*) accessed 8–12–08, an overview of the development of ICD–10–CM and ICD–10–PCS (*http://www.ncvhs.hhs.gov/031105a1.htm*) accessed 8–12–08, summaries of the NCVHS activities (*http://www.ncvhs.hhs.gov/031105a2.htm*) accessed 8–12–08, a list of organizations that have provided testimonies (*http://www.ncvhs.hhs.gov/031105a3.htm*) accessed 8–12–08, and the RAND Corporation study (*http://www.rand.org/pubs/technical_reports/2004/RAND_TR132.pdf*) are available on the NCVHS Web site (*http://www.ncvhs.hhs.gov*) accessed 8–12–08.

### *B. General*

The ICD–9–CM code set has been in use for over 27 years, and additional codes have been added during that period to describe new procedures and diagnoses that reflect changes in medical practice. The total number of codes (approximately 13,000 for diagnoses and 3,000 for procedures) is insufficient to continue to respond to the need for new codes. Moreover, the 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. These limitations are discussed in detail below and have led to the current industry debate regarding replacement of ICD–9–CM. Industry experts have discussed and commented on these issues during testimony to the NCVHS, expressing their belief that the ICD–9–CM code set is nearing the end of its useful life. We invite public comment on concerns with continued use of the ICD–9–CM code set.

#### 1. Space Limitations

The ICD–9–CM code set that we adopted in 2000 as a HIPAA standard had been evolving since 1979. Because of the new and changing medical advancements during the past 20 plus years, the functionality of the ICD–9–CM code set has been exhausted. This code set is no longer able to respond to additional classification specificity, newly identified disease entities, and other advances. Many chapters of ICD–9–CM are full, and the American Hospital Association (AHA) has estimated that we will run out of procedure codes in the appropriate, logical sections of ICD–9–CM as well as the overflow chapters in 2009. As a temporary solution, CMS has already begun to assign codes to the inappropriate sections of ICD–9–CM (for example, codes for heart procedures being placed in the eye chapter). We will continue to take this unusual step of making illogical code assignments in order to maintain the ability to capture emerging technologies. This illogical assignment of codes will lead to challenges for coders in identifying and assigning codes, but establishing new codes to identify new procedures remains important. The diagnosis-related group (DRG) system classifies hospital cases into groups that are expected to have similar hospital resource needs. DRGs are assigned

based on diagnoses, procedures, age, sex, and the presence of complications or co-morbidities.

The technologies included in the DRGs are identified by ICD–9–CM procedure codes. ICD–10–PCS allows the use of DRG definitions that better define new technologies and devices, and that could be refined to take advantage of their additional specificity through more detailed descriptions. This critical lack of space for new procedures and conditions is one important consideration for proposing to adopt ICD–10–CM and ICD–10–PCS. In addition, ICD–9–CM's space limitations are creating other problems, which are discussed below.

2. Impact of Workarounds on Structural Hierarchy

The hierarchical structure of the ICD–9–CM procedure code set is compromised. Some chapters can no longer accommodate new codes, with the result that any additional codes must be assigned to other topically unrelated chapters. For example, new hip replacement procedures must now be assigned to an ''overflow'' chapter for procedures that are not classified elsewhere. When those chapters become full, new procedures would have to be assigned to a chapter now devoted to procedures related to the eye. When a code is isolated in a separate, unrelated part of the ICD–9–CM book because there is no available space in the section where the code normally would be assigned, coders may not easily find the code. Researchers and statisticians also may miss cases in their analyses.

3. Lack of Detail

Industry experts have pointed out that in an age of electronic health records, it does not make sense to use a coding system that lacks specificity and does not lend itself well to updates. Another consideration about the limitations of ICD–9–CM is that to generate meaningful research results, researchers need to have access to comprehensive, rich data with a level of detail that does not exist with ICD–9–CM. Emerging health care technologies, new and advanced terminologies, and the need for interoperability amid the increase in electronic health records (EHRs) and personal health records (PHRs) require a standard code set that is expandable and sufficiently detailed to accurately capture current and future health care information. Coding that accurately describes diagnoses and procedures will capture information that is critical for research, and ultimately improves the quality of health care and cost containment by enabling the study of specific conditions and options for treating them. Accuracy also is a critical factor in the development of Pay for Performance (P4P) programs, because successful programs require detailed coding of diagnoses and the procedures performed to treat specific conditions.

The details for advanced technology procedures currently being performed today were not available when ICD–9–CM was being developed. Numerous ICD–9–CM procedure codes are based upon technology that is now outdated. As we move toward more sophisticated monitoring and quality reporting, this level of detail when reporting diagnoses and procedures becomes critical. Examples are noted below:

- ICD–9–CM has a single diagnosis code for fracture of the wrist. If a patient is treated for two successive wrist fractures, the ICD–9–CM code does not provide enough detail to determine if the second fracture is a repeat fracture of the same wrist, a fracture of the other wrist, incorrect billing for delayed healing, or non-union or mal-union of the original fracture.
- ICD–9–CM contains a single procedure code that describes the endovascular repair or occlusion of head and neck vessels (39.72). It does not describe the artery or vein on which the repair is performed, the precise nature of the repair, or whether the approach is a percutaneous procedure or is transluminal with a catheter.
- Four or more ICD–9–CM procedure codes are needed to delineate a spinal fusion procedure with sufficient detail to describe the level of the spine and the devices inserted.

4. Mortality Reporting and Biosurveillance

The ICD–9 diagnosis code set is no longer supported or maintained by the WHO. As of October 2002, 138 countries have adopted ICD–10 for coding and reporting mortality data, and 99 countries have adopted ICD–10 or a clinical modification for coding and reporting morbidity data. In 1999, the United States adopted ICD–10, but only for mortality reporting. Until the United States implements ICD–10 for morbidity reporting applications, data incomparability will continue to increase throughout the world.

As we become a global community, it is vital that our health care data represent current medical conditions and technologies, and that they are compatible with the international version of ICD–10. Because the United States is capturing morbidity data using the outdated ICD–9–CM, there are problems identifying new health threats such as anthrax, Severe Acute Respiratory Syndrome (SARS), and Monkeypox.

The lack of specificity in ICD–9–CM also limits our ability to develop rapid interventions for emerging diseases affecting international populations. Diagnosis and procedure information are captured from administrative data that are submitted on health care claims, and admission and discharge summaries, but if the codes do not match the international standard and are unable to be compared, their significance is lost. Additionally, hospitals utilize diagnosis and procedure codes for utilization review, disease management, and research. Therefore, in addition to the need for precise diagnosis and procedure codes for payment purposes, detail and precision in coding are critical to the national and international health care community for mortality reporting, biosurveillance, treatment of patients, hospital management, and research.

## IV. ICD–10 and the Development of ICD–10–CM and PCS

*A. Overview*

The WHO developed ICD–10 in 1989, and it was adopted by the World Health Assembly in 1990. Currently, the United States is the only G7 nation (the other G7 nations are Canada, France, Germany, Great Britain, Italy and Japan) continuing to use ICD–9 for morbidity reporting. Furthermore, Great Britain, Denmark, Finland, Iceland, Norway, Sweden, France, Australia, Belgium, Germany, and Canada use a clinical modification of ICD–10 for reimbursement and/or administrative purposes.

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.

For quality improvement programs to effectively result in meaningful clinical outcomes, improved practice management processes that document and measure patient care, and sustain provider investment in services that improve quality of care, the ability to modify or add to a list of treatments, diseases and conditions is essential. The ICD–10 code sets provide a standard coding convention that is flexible, providing unique codes for all substantially different procedures or health conditions and allowing new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols.

*B. ICD–10–CM Diagnosis Codes*

The NCHS has developed a clinical modification of the WHO's ICD–10 called ICD–10–CM for reporting diagnosis codes. As in the relationship between ICD–9 and ICD–9–CM Volumes 1 and 2, ICD–10–CM codes can be mapped back to the ICD–10 codes. The NCHS has worked closely with specialty societies to ensure clinical utility and input into the process of creating the clinical modification, 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. The NCHS also had discussions with other users of the classification, 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 classification.

ICD–10–CM diagnosis codes are three to seven alphanumeric characters; the number of ICD–10–CM codes is approximately 68,000. 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 the following improvements over ICD–9–CM:

- Significant improvements in coding primary care encounters, external causes of injury, mental disorders, neoplasms, and preventive health.
- Advances in medicine and medical technology that have occurred since the last revision.
- Codes with more detail on socioeconomic, family relationships, ambulatory care conditions, problems related to lifestyle, and the results of screening tests.
- More space to accommodate future expansions (alphanumeric structure).
- New categories for post-procedural disorders.
- The addition of laterality—specifying which organ or part of the body is involved when the location could be on the right, the left, or could be bilateral.
- Expanded distinctions for ambulatory and managed care encounters.

ICD–10–CM codes with the same first three digits have common traits, and each additional digit adds more specificity. For example:

I49. Other cardiac arrhythmias
I49.0 Ventricular fibrillation and flutter
I49.01 Ventricular fibrillation
I49.02 Ventricular flutter

Post-procedural disorders specific to a particular body system are located in categories created at the end of each chapter. Diseases are arranged according to an axis of classification based on etiology, anatomy, or severity, with anatomy being the primary axis for ICD–10–CM. (See section V of this proposed rule for a chart that compares ICD–9–CM, ICD–10–CM, and ICD–10–PCS codes).

*C. ICD–10–PCS Procedure Codes*

CMS developed a procedure coding system, ICD–10–PCS. ICD–10–PCS has no 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. The first character shows the type of procedure by clinical specialty. Nearly half of these 16 sections remain undesignated at this time, leaving room for future expansion. Each subsequent place in the code has a specific function, the meaning of which may change depending on the section. For example, the fifth character in the imaging section identifies the contrast material used, while the fifth character in the medical and surgical section identifies the surgical approach. The second character defines the body system with the exception of the rehabilitation and mental health sections, in which the second character defines the type of procedure performed.

Example: the Medical and Surgical Section is organized as follows:

CHARACTERS

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Name of Section | Body System | Root Operation | Body Part | Approach | Device | Qualifier |

*D. Statutory Requirements for Adoption of ICD–10–CM and ICD–10–PCS*

Under sections 1172(b), (c), (f), and (g) of the Act, the Secretary must follow certain procedures and pursue certain objectives when adopting a modification to an initial standard. Under section 1172(b) of the Act, any standard adopted by the Secretary must be consistent with the objective of reducing the administrative costs of providing and paying for health care. As discussed in detail in section XI of this proposed rule, we believe that the costs for implementing ICD–10–CM and ICD–10–PCS would be offset by the benefits within four years of implementation.

Under section 1172(c)(1) of the Act, any standard adopted by the Secretary must be a standard that has been developed, adopted or modified by a standard setting organization (SSO). Under section 1172(c)(2)(B) of the Act, however, section 1172(c)(1) does not apply if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under HIPAA. 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. Therefore, we are proposing to adopt ICD–10–CM and ICD–10–PCS under section 1172(c)(2)(B) of the Act.

We note that the SNOMED Clinical Terms (CT)® code set may initially appear to be a standard developed by an SSO for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. The College of American Pathologists (CAP), which developed SNOMED CT®, is accredited by the American National Standards Institute (ANSI) as an

accredited standards developer. The scope of the CAP's accreditation, however, is limited. The CAP is accredited for activity relating to clinical terminology that focuses on standardizing that terminology across the breadth of medicine. Consistent with this scope of focus, SNOMED CT®, which is now supported by the International Health Terminology Standards Development Organization (*http://www.ihtsdo.org*), is clinical terminology that is primarily designed for primary documentation of clinical care. SNOMED CT® is not designed for carrying out health care transactions. In fact, part of the CAP's scope of ANSI accreditation is deriving mapping strategies from clinical reference terminology and medical classification schemes and codes sets used for statistical, billing, or user interface purposes. Thus, in order to be useful for health care transactions, the SNOMED CT® code set would first have to be mapped to a classification coding system, such as ICD–10–CM. (For further discussion of SNOMED CT® and its potential value to the development of electronic health records (EHRs), please refer to section VI of this proposed rule.) For these reasons, we do not believe that SNOMED CT® qualifies under section 1172(c)(1) of the Act as a standard developed by an SSO for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions.

Under section 1172(c)(3) of the Act, the Secretary must consult with the following organizations before adopting a standard that was not developed, adopted, or modified by an SSO:

- The National Uniform Billing Committee (NUBC).
- The National Uniform Claim Committee (NUCC).
- The Workgroup for Electronic Data Interchange (WEDI).
- The American Dental Association (ADA).

These organizations are members of the Designated Standard Maintenance Organization (DSMO) Steering Committee. The DSMO Steering Committee considered a January 8, 2003 DSMO Change Request submitted by the Centers for Disease Control seeking modification to the transaction code set to accommodate ICD–10–CM and ICD–10–PCS. The DSMO Steering Committee approved the change request and recommended the adoption of implementation specifications that would support the implementation of ICD–10–CM and ICD–10–PCS to the NCVHS.

Furthermore, CMS also consulted with WEDI regarding ICD–10–CM and ICD–10–PCS after two industry-focused informational forums they conducted on ICD–10–CM and ICD–10–PCS during 2006. In a letter to the Secretary dated May 31, 2006, WEDI outlined discussions that occurred during an ICD–10–CM and ICD–10–PCS forum on April 19th and 20th 2006 in Chicago that was co-chaired by representatives of the American Hospital Association, and Blue Cross and Blue Shield of South Carolina. The purpose of the forum was to solicit audience discussion and input on various implementation issues surrounding the possible adoption of the ICD–10–CM and ICD–10–PCS code sets. The forum was not intended to debate the issue of whether these code sets should be adopted, but rather what would need to occur if they were adopted. CMS will further consult directly with NUBC, NUCC, and the ADA before adopting any ICD–10 code set as a modification.

Under section 1172(f) of the Act, the Secretary must rely on the recommendations of the NCVHS established under section 306(k) of the Public Health Service Act and must consult with appropriate Federal and State agencies and private organizations.

The Secretary must publish notification in the **Federal Register** of any recommendation of the NCVHS. The NCVHS has conducted 8 days of hearings with providers, health plans, clearinghouses, vendors, and interested stakeholders on the adoption of ICD–10–CM and ICD–10–PCS in place of ICD–9–CM as the HIPAA adopted standard for reporting diagnoses and hospital inpatient services in standard transactions. (A list of organizations that provided comments to the NCVHS is available at *http://www.ncvhs.hhs.gov/031105a3.htm*, accessed 8–12–08.) In a letter dated November 5, 2003, the NCVHS submitted to the Secretary its recommendation to adopt ICD–10–CM and ICD–10–PCS. This letter is available at *http://www.ncvhs.hhs.gov/031105lt.htm*, accessed 8–12–08. The Secretary also has considered input from Federal and State agencies and private organizations regarding the adoption and implementation of ICD–10–CM and ICD–10–PCS, and has received input from a number of professional organizations and other industry stakeholders. The following organizations representing providers, health plans, clearinghouses, and vendors are among the stakeholders that have provided input:

- The American Health Information Management Association (AHIMA).
- The American Medical Association (AMA).
- The Blue Cross Blue Shield Association (BCBSA).
- The Medical Group Management Association (MGMA).
- Health Information and Management Systems Society (HIMSS).
- America's Health Insurance Plans (AHIP).

## V. Comparison of ICD–9–CM Versus ICD–10–CM and ICD–10–PCS

COMPARISON

| ICD–9–CM diagnosis codes | ICD–10–CM diagnosis codes |
|---|---|
| 3–5 characters in length | 3–7 characters in length. |
| Approximately 13,000 codes. | Approximately 68,000 available codes. |
| First digit may be alpha (E or V) or numeric; Digits 2–5 are numeric | Digit 1 is alpha; Digits 2 and 3 are numeric; Digits 4–7 are alpha or numeric. |
| Limited space for adding new codes | Flexible for adding new codes. |
| Lacks detail | Very specific. |
| Lacks laterality | Has laterality. |
| Difficult to analyze data due to non-specific codes | Specificity improves coding accuracy and richness of data for analysis. |
| Codes are non-specific and do not adequately define diagnoses needed for medical research. | Detail improves the accuracy of data used for medical research. |
| Does not support interoperability because it is not used by other countries. | Supports interoperability and the exchange of health data between other countries and the U.S. |

COMPARISON—Continued

| ICD–9–CM procedure codes | ICD–10–PCS procedure codes |
|---|---|
| 3–4 numbers in length | 7 alpha-numeric characters in length. |
| Approximately 3,000 codes | Approximately 87,000 available codes. |
| Based upon outdated technology | Reflects current usage of medical terminology and devices. |
| Limited space for adding new codes | Flexible for adding new codes. |
| Lacks detail | Very specific. |
| Lacks laterality | Has laterality. |
| Generic terms for body parts | Detailed descriptions for body parts. |
| Lacks description of methodology and approach for procedures | Provides detailed descriptions of methodology and approach for procedures. |
| Limits DRG assignment | Allows DRG definitions to better recognize new technologies and devices. |
| Lacks precision to adequately define procedures | Precisely defines procedures with detail regarding body part, approach, any device used, and qualifying information. |

Both ICD–10–CM and ICD–10–PCS provide laterality, precise anatomical descriptions, methods to report the exact causes of injury in diagnosing conditions, and approaches used to perform specific procedures. Laterality refers to the precision with which ICD–10–CM and ICD–10–PCS describe conditions and treatments for the anatomical right and left side. Information comparing ICD–10–CM and ICD–9–CM Volumes 1 and 2 is available at: *http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm* (accessed 8–12–08). Information comparing ICD–10–PCS and ICD–9–CM Volume 3 is available at: *http://www.cms.hhs.gov/icd9providerdiagnosticcodes/08_icd10.ASP* (accessed 8–12–08).

**VI. Discussion of SNOMED CT®**

SNOMED Clinical Terms® (CT) is a comprehensive clinical terminology that provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms that are unique to particular organizations or localities. It contains over 366,170 concepts with unique meanings and formal logic-based definitions that are organized into hierarchies. Some examples of these hierarchies are:

- Staging and scales—contains concepts naming assessment scales and tumor staging systems.
- Social context—contains social conditions and circumstances significant to health care.
- Observable entity—concepts represent a question or procedure which, when combined with a result, constitute a finding.

In order to express these clinical concepts, SNOMED CT® contains more than 993,420 English language descriptions, and approximately 1.46 million semantic relationships. It would be impractical to attempt to manually assign SNOMED–CT® codes. The number of terms and level of detail in a reference of clinical terminology such as SNOMED CT® cannot be effectively managed without automation, and are not suited for the secondary purposes for which classifications systems such as ICD–10–CM and ICD–10–PCS are used because of their immense size, considerable granularity, complex hierarchies, and lack of reporting rules.[1]

SNOMED CT® is a clinical terminology that is described as an input system that is primarily designed for the primary documentation of clinical care. A clinical terminology intended to support clinical care processes should not be manipulated to meet reimbursement and other external reporting requirements. Such manipulation presents the potential to adversely affect patient care, the development and use of decision support tools, and the practice of evidence-based medicine.

ICD–9–CM, ICD–10–CM, and ICD–10–PCS are classification coding conventions that are typically used for reporting requirements where data aggregation is advantageous. A classification system such as ICD arranges like entities for retrieval. It aggregates granular clinical concepts into categories for secondary data purposes. Examples of current use of this data include:

- Designing health care delivery systems.
- Setting health policy.
- Tracking public health and risks.
- Monitoring resource utilization.
- Processing claims for reimbursement.

The benefits of using SNOMED CT® increase if it is linked to a classification system such as ICD–10–CM and ICD–10–PCS for the purpose of generating health information that is necessary for statistical analysis and reimbursement. The use of both SNOMED–CT® and ICD–10–CM and ICD–10–PCS brings value to the development of interoperable electronic health records (EHR). The linkage of these two different coding systems for multiple purposes is accomplished through mapping.

''Mapping is the process of linking content from one terminology to another or to a classification.'' (*http://library.ahima.org*), accessed 8–12–08. It requires deciding how different terminologies match, are similar, or differ. Mapping provides a link between terminologies to facilitate—

- Use of data collected;
- Retaining the value of data when migrating to newer databases; and
- Avoiding entering data multiple times, and the risk of increased costs and errors.

Using SNOMED CT® mapped to ICD–10–CM and ICD–10–PCS permits the use of a clinical terminology that could be the basis for EHRs and the ICD–10–CM and ICD–10–PCS classification coding system that is used for reporting and data trend analysis.

As discussed in section IV of this proposed rule, we did not consider adopting SNOMED CT® as an alternative for ICD–10–CM and ICD–10–PCS because the code sets are designed for distinctly different purposes. We do not believe that SNOMED CT® qualifies under section 1172(c)(1) of the Act as a standard for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions. For similar reasons, we do not believe that we are required under the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, to consider adopting SNOMED CT®. The NTTAA and Office of Management and

[1] ''Coordination of SNOMED–CT® and ICD–10: Getting the Most out of Electronic Health Record Systems'' Sue Bowman, RHIA, CCS, director of coding policy and compliance, AHIMA; Perspectives in Health Information Management Spring 2005 (May 26, 2005) *http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_027179.html*, accessed 8–12–08.

Budget (OMB) Circular No. A–119, which provides some historical background and interpretation of parts of the NTTAA, directs Federal agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. Because we do not believe that SNOMED CT® is a suitable standard for reporting medical diagnoses and hospital inpatient procedures for purposes of administrative transactions, we believe that neither the NTTAA nor OMB Circular A–119 requires that we consider it for adoption.

**VII. Alternatives To Adopting ICD–10 Code Sets**

In deciding to propose adoption of ICD–10–CM and ICD–10–PCS, we considered a number of alternatives. We invite public comment on the following discussion of those alternatives and our rationale:

*A. Utilize Unassigned Codes*

It would be possible to extend the life of ICD–9–CM by assigning codes to new diagnoses and procedures without regard to the hierarchy of the code set. This hierarchy groups procedures by body systems, and then groups similar procedures that apply to a specific body system into categories. For example, ICD–9–CM Volume 3 was examined to identify any open series of codes that could be used for new procedures and technologies. Codes 17.00–17.99 (located between Chapter 3: Operations on the Eye, and Chapter 4: Operations on the Ear) were not being used. This series of 100 codes could be used for a wide range of new procedures and technologies, adding additional space for expansion within the existing structure of the ICD–9–CM procedure volume. Additionally, codes 00.00—00.99 were not in use. The ICD–9–CM Coordination and Maintenance Committee decided to create a chapter in this unused location. This decision enabled the creation of 100 new codes to identify procedures that could not be assigned a code within the existing, and more appropriate, chapters because of space limitations. CMS departed from the current organizational structure of ICD–9–CM procedures when we created a variety of procedure codes in a new chapter 00, Procedures and Interventions NEC (NEC means *Not Elsewhere Classified*). CMS has created new codes in all 10 categories within chapter 00. Details on CMS coding changes are available on the CMS Web site at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes*, accessed 8–12–08.

While this approach of placing codes in a non-hierarchically-created structure does extend the ability to assign ICD–9–CM codes to new diagnoses and procedures, it does not represent a long-term solution to the code shortage. It will only be an effective solution as long as there are empty code slots. Moreover, it does not address the remaining shortcomings of ICD–9–CM discussed above, such as the critical lack of detail that is required to support evolving business needs, for example, in the areas of biosurveillance and quality monitoring. While there have been space issues in ICD–9–CM Volumes 1 and 2, they have not been as pressing as the space needs in ICD–9–CM Volume 3. New categories/codes have been added within the chapters (body systems) of the classification, but not necessarily within the appropriate section within the chapter. New concepts have been incorporated into the existing structure, and in some instances this has meant not fully representing the concept as proposed because of space limitations. Some issues have been deferred and incorporated into ICD–10–CM because the concepts were inconsistent with the existing structure of ICD–9–CM. Unlike the procedures in ICD–9–CM Volume 3, which is a United States-developed system, the ICD–9–CM diagnosis codes are based on the WHO codes and must be consistent with the established structure.

The disadvantage of this solution is that it destroys the natural hierarchy inherent in the code set. This hierarchy assists a coder or health care professional in choosing the most appropriate code since one can quickly review closely-related codes. Common coding practices do not require searches for unrelated procedures in a separate part of the coding book. However, these new chapters capture a very diverse group of unrelated procedures that affect a variety of body systems and are not logically placed in the chapters to which they relate. This creates considerable confusion for coders and difficulty locating the new codes, raising the likelihood of coding errors and negatively affecting productivity.

*B. Use CPT–4 for Coding Hospital Inpatient Procedures*

The American Medical Association (AMA) developed and maintains the Physicians' Current Procedural Terminology (CPT) coding system to capture physician services. CPT also has been used to capture services performed in outpatient and ambulatory care settings, and is the HIPAA-adopted standard code set for reporting physician and certain other health care services. While evaluating the need to replace ICD–9–CM, the AMA recommended that CPT be used for coding inpatient services. A letter from the AMA's medical organizations supporting the use of CPT for inpatient coding was sent to the Secretary on September 23, 2002. A copy of this letter is included in the Summary Report of the ICD–9–CM Volume 3 Coordination and Maintenance Committee, December 6, 2002 meeting at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes* (accessed 8–12–08). The AMA was concerned about industry suggestions that a uniform procedure coding system be identified for use in all health care settings. If this were to be the case, the AMA wanted CPT to be considered as that uniform procedure coding system.

The NCVHS had previously evaluated ICD–9–CM Volume 3 and CPT as potential coding systems that could be used to capture services in all health care settings. After extensive hearings and discussions, the NCVHS issued a ''Report of the National Committee on Vital and Health Statistics Concerning Issues Relating to the Coding and Classification Systems'' in November 1990. It found structural problems and serious flaws with both CPT–4 and ICD–9–CM Volume 3. During 1993, an NCVHS subcommittee held three meetings and three working sessions which addressed the creation of a single procedure classification system for multiple purposes in the United States. It was felt that neither system could capture services in all health care settings. Despite continuing NCVHS hearings, there has been no endorsement of the use of CPT for hospital inpatient procedure coding.

The Government Accountability Office (GAO) undertook a study on the use of multiple procedure coding systems, issuing a final report in August 2002 entitled, ''HIPAA Standards, Dual Code Sets Are Acceptable for Reporting Medical Procedures'' (GAO–02–796). The report concluded that ICD–9–CM Volume 3 and CPT do not meet all of the criteria for standard code sets under HIPAA and the procedural code set requirements recommended by NCVHS, including the criteria for adequate levels of detail for data analysis, and a capacity to add new codes in response to new technology. GAO sought advice from industry experts such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) as to whether CPT could be used for inpatient coding. AHA and AHIMA reported that CPT ''does not adequately capture

facility-based, non-physician services.'' The GAO report states that CPT has not been shown to be acceptable or comprehensive enough to serve as a single procedure code set for reporting both hospital inpatient and outpatient physician services. Therefore, GAO did not recommend the use of CPT–4 to capture inpatient services. Additional criticisms of CPT are that it does not include laterality, it has no predictable syntax, and the detail provided is inconsistent across procedures.

The AHA, Federation of American Hospitals, and AdvaMED wrote a letter to the NCHVS on November 19, 2002 regarding the implementation of ICD–10–CM and ICD–10–PCS. The letter endorsed the implementation of ICD–10–CM and ICD–10–PCS as a national standard, and opposed the use of CPT for hospital inpatient services because it was designed for services more commonly provided in physicians' offices, not services provided in a hospital inpatient setting.

*C. Wait and Adopt ICD–11*

One possible option is to forego adoption of ICD–10 and wait until ICD–11 is ready for implementation. The WHO, the developer of the ICD classification, has begun preliminary work on ICD–11. However, no firm timeframes for the completion of developmental work or testing have been identified, and no firm implementation date has been designated. Work has not yet begun on developing the companion procedure codes needed to implement ICD–11 in the United States. This means that the earliest projected date for implementation would be 2020, assuming that no clinical modification is needed for the ICD–11 and that the companion procedure code set could be completed in time. We project that we could not implement ICD–11 until 2016 because it is still in development, testing would be required, and there are no firm timeframes for completion of developmental work.

In addition, ICD–11 will follow the same alphanumeric structure as ICD–10, which differs from that of ICD–9. Since ICD–11 would build upon ICD–10, many of the costs and much of the work associated with upgrading to ICD–11 will be mitigated by ICD–10 implementation. This option of waiting for ICD–11 was eliminated because there are no confirmed dates for ICD–11 readiness or adoption, ICD–11 will not include a procedure classification system and without ICD–10 to build upon, use of ICD–11 is likely to take longer to implement. ICD–9–CM would still have to be used in the interim, and ICD–9–CM is not the pathway to ICD–11 because it has a different structure than both ICD–10 and the anticipated ICD–11.

## VIII. Provisions of the Proposed Regulation

*A. Use of ICD–10–CM and ICD–10–PCS by Covered Entities*

In this proposed rule, we propose to adopt the ICD–10–CM and ICD–10–PCS code sets to replace the ICD–9–CM Volumes 1 and 2 code sets for reporting diagnoses and Volume 3 code set for reporting procedures when conducting standard transactions. We would revise § 162.1002(b) and § 162.1002(c), and adopt ICD–10–CM and ICD–10–PCS in place of ICD–9–CM, Volumes 1 and 2, and 3. We would adopt ICD–10–CM 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, impairment, or other health problems. Additionally, we would adopt ICD–10–PCS 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.

HIPAA covered entities would be required to use these codes when diagnoses and hospital inpatient procedures need to be coded in HIPAA transactions. Because ICD–10–PCS codes are only used for inpatient hospital procedures, the ICD–10–PCS codes would not be used in outpatient transactions.

In arriving at this proposal, we considered myriad input from the public, NCVHS, professional organizations, and others. Our deliberations centered around two sets of issues: the limitations of ICD–9–CM (Volumes 1 and 2, and 3), as discussed above, and the adoption of alternatives to ICD–10–CM and ICD–10–PCS code sets.

We will establish an ICD–10–CM/PCS Coordination and Maintenance Committee. This committee will follow the same procedures currently used by the ICD–9–CM Coordination and Maintenance Committee to consider new codes and revisions to existing codes.

We acknowledge that this proposed rule does not specifically address impacts on prospective payment systems that currently use ICD–9–CM codes. We determined that these issues can best be addressed through the usual IPPS and other proposed rules that impact payment decisions and applications.

*B. Effective Dates*

The effective date of revised § 162.1002 would be 60 days after a final rule is published in the **Federal Register**.

*C. Proposed Compliance Dates*

Under section 1175 of the Act, the compliance date of a modification to a HIPAA standard may not be earlier than the 180th day following the effective date of the adoption of the modification. The Secretary may consider the nature and extent of the modification when determining the compliance date. If the Secretary determines an extension is appropriate for small health plans, he may extend the time for their compliance. NCVHS testimony and subsequent industry input clearly indicate that the implementation of ICD–10 will be a significant undertaking. The activities involved in this implementation are discussed in detail in the impact analysis section of this proposed rule.

Many covered entities have stated that they will need at least 2 years from the publication of a final rule to implement ICD–10. Some have argued that 3 years will be needed, noting that the original 2-year implementation period for the initial HIPAA transaction standards proved to be insufficient. Others note that ICD–10 implementation should be viewed in the context of other HIPAA requirements (including the implementation of the National Provider Identifier and the claims attachment transaction standard) and other information technology initiatives, including IT initiatives integral to the Department's transparency activities, and that ICD–10 compliance should not be required until 2012 or later. Coordination with these other health information technology (HIT) initiatives is discussed in the impact analysis of this proposed rule.

HHS and industry health information technology initiatives include interoperability specifications, certification criteria, and standards developed under HIPAA and the Medicare Modernization Act. We describe these initiatives and associated known or projected publication, delivery, or compliance dates below:

- Beginning in September 2006 (and annually thereafter)—Delivery of Healthcare Information Technology Standards Panel (HITSP) interoperability specifications supporting specific use cases.

• May 2007—Compliance date for all covered entities other than small health plans, implementing the HIPAA National Provider Identifier (NPI) in all HIPAA transactions.

• June 2007—Publication of the Certification Commission for Healthcare Information Technology (CCHIT) criteria for certifying inpatient electronic health record products.

• November 2007—Publication of Electronic Prescribing Standards for Medicare Part D Notice of Proposed Rulemaking.

• April 2008—Publication of Final rule regarding standards for Electronic Prescribing under Medicare Part D and adoption of NPI in Electronic Prescribing transactions.

• May 2008—Publication of CCHIT criteria for certifying health information technology networks and systems.

• May 2008—Compliance date for small health plans implementing the HIPAA National Provider Identifier (NPI) in all HIPAA transactions.

• April 2009—Projected compliance date for new e-prescribing standards for the Medicare drug program, and use of NPI in e-prescribing transactions, pursuant to the Medicare Modernization Act. Medicare Part D Sponsors are required to support the standards. Prescribing providers and pharmacies are required to use them only if they choose to engage in e-prescribing.

• 2010—Projected compliance date for the updated retail pharmacy drug claim, which will facilitate processing of Medicare drug claims and affects all pharmacies and plans that process pharmacy claims.

• 2010—Projected compliance date for updated non-pharmacy HIPAA financial and administrative transactions which affects all HIPAA-covered entities. These transactions include the claim, remittance advice, eligibility, and claim status query and response transaction, plan enrollment, and referral authorization. Version 4010/4010A1 of the American Standards Committee X12 group is the currently adopted standard. Version 4010/4010A1 transactions cannot accommodate the larger size of ICD–10 code set; therefore, the new version, 5010, must be implemented in order to implement ICD–10 code sets. Industry representatives have recommended that the compliance date for these standards be at least 18 months before the compliance date for ICD–10 to allow for needed testing and to reduce risk. CMS is currently working on regulatory action regarding the transition to 5010 in order to accommodate the ICD–10 code set.

• 2011—Projected compliance date for the new HIPAA standard for the claims attachment transaction, which would affect all HIPAA-covered entities that are not health plans. This standard addresses the communication of additional information, often of a clinical nature, that may be needed in order to adjudicate a claim.

• 2012—Projected compliance date for small health plans conducting HIPAA claims attachment transactions.

We acknowledge that implementing ICD–10 code sets will require significant effort on the part of covered entities and their vendors. We also recognize the need to transition to a new code set before ICD–9–CM becomes unworkable. Moreover, the enhanced functionality that ICD–10–CM and ICD–10–PCS code sets bring to quality assessment, research, and biosurveillance argue for an earlier implementation. We have weighed all these factors in arriving at our proposal.

We propose October 1, 2011 as the compliance date for ICD–10–CM and ICD–10–PCS code sets for all covered entities. It is important to note that the compliance date must occur on October 1 in order to coincide with the effective date of annual Medicare inpatient PPS updates. We believe that a 2011 compliance date permits adequate time for covered entities and their vendors to complete the necessary implementation activities. As shown above, our projected compliance dates for other health IT initiatives have been sequenced in a manner that will allow covered entities to concentrate their efforts on ICD–10 implementation (including the implementation of the 5010 transactions) during the relevant period.

CMS believes it is in the industry's best interest (including small health plans) to have a single compliance date for ICD–10–CM and ICD–10–PCS. This will reduce 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, 2011. The proposed compliance date, we believe, is also sufficiently far in the future to provide all sectors of the industry, including small health plans, adequate time to implement the code sets. A single compliance date also will significantly reduce confusion in processing claims and analyzing data. Historically, all previous versions of the ICD coding systems, such as ICD–7 and ICD–8, have been implemented on a single date. The health care industry has come to expect this consistent approach to updating ICD coding systems. To allow two different compliance dates would create problems for all sectors of the health care industry. Examples of problems that would arise if both ICD–9–CM and ICD–10 codes were allowed to be reported for the same date of service include:

• Increased errors—ICD–9–CM and ICD–10–CM have codes that can include the same number of digits and similar codes. Allowing both code systems to be used and reported will create confusion in processing and interpreting coded data. Claims may be denied for services if the edits are established for ICD–10–CM codes, but ICD–9–CM codes are reported. Claims may be returned as errors if edits indicate there are too many or too few digits, when in fact a different coding system is being used.

• Provider burden—Maintaining both ICD–9–CM and ICD–10–CM will place a significant burden on providers. Providers would have to maintain both coding systems for a year because of different reporting requirements by some payers or entities if there were two implementation dates. This will not only increase burden, but would also lead to additional error messages and returned claims if the provider does not select the required coding system when claims are coded. Coders would be burdened by having to recall and apply codes from different coding systems for a year. It is much easier to simply learn and move to the new coding system for encounters occurring on a single fixed date.

• Systems problems—if providers, insurers, and other entities are required to report and accept both coding systems for encounters occurring during a year, there would be significant system implications in trying to determine which coding system was being used to report the coded data. As indicated above, this may lead to denied and returned claims.

• Payment update challenges—coded data are used to update payment systems such as the inpatient prospective payment system. If codes are reported in both ICD–9–CM and ICD–10–CM during a given year, it will be difficult to assess the need to update and refine the payment system based on coded data.

• Problems with national health care data—by allowing the use and reporting of two different payment systems, the national data will be difficult to analyze and interpret. This not only creates problems with updating payment systems, as indicated above, but also creates problems in interpreting trend data on health care conditions. It will be problematic to make national projections on quality of care and outcomes when two different coding

systems are used for encounters during the same time period. This is further amplified when single providers report with two different coding systems to small entities, but with ICD–10 to large entities. Comparing national data and assessing outcomes will be challenging.

We solicit public comment on the proposed compliance date of October 1, 2011.

We anticipate that upon publication of this proposed rule in the **Federal Register**, both the industry and CMS will actively initiate and/or complete planning for implementation of ICD–10. While not included under the auspices of this proposed rule, we also acknowledge the impact of the implementation of the ASC X12 Technical Reports Type 3, Version 005010, hereinafter referred to as Version 5010, on ICD–10 implementation timelines. Once the ICD–10 and Version 5010/NCPDP Version D.0 final rules are published, we estimate that both CMS and the industry will begin documenting the requirements for both ICD–10 and Version 5010 system changes, initiate and/or complete any gap analyses, and then undertake design and system changes, with Version 5010 progressing first, based on the need to have it in place prior to ICD–10 implementation to accommodate the increase in the size of the fields for the ICD–10 code sets. In the case of Version 5010, system building and testing could commence approximately 12 months prior to a Version 5010 compliance date. We anticipate that ICD–10 external testing could start approximately 15 months prior to the October 2011 compliance date.

Upon publication of these proposed rules for both ICD–10 and Versions 5010/D.0 in the **Federal Register**, the Department, through CMS, plans on proactively conducting outreach and education activities, as well as engaging industry leaders and other stakeholder organizations to provide education and other resources to their respective constituencies. These activities would include roundtable conference calls with the industry, including Medicare contractors, fiscal intermediaries and carriers; hospitals; physicians; other providers; and other stakeholders.

CMS will also develop and make available ''Frequently Asked Questions'' documents, fact sheets, and other supporting education and outreach materials for partner dissemination. Other potential activities will be identified and developed based on stakeholder input. The draft proposed timeline shown below is for preliminary planning purposes, and represents our best estimate, given our current knowledge, of what an implementation timetable might look like. It is subject to revision as updated information becomes available. We solicit industry and other stakeholder comments on our timeline assumptions and our proposed education and outreach strategy.

**Draft Proposed Timeline for ICD-10 and Versions 5010/D.0 Implementation**

| ICD-10 | Versions 5010/D.0 |
|---|---|
| **8/08** Publish Proposed Rule | **8/08** Publish Proposed Rule |
| | **9/08** Industry begins requirements documentation for systems changes; CMS and industry initiate education and outreach |
| **12/08** CMS/industry begin ongoing education and outreach | |
| | **4/09** Industry build and test systems changes (internal and external testing) |
| **6/09** Industry begin design documentation | |
| **12/09** Industry builds and internally tests systems changes | |
| | **4/10** Compliance date for all covered entities |
| **7/10 – 10/11** Conduct external testing | |
| **10/11** Compliance date for all covered entities | |

**IX. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3520).

**X. Response to Comments**

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

**XI. Regulatory Impact Analysis**

*A. Overall Impact*

We have examined the impacts of this 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, section 202 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 proposed rule to be a major rule, as it will have an impact of over $100 million on the economy. The RIA section of this proposed rule explains our calculations for costs and benefits. We attempt to provide information for the impact analysis, focusing on savings projections and cost estimates. Tables 13 and 14 summarize cost benefit projections. We solicit comments on these data during the comment period for this proposed rule. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess the anticipated costs and benefits before issuing any rule whose mandate requires spending in any 1 year 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 in the first 2 years following publication of the final rule. Our analysis indicates that States would not experience costs exceeding $130 million.

The anticipated benefits and costs of these proposed modifications to the medical data code sets, and other issues raised in section 202 of the UMRA, are addressed later in this document. In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives that are referenced in the RIA section of this proposed rule, HHS has concluded that the provisions in this proposed rule are the most cost-effective alternative for implementing HHS' 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. The Department consulted with appropriate State and Federal agencies, including tribal authorities and Native American groups, as well as private organizations. These private organizations included WEDI and the Designated Standard Maintenance Organization (DSMO) coordinating committee according to section 1178(c)(3) of the Social Security 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 RIA of this proposed rule industry studies that were conducted and that may provide some insight into this information for States. In addition, during the comment period, we hope that State Medicaid agencies will provide any additional and/or updated information.

The Department has examined the effects of provisions in this proposed rule as well as the opportunities for input by the States to the proposed rule. The Federalism implications of the proposed rule are consistent with the provisions of the Administrative Simplification subtitle of HIPAA by which the Department is required by the Congress to promulgate standards for the interchange of certain health care information via electronic means. Under section 1178(a)(1) of the Act, these standards preempt contrary State law.

The States are invited to comment on this section and all sections of this proposed rule. The Department concludes that the policy in this proposed rule has been assessed in accordance with the principles, criteria, and requirements in Executive Order 13132; that this proposed rule is not inconsistent with that Order; that this proposed rule would not impose significant additional costs and burdens on the States; and that this proposed rule would not affect the ability of the States to discharge traditional State governmental functions.

1. Regulatory Flexibility Act—Impact on Small Businesses

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief 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 nonprofit status or by qualifying as small businesses under the Small Business Administration's (SBA's) size standards (revenues of $6.5 million to $31.5 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) (accessed 8–12–08).

We discuss the impact of the proposed rule on small entities in section XI.D of this document.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. (See the discussion at section XI.D for our discussion of the expected impact on small rural hospitals.)

*B. Anticipated Effects*

1. Objective

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.

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 this 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 section XI.B of this regulatory impact analysis.

2. Background

Two major papers analyzed the costs and benefits of adopting the ICD–10 codes: (1) a March 2004 RAND study, *http://www.rand.org/pubs/technical_reports/2004/RAND_TR132.pdf* (accessed 8–12–08) and (2) an October 2003 study by the Robert E. Nolan Company commissioned by the Blue Cross and Blue Shield Association, *http://www.renolan.com/healthcare/icd10study_1003.pdf* (accessed 8–12–08). Both studies agreed that the basic elements driving the cost of implementing the ICD–10 code sets were training, productivity losses, and system changes. Table 6 summarizes the differences in cost and benefit estimates between the two studies.

In considering the studies, HHS evaluated both on the basis of the following criteria:

- The depth and completeness of the analysis and supporting evidence for the conclusions;
- Data sources and a presentation of the data limitations;
- The perceived objectivity of the analysis as demonstrated by the discussion of data sources and the rigor of the analysis;
- The point of view the analysis adopted—whether from the general societal perspective or from a specific point of view (for example, from the payer or provider view point); and
- HHS' ability to explain and justify in a Regulatory Impact Statement the findings and conclusions presented in each of the studies.

a. Nolan and RAND Studies: Analysis and Limitations

ICD–10 code sets would likely represent the most complex of all the HIPAA code sets. Also, because the ICD–9–CM code set is used for reporting diagnoses, adoption of the new codes will likely touch every provider who submits diagnostic codes, and every payer that processes health care claims. Given the lack of quantifiable data, both studies were compelled to make numerous assumptions as to the possible behavioral changes resulting from the new codes. The key differences are how each study justifies its assumptions and seeks to provide detailed and plausible scenarios.

As the Nolan and RAND reports were the only studies available at the time that outlined the costs and benefits for transitioning from ICD–9 to ICD–10, we employ them for purposes of this impact analysis along with their associated assumptions and limitations. We later discuss HHS' analysis based on our selected model. Overall, NOLAN estimates that it will cost providers and payers between $5.5 billion and $13.5 billion to implement ICD–10–CM and PCS code sets. In addition, Nolan expects there to be an additional $150 million to $380 million in lost productivity.

**i. Training**

Nolan expects the following number of individuals would require training on the new codes:

TABLE 1—NOLAN STUDY—TRAINING ESTIMATES

| *Category | Number of staff | Hours | Training cost in millions $ (including follow-up) |
|---|---|---|---|
| Full-time coders | 142,170 | 24–40 | 94–141 |
| Physicians/practitioners | 754,636 | 4–12 | 332–499 |
| Part-time coders and other clinicians | 1,455,015 | 4–40 | 456–684 |
| Other hospital | 44,207 | 4–40 | 30–45 |
| Payer plans | 117,020 | 4–80 | 54–80 |

*Nolan adapted from chart 6 on page 17.

The Nolan study estimates that 142,170 coders would need training at a cost of $94 million to $141 million. But the study does not differentiate between hospital-based coders and those working in physician offices and clinics. In addition, Nolan identifies another set of 44,207 coders as ''other hospital'' coders, but there is no explanation as to which hospitals are included under this category versus ''full-time coders,'' nor does the Nolan study document the sources of its numbers. According to the American Health Information Management Association Web site (*http://www.ahima.org*, accessed 8–12–08), there are more than 51,000 AHIMA members. As AHIMA is the leading professional association representing specially educated and certified health information management professionals throughout the healthcare industry, we assume, as does the RAND study, that this represents the majority of the number of full-time coders employed in hospitals. Without supporting documentation, we cannot accept Nolan's estimate of 142,000 full-time coders.

The Nolan study estimates that 754,000 physicians would require between 4 to 12 hours of training at a cost of $332 million to $500 million, or $440 to $663 per physician. Given the wide use of ''super-bills'' (forms with codes for diagnosis and procedure codes with their descriptions that are most frequently used by physician practices, and that may or may not include specific charges) to document encounters in office-based practices,

and familiarity with the few codes for which they routinely bill, it seems unlikely that most physicians would require or desire training on the new code sets. We believe that only some physicians would have an interest in learning the new system. Also, it seems likely that large practices would have sufficient need to hire either a part-time or full-time coder. In comparison, RAND estimates that only one out of ten (45,000) physicians would want up to 8 hours of training, and these would most likely be emergency room physicians and surgeons. For these reasons, we believe the RAND numbers more accurately reflect the number of physicians likely to seek training.

Nolan predicts that some 1.5 million clinicians, including nurses and physician assistants, would seek training in the ICD–10 codes at a cost ranging between $313 and $470 per clinician. As in the case of physician training, the Nolan study does not present any explanation for why over a million nurses and physician assistants would want or require training. In some offices, clinicians may perform coding along with their clinical duties, but in most cases, we again expect that superbills or similar forms would be used which require minimal knowledge of the coding structure. On this basis, we rejected Nolan's estimates of clinician training.

Training would be necessary for insurance and health plans that make payments to providers based on the submitted codes. The Nolan study estimates that 117,000 coders working for health plans would require between 4 to 80 hours of training at a cost of between $54 million to $80 million. In this regard, both studies are close on their estimate of the number of personnel and time required for training, with RAND estimating 150,000 personnel requiring 4 to 8 hours of retraining.[2] However, the Nolan study is rather opaque in providing evidence or rationale for its conclusions.

ii. Productivity Losses

The Nolan study distinguishes between short-term (6 months to a year) and permanent productivity loss.

TABLE 2—SHORT-TERM PRODUCTIVITY LOSS

| | |
|---|---|
| Payer and provider productivity losses resulting from claims rework | $300–600 (million) in first year. |
| Coder productivity loss for first 3 months | $300–440 (million). |

Nolan, adapted from Chart 8, page 20.

TABLE 3—LONG-TERM PRODUCTIVITY LOSS

| | |
|---|---|
| Coder productivity loss resulting from the greater number of codes and more complex coding structure | $152–380 million. |

Nolan, adapted from Chart 9, page 21.

The Nolan study concludes that the extra time ICD–10 requires for coding is largely the result of initial unfamiliarity with the code structure and terminology. However, because of the intrinsic greater complexity of coding and vastly greater number of codes, Nolan assumes there would be a permanent loss of productivity of $152 million to $380 million.

The American Health Information Management Association (AHIMA) and the American Hospital Association (AHA) conducted a field test of the ICD–10–CM codes and issued their report in September 2003. The full report is available at *http://www.AHIMA.org.* The study imposed certain limitations that may have contributed to the extended times in using the new code system (the principal limitation being the absence of digital documents which would enable faster searching for codes).[3] However, overall, the study found that with adequate training and proper coding tools, there should be no loss in coder productivity in the long-run (AHIMA/AHA study, page 25).

Nolan also cites Canadian sources who reported productivity losses during the first 6 months after ICD–10 was implemented, but according to its source, production rebounded to pre-ICD–10 levels.[4]

iii. System Changes

Nolan's analysis of the cost to make system changes rests largely on statements made by various executives who cited the costs of preparing for Y2K and HIPAA. The Nolan study analysis consisted of adjusting those figures for factors such as avoiding hardware purchases, or the inclusion of security and privacy costs in the HIPAA estimates. Nolan estimates the system changes based on an aggregate number that includes privacy and security, and then backs out the cost for implementing the code portion of the costs, concluding that 50 to 70 percent of the costs would be attributable to code changes.[5] However, there is no explanation for how Nolan determined this number. The following table summarizes Nolan's estimates for the cost of implementing system changes in the various affected health care sectors. The estimates are drawn from tables in the Nolan report.

TABLE 4—NOLAN STUDY ESTIMATES OF SYSTEM CHANGES COSTS ACROSS HEALTH CARE SECTORS

| | In billions |
|---|---|
| Facilities and physician offices | $2.6–$8.2 |
| Health plans and insurers | 0.4–1.0 |
| Medicaid/Medicare | 0.7–1.4 |

Nolan report, pages 8, 9, 11, 24.

In estimating the costs of the system changes, Nolan compared the implementation of the codes sets to the implementation of the HIPAA sets and broke down the activities into the following tasks:

[2] RAND page 10.

[3] ''ICD–10–CM Field Testing Project'' AHIMA/AHA; September 2003 (*http://www.ahima.org/icd10/documents/FinalStudy_000.pdf*), accessed 8–12–08 page 11; ICD–10 not available in electronic format.

[4] Nolan, page 21.

[5] Nolan, page 6.

TABLE 5—NOLAN STUDY ESTIMATES OF SYSTEM CHANGES COST BY TASK

| Project steps | Sub-steps | FTEs | HIPAA | FTEs | ICD–10 |
|---|---|---|---|---|---|
| * Team Formation and Analysis ..... | Assign project leader ..... | 0.25–1.0 | $25–$70,000 | 0.25–1.0 | $25–$70,000 |
| | Assemble project team and develop plan. | 0.5–2.0 | 50–140,000 | 0.5–4.0 | 50–280,000 |
| | Perform gap and systems analysis .. | 0.25 | 5–25,000 | 0.5–3.0 | 50–210,000 |

* Nolan, page 5, chart 2.

HIPAA required a number of system changes and adoption of a number of new code sets. In the final HIPAA transaction rule, we estimated the cost to implement the Administrative Simplification provisions to be approximately $7.1 billion (65 FR 50356).

Nolan estimates that system changes in hospitals would cost between $2 billion and $6 billion, and $645 million to $2.2 billion for implementing the ICD–10 codes in physician and group practice offices. Nolan, however, does not take into account that hospitals would need to implement both ICD–10–CM and ICD–10–PCS, whereas physician and group practice offices will only need to implement ICD–10–CM. Payers would incur $400 million to $1 billion in costs to implement the ICD–10 code sets. The total cost of $3.045 billion to $9 billion represents from 43 to 127 percent, respectively, of the $7.1 billion estimated for implementing the HIPAA provisions for both provider and plan costs. In addition, the Nolan study separately identifies the system change costs for government programs, including Medicaid and Medicare, at between $700 million and $1.4 billion.[6] In analyzing the cost of implementing ICD–10 code sets for Medicaid State plans, Nolan cites several sources that refer to the costs of modifying the Medicaid Management Information Systems (MMIS), which may require some modifications to accept payments based on the new codes.

Nolan did not estimate any quantitative benefit which is a serious shortcoming of the study, given the Office of Management and Budget's (OMB's) guidance on preparing cost/benefit analyses for major rules.

Based on the studies' designs, it appears that the RAND and Nolan reports had different target audiences; therefore, their respective methodologies differed. RAND considered costs and benefits from the perspective of the general public, while the Nolan study focused on major health care sectors. A key result of this difference is that potential winners and losers in each health care sector are not clearly highlighted in the RAND report.

RAND's methodology is more analytical than Nolan's methodology, albeit there are still limitations to the RAND report. Both RAND and Nolan express the uncertainty in their estimates through presenting ranges for their estimates. RAND, however, provides more detailed scenarios and offers a qualitative analysis of the uncertainty in the variables it uses in its scenarios. Nolan does not offer any explanation for its ranges. Both studies conducted extensive literature reviews.

In conducting the cost and benefit analysis, both reports dissected the estimates into a one-time cost and one-time and recurring benefits in the RAND study. In both the Nolan and RAND studies, nursing homes, clinical labs, Durable Medical Equipment suppliers (DMEPOS), third party administrators, clearinghouses, and small/medium insurers were excluded from their analysis. Table 6 below provides a high-level comparison between the RAND and Nolan studies.

Although RAND does not explicitly break down its analysis beyond the broad categories of ''payer'', ''hospital'', ''physician'', for costs of coding, productivity losses, returned and improper claims, by examining the costs of the generic categories of training, administration, and claims processing, RAND's approach cuts across the subcategories of providers and payers. Only in the analysis of system change costs is there a defect in RAND's method. From the documentation provided, RAND conducted interviews with executives of health care systems of various sizes as measured by membership.[7] It is not clear, however, the span of the interviewed health systems in terms of the types of providers. Without more details, we cannot conclusively determine the extent of the system conversion costs of long-term care facilities, home care providers and other non-hospital organizations. It may be that the system conversion costs for these types of health providers are underrepresented. Similarly, it is not clear how far-ranging is RAND's examination of the various types of payer organizations. It is possible that third party administrators, clearinghouses, and small health plans may be underrepresented in the analysis.

TABLE 6—COMPARISON OF COST AND BENEFIT ESTIMATES IN RAND AND NOLAN STUDIES

[In $ millions]

| | RAND | Nolan | Difference | Comments |
|---|---|---|---|---|
| Costs Training: | | | | |
| One-time ..... | $200–450 | $950–1,500 | $750–1,050 | • 35 to 50 percent difference attributable to the assumption of part-time coders: RAND assumed 200,00 compared to 1.5 million in the Nolan report.<br>• 25 to 40 percent difference attributable to the number of physicians: RAND assumed 1:10 physicians would be trained compared to most physicians in the Nolan report. |
| Productivity Losses: | | | | |
| One-time ..... | 50–350 | 600–1,040 | 550–690 | • The Nolan report treated re-work and short-term losses separate from productivity losses—which may account for the Nolan Report figures. |

[6] Nolan, page 7.

[7] RAND, pages 15–16 and Appendix B.

TABLE 6—COMPARISON OF COST AND BENEFIT ESTIMATES IN RAND AND NOLAN STUDIES—Continued

[In $ millions]

| | RAND | Nolan | Difference | Comments |
|---|---|---|---|---|
| Recurring | 0–30 | 152–380 | 152–350 | |
| System Changes: | | | | |
| One-time | 225–700 | 3,700–10,600 | 3,475–9,900 | • The Nolan report compared ICD–10 code set implementation to other large scale system changes such as Y2K and HIPAA. |
| Contract Negotiations | 0 | 82–416 | 82–416 | |
| Benefits: (in millions) | | | | |
| More accurate payments for new procedures. | 100–1,200 | (1) | | • The Nolan report claims that vast majority of benefits cannot be achieved without a standard clinical vocabulary. Also, the report states that the benefits asserted by proponents are uncertain and unproven based on literature reviews. |
| Fewer rejected claims | 200–2,500 | (1) | | |
| Fewer fraudulent claims | 100–1,000 | (1) | | |
| Better understanding of new procedures. | 100–1,500 | (1) | | |
| Improved disease management. | 200–1,500 | (1) | | |

[1] Uncertain.

Finally, Nolan also argues that implementing ICD–10 codes would lead to increased incidences of fraud and abuse in its introductory period. We agree with this view since we anticipate that people may take advantage of the initial ambiguity of the new codes, but we also believe that the greater precision of the coding requirements would eventually lead to lower incidences of abuse.

Both studies presented valuable input and relevant information, but based on questions regarding the methods and assumptions presented in each report, we believe that neither should be used as the sole basis for an ICD–10–CM and ICD–10–PCS impact analysis. To address these shortcomings, HHS convened a workgroup to develop a framework consistent with OMB's requirements for an impact analysis. The framework extracted relevant points from both the RAND and Nolan studies, and also identified new internal and external data sources.

Also taken under consideration for purposes of this impact analysis, is a report authored by the Hay Group, Inc., ''Examining the Cost of Implementing ICD–10'', commissioned by America's Health Insurance Plans (AHIP) (hereinafter referred to as the AHIP report'') in October 2006.[8] This report, a white paper based on the previously-referenced RAND and Nolan reports on ICD–10 implementation, is intended to identify the primary sources of ICD–10 implementation costs. It includes a review of existing cost estimates from RAND and Nolan and uses those estimates to develop preliminary estimates of the likely cost to the U.S. health system as a whole. Its scope includes health care providers, private payers, and government payers. The types of costs considered are systems implementation, training, and provider contract renegotiations. Only direct implementation costs are considered. The report does not include the cost of work that must be re-done due to error rates or other forms of lost productivity.

For purposes of this regulatory impact analysis, we used the AHIP report as a litmus test in that it was authored a full 2 years after the RAND and Nolan reports, and held the potential for providing more updated cost estimates. However, it again relies on RAND and Nolan data, and notes that its cost estimates would still have to be adjusted for inflation, which we have already done for this impact analysis. The AHIP report also lacks discussion regarding the monetary benefits that would occur once ICD–10 is implemented. It also does not specifically reference how their estimates were calculated or the sources for many of their assumptions.

We agree with selected segments of the AHIP report, namely its conclusion that implementation of ICD–10 for Medicare and Medicaid would run between $250 and $370 million; we estimate an average of $315 million. Where our analysis and the AHIP report differ is in the cost for the training of physicians on the ICD–10 codes sets, and in the cost of re-negotiating contracts. In the case of the former, we continue to believe that there will be a minimum number of physicians who will desire such training, leaving it instead to their staff coders, or the use of ''super-bills'' to update their coding information. In the case of the latter, we continue to believe that contract re-negotiation costs are considered for purpose of this analysis to be a cost of doing business, and would take place whether or not the transition to ICD–10 took place. We believe that the level of effort to re-negotiate contracts for the purposes of implementing ICD–10 would not be significantly different from other policy-related changes requiring contract renegotiations. We also do not account for AHIP's increase in system implementation costs of between $115 to $416 million due to an accelerated implementation of the ICD–10 code sets versus an orderly, staged rollout as we have proposed.

3. Framework for Impact Analysis

a. The Impact Analysis Workgroup

HHS created a workgroup from a cross-agency, multidisciplinary team with actuarial, economic and coding subject matter expertise from HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE); Centers for Disease Control (CDC)/ National Center for Health Statistics (NCHS); Centers for Medicare & Medicaid Services (CMS); and the Office of the National Coordinator for Health Information Technology (ONC). The workgroup sought guidance from the Department of Defense (DoD), the Department of Veterans Affairs (VA), and contacts from other countries that have implemented ICD–10, to lead the cost-benefit analysis for transition from

[8] ''Examining the Cost of Implementing ICD–10'' White Paper prepared by Thomas F. Wildsmith, FSA, MAAA of HayGroup, Inc. on behalf of the America's Health Insurance Plans, October 12, 2006. *http://www.ehcca.com/presentations/hithipaa414/3_04_1.pdf.*

ICD–9–CM to ICD–10–CM and ICD–10–PCS. Also, Actuarial Research Corporation (ARC) was hired to help the team evaluate and update the data sources and available information. The team critically reviewed several cost-benefit studies and international experiences with ICD–10 implementation. Data were drawn from the RAND study (sponsored by NCVHS), the Nolan study (sponsored by the Blue Cross Blue Shield Association), the American Health Information Management Association (AHIMA), and CMS.

In 2005, the workgroup began the analysis of the costs and benefits by examining and comparing the RAND and the Nolan studies. While both contain useful information, the requirements for regulatory impact estimates demand a somewhat different framework. The workgroup incorporated the basic results from both studies, as well as the Secretary's vision of health care information technology, and reflected costs and benefits by year based on assumed implementation schedules.

The workgroup's analysis assumes that the implementation of ICD–10 code sets would be coordinated with existing HHS health information technology initiatives, and include the required changes to dependent regulations and standards. HHS health initiatives, such as public health/biosurveillance, disease registries, quality monitoring, utilization review, and pay for performance, could employ either ICD–9–CM or ICD–10–CM and ICD–10–PCS code sets.

Conversion costs from ICD–9–CM to ICD–10 code sets are unavoidable and do not include costs associated with the American Standards Committee (ASC) X12N version 5010 standard. ICD–9–CM is an adopted HIPAA code set and the adopted HIPAA Transaction standard (ANSI ASC X12N version 4010/4010A1) does not support ICD–10–CM and ICD–10–PCS code sets. Also, the CMS IPPS uses ICD–9–CM-based Diagnostic Related Groups (DRGs), and the annual regulatory IPPS update would require conversion to ICD–10-based DRGs. Regulatory and standards changes, including implementation of Version 5010 must occur before, or parallel to, conversion to ICD–10–CM and ICD–10–PCS code sets, with sufficient notice to the industry to reconfigure systems, policies and methodologies. For initiatives in the early stages of development, costs to implement ICD–9–CM now, with conversion to ICD–10 code sets later, could be avoided by direct conversion to ICD–10 code sets concurrently with the initiatives.

The following is a detailed discussion of the workgroup's approach, method, and assumptions underlying its costs/benefit analysis.

First, we present an overview of HHS' approach to estimating the costs and benefits based largely on the RAND study but also drawing from the Nolan study and the AHIMA/AHA study.[9] The second part of this section describes in detail the assumptions and models that RAND developed for its estimates and which were adapted for this analysis.

The workgroup's calculations began with the RAND[10] estimates, incorporating additional information from CMS, and some input from Nolan.[11] For each category for which RAND provided a range of high and low costs, a point estimate was generated. When RAND did not include a specific estimate, HHS' point estimate was based on the midpoint of their high and low estimates. RAND's descriptions and 10-year numbers were used to create a year-by-year spread of both costs and benefits. Modifications were made after reconsideration of the RAND study regarding their calculations. These modifications included the addition of productivity losses for outpatient claims; the separation of costs from the benefits for rejected and improper claims; and reconciliation of what were considered inconsistencies in the RAND study. We selected the computed values from the text of the RAND report rather than relying on the values presented in the tables.

HHS also examined estimates from the Nolan study. Nolan specifically estimated outpatient productivity losses, a cost that RAND did not estimate. For outpatient productivity, the Impact Analysis Work group assumed the short-term impact may be very small in terms of extra time per claim, but because of the large number of claims, the loss was judged to be significant. In its analysis, Nolan identifies potential productivity and other losses for physician and facilities. RAND did not examine the possible loss of productivity for physician and other outpatient claims. We believe that there may be a productivity loss of outpatient and physician office-based services. The loss per claim may be very small, but because of the huge volume of physician and outpatient facility claims, the productivity loss may be significant.

To allow analysis of longer-term conversion impacts, HHS' estimates are moved to a year-by-year basis. Also, since we expect new procedures to be introduced each year, the savings from the introduction of the new codes are estimated to increase annually over the period for which the analysis was conducted.

For two benefit categories, ''fewer rejected'' and ''improper claims,'' RAND estimated a net cost of zero over the first 5 years, expecting that there would be some short-term losses before benefits materialized. For the purpose of calculating both year-by-year estimates and 10-year estimates, these categories are included on the cost side as well as on the benefit side. This is reflected by including costs of rejected and improper claims for the first 2 years.

The next section details the assumptions used to estimate the costs and benefits, and the models used to estimate the benefits. Upper and lower bound estimates are also presented.

4. Assumptions Underlying the Cost and Benefit Analysis

The estimates for the impact of replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS code sets as the HIPAA standard code sets is based primarily on the RAND analysis previously cited. After reviewing that report versus other reports (for example, Nolan), comments from other entities, experience from other countries, and conversations with government analysts, we adapted the RAND results as the base for developing the regulatory impact estimates. As noted above, we adopted the RAND approach and results but made several modifications to the underlying RAND estimates.

5. Impacted Entities

Entities covered under HIPAA would be required to comply with the provisions of this proposed rule once finalized. Covered entities include all health plans, all health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. In the sections that follow, we attempt to outline the ICD–10 transition cost impacts to various covered entities; however, we acknowledge that the cost analysis for training, productivity loss, and system changes are impacts of varying degrees on all covered entities.

There are multiple ways to implement the ICD–10 code sets. As the codes will be integrated into systems and

[9] ''ICD–10–CM Field Testing Project.'' AHIMA/AHA; September 2003 (*www.ahima.org/icd-10/documents/FinalStudy/pdf.*), accessed 8–12–08

[10] ''The Costs and Benefits of Moving to the ICD–10 Code Sets.'' Martin Libicki and Irene Brahmakulaum, The RAND Corporation. MHHSh 2004.

[11] ''Replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS: Challenges, Estimated Costs and Potential Benefits.'' Robert E. Nolan Company. October 2003.

processes, some providers, plans, and vendors may decide to populate the new codes throughout their entire system 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.

Many small and specialty practices may continue to submit paper claims as well, using preprinted forms that include all of the appropriate codes required for use in such offices. In most instances small practices and direct billing practitioners may assign the diagnosis themselves and may include the ICD–10 code on the paper billing form. As time goes on, we anticipate that the industry will migrate to the full use of the more robust codes to realize the full benefit potential of ICD–10.

We solicit industry and other stakeholder comments on ICD–10 integration and use of workarounds.

6. Estimated Costs

As identified in both the Nolan and RAND studies, HHS estimates the following three basic categories of costs:

- Training.
- Productivity Losses.
- Systems Changes.

In general, costs may be categorized into one-time costs and recurring costs. In our analysis, some costs are considered one-time costs associated with conversion and training, which will be expended within less than a year. Other costs, such as the cost for additional claims processing resulting from errors and delays in implementing system changes, are projected to extend out for several years and are considered recurring costs. (see Table 13a) Both RAND and Nolan identify short-term (6 months or less) and long-term productivity losses (extending beyond the initial 6-month period).

For purposes of this analysis, we consider a primary estimate to include all estimated costs, and estimated benefits incorporating both one-time and recurring costs, extended over a 15-year period based on the data provided from the RAND and Nolan studies. (Please refer to Table 13a and b for more information on costs and benefits as well as primary estimates).

In developing our estimates for both the costs and benefits of converting to the ICD–10 codes, we developed ranges, intended to express the uncertainty in our point estimates. The low point of each range represents for the most part, half of the point estimate, with the high point of the range representing a doubling of the point estimate.

For some of the cost estimates, we use the higher end of the scale to be more conservative. For example, when we suggested that training would take four to eight hours, we based our calculations on eight hours. Also, we use a 15-year timeframe to show the point at which benefits exceed costs. For purposes of this impact analysis, in some instances we base our ranges on that of the RAND study and extend them out over 15 years. Also, because our analysis shows that costs will be expended within the first 3–5 years, in most cases we use the midpoint of our ranges for the primary estimate.

We also estimate that there will be a phase-in of costs. In most cases, costs begin showing in the 2 years prior to implementation and zero out the year after implementation. The only exception is the costs for improper and returned claims, which we estimate will not be incurred until after implementation since claims using ICD–10 will not be submitted until after the implementation date.

In terms of a phase-in of benefits, we do this in order to show that benefits will increase the more the industry becomes familiar with using the new codes. We do not expect benefits to begin until the year after implementation, but will continue to increase each year thereafter with 100 percent of the benefit being realized 5–6 years after implementation.

Since we base our figures on 2004 dollars, for purposes of this analysis, we account for inflation by increasing the cost estimates by the Consumer Price Index (CPU–I) figures from 2004 to 2007 and the benefit estimates by the growth rate in the National Health Expenditure accounts for 2005 to 2007.

For estimation of the costs estimates, we divide the CPI–U annual index for 2007 by 2004's index to determine the adjustment factor in which to apply to each cost estimate and range. This adjustment factor equals approximately 1.098.[12] 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 for inflation. That is, most of the costs are so heavily allocated to the first few years, the inflation adjustment does not have a significant effect.

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.[13]

Although we base most of our assumptions on the RAND study, we take into account the concerns expressed by the Nolan study that RAND did not raise:

- Cash flow.
- Contract renegotiations.

We agree with Nolan's assumption that the slowdown associated with the implementation of the new code sets may cause serious cash flow problems for providers. The risk of a payment slowdown always exists whenever a new payment system or policy is implemented. However, even with major policy changes, plans have learned over time to anticipate these problems and have instituted measures to provide periodic interim payments (PIP) for providers who may be affected by the processing slowdown. Most payers have learned through experience the cash flow needs of their providers and can easily set up PIPs and perform reconciliation at the end of the fiscal year.

With respect to contract renegotiation, this is an activity that providers and payers must perform on a regular basis, and every time a new policy is issued. The implementation of the new codes would require contract renegotiations. However, we do not see the level of effort to be significantly greater than with other renegotiation efforts, especially in the recent past with the initiation of a number of prospective payment systems for long-term care, psychiatric, rehabilitation, and outpatient services.

Therefore, for purposes of this impact analysis, we do not address the concerns of Nolan as stated above.

a. Training

For training costs associated with the ICD–10 transition, we account for both full-time and part-time coders. We surmise that full-time coders are primarily dedicated to hospital inpatient coding while the part-time coders work in outpatient ambulatory settings. The classifying of hospital inpatient coders as full-time may roughly represent the employment status of this group of coders. However, we believe it is more accurate to categorize coders based on their job location as inpatient or ambulatory setting coders. The difference in categorizing coders based on the job setting rather than full- or part-time has to do with the need to learn ICD–10–

[12] From the Consumer Price Index 2004 and 2007, *http://www.bls.gov/CPI/*, accessed 8–12–08.

[13] National Health Expenditures and Selected Economic Indicators, Levels and Annual Percent Change: Calendar Years 2002–2017.

PCS in addition to ICD–10–CM. All coders will need to learn ICD–10–CM while the coders working in the hospital inpatient setting will also need to learn ICD–10–PCS. This will apply to inpatient coders regardless of their status as part-time or full-time coders.

For full-time/inpatient coder training, we use the estimation calculated by AHIMA and others that getting full-time coders to proficiency on both ICD–10–CM and ICD–10–PCS could take as little as a few days or up to a full 40 hours.[14] Based on AHIMA membership, we assume that 50,000 full-time hospital coders would need one week of training, at $2,750 per coder, which includes $2,200 for lost work time and $550 for training expenses, for a total of $137.51 million.[15]

Therefore, we estimate that the training costs for full-time coders associated with adopting ICD–10 is approximately $137.51 million with a low range estimate of approximately $110 million and a high of approximately $165 million.

As explained previously, we expect training of full-time coders to start in 2010 (the year before ICD–10 implementation). We assume that 15 percent of training costs will be expended in this year. In the following year (the year ICD–10 implementation occurs), we assume 75 percent of training cost will be expended in 2011 and 10 percent of training costs in 2012.

Estimating the distribution of coders in ambulatory settings is more complicated because not every ambulatory setting may employ a coder. In many physician and practitioner offices, the use of ''super-bills''—preprinted forms that include all of the appropriate codes required for use in such offices—minimizes the need for a coder. Based on our knowledge of the industry, in most instances physicians and direct billing practitioners will assign the diagnosis themselves and may include the ICD code on the billing form. Yet we believe that all but the smallest practices will have someone whose responsibilities either formally as part of their job description or informally include handling coding issues.

Table 7 below summarizes the number of part-time coders by North American Industry Classification System (NAICS) code for ambulatory entities (*http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08).

TABLE 7—AMBULATORY ENTITIES ASSUMED TO EMPLOY PART-TIME CODERS BASED ON THE 2005 STATISTICS OF U.S. BUSINESSES

| NAIC code | Type of entity | Total number of entities (establishments) and employees[16] | 5–9 employees | 10–19 employees | 20–99 employees | 100–499 employees | Total number of part-time coders |
|---|---|---|---|---|---|---|---|
| 6211 .... | Office of Physicians ..... | 213,611 | 44,457 | 25,178 | 21,500 | 7,062 | ..... |
| | Employees ..... | 2,041,704 | 286,741 | 316,111 | 555,259 | 256,996 | 100,875 |
| 6213 .... | Office of Other Health Practitioners. | 115,378 | 19,357 | 7,654 | 5,043 | 11,774 | ..... |
| | Employees ..... | 553,658 | 121,527 | 88,196 | 96,754 | 47,155 | 30,962 |
| 6214 .... | Outpatient Care Centers ..... | 26,901 | 1,897 | 1,907 | 4,190 | 5,440 | ..... |
| | Employees ..... | 658,507 | 12,510 | 24,766 | 109,237 | 186,883 | 17,941 |
| 6215 .... | Medical and Diagnostic Laboratories. | 11,856 | 1,324 | 1,324 | 1,492 | 928 | ..... |
| | Employees ..... | 222,651 | 8,577 | 13,194 | 41,707 | 40,221 | 6,080 |
| 6216 .... | Home Health Care Services ... | 20,184 | 1,426 | 1,569 | 4,109 | 2,445 | ..... |
| | Employees ..... | 913,514 | 9,558 | 22,111 | 171,704 | 245,827 | ..... |
| | | | | | | | 179,267 |

Based on the 2005 Statistics of U.S. Businesses data, our analysis suggests that there are approximately 179,000 part-time coders who will require training on the ICD–10 CM codes, but not on the ICD–10–PCS codes. Based on contacts with industry and our own experience, we assumed that for every 20 employees employed in an ambulatory setting, there would be one part-time coder. Using the size categories that the Office of Advocacy in the U.S. Small Business Administration created with the Statistics of U.S. Businesses data, we calculated the number of part-time coders in outpatient ambulatory practices with 20 to 499 employees. (*http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08) We further assumed, that based on their size, the administrative complexities and the types and volume of services provided, that facilities with 500 or more employees would require full-time coders. Thus, we did not include ambulatory practices with 500 or more employees in our analysis of part-time coders.

We also assumed that very small providers with between 5–10 employees would have someone responsible to manage coding issues, who would need some amount of training. We assume that the 179,000 coders would have training costs per coder of $550. This includes $440 for lost work time and $110 for training expenses, for an estimate total of $98.5 million.[17]

For purposes of this impact analysis, we estimate the cost associated with part-time coder training in adopting ICD–10 is approximately $98.50 million, with a low range of approximately $55 million and a high range of $165 million.

Code users can include 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. 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

[14] RAND, page 8.

[15] RAND, page 8.

[16] *http://www.census.gov/csd/susb/susb05.htm,* accessed 8–12–08.

[17] RAND, page 8.

coded data, etc., but are not people who actually assign codes.

We estimate that there are approximately 250,000 code users.[18] We assume that of these 250,000 only 150,000 work directly with codes and would require eight hours of training at approximately $250 ($31.25 per hour × 8 hours). We estimate training costs for code users at $37.50 million with a low range estimate of $27 million and the high range is $55 million.[19]

For physicians, we assume that only 1 in 10 physicians, or 150,000 (there were a total of 1.5 million physicians in the U.S. as of 2005 [20]), would require training. Based on our experiences and the testimonies of various providers, we estimate physicians would only need 4 hours of training, which is half of what RAND assumes, at $137 per hour. [21] However, after conversations with industry experts and various physician types, we believe that since it is likely that physicians will obtain ICD–10 training through hospital-sponsored staff in-services, county medical society in-services, continuing physician education programs, etc., which they would attend nonetheless, physician ICD–10 training costs will be even less. Based on the assumptions above, we estimate the cost associated with physician training for adopting ICD–10 is $82.20 million with range estimates including a minimum of $0 and a maximum of $165 million.

We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

b. Productivity Losses

Productivity loss refers to the cost resulting from a slow-down in coding bills and claims because of the need to learn the new coding systems. [22] One can think of productivity loss as the number of additional staff hours that would be required to code the same number of bills and claims per hour before the code conversion. With the adoption of a new code set, there would be an initial loss in productivity. All personnel, including coders and practitioners, would be affected to some degree. Coders would be directly affected because of the need to learn new codes and definitions. Time would be lost, and undoubtedly some claims would require resubmission to payers as both providers and payers adjust to the new codes.

i. Inpatient

We assume that there would be a significant amount of short-term losses during the first 6 months after implementation. Beyond that point, we believe that productivity would return to its previous level. Studies from Canada and Australia have shown that the productivity losses disappeared within 6 months after transition to their versions of ICD–10.

According to a field test conducted by the American Health Information Management Association (AHIMA) and the American Hospital Association (AHA) in 2003 (*http://www.ahima.org/icd10/documents/FinalStudy_000.pdf*), coders reported no difference in the time it took to code the claims in 58 percent of the cases. Ninety-one percent of the remaining records took more than five additional minutes over the ICD–9 coding in part due to:

- Unfamiliarity with the index structure of ICD–10;
- Use of different main terms and sub-terms in ICD–10 versus ICD–9;
- Spending more time reviewing the medical record; and
- Having greater familiarity with ICD–9 than with ICD–10, as many coders had common codes memorized.

AHIMA concluded that the availability of much-improved coding tools, more training, and increased familiarity with ICD–10–CM would significantly reduce the amount of time needed to code records in ICD–10–CM, possibly to the point where ICD–10–CM actually may require less coding time than ICD–9–CM.[23]

Although the field study suggests a larger initial loss of coder productivity, the lack of training, the unavailability of user-friendly coding tools, and other limiting factors, it did not represent the ''real-world'' conditions under which coding would be performed. Because of the restrictions and the absence of the ''real world'' conditions under which we believe coders will be working once the ICD–10 code system is implemented, we did not base the estimate of productivity loss on the field study.

For purposes of this impact analysis, we estimate that it would take coders 1.7 additional minutes in the first month to code an inpatient claim that includes an inpatient procedure.[24] We estimate that the first month's productivity loss at 1.7 minutes per claim and applying this to 1.8 million inpatient claims requiring procedures per month (20,000,000 claims per year divided by 12 months) at $50 per hour or $1.41 per claim will result in productivity losses equaling $2.7 million in the first month. For purposes of this analysis, we assume that resumption of productivity will increase the same amount each month over the next five months. Dividing $2.7 million by 6 gives a monthly increase in productivity of $450,000. Thus, within 5 months following implementation of the ICD–10 codes for inpatient services, coding productivity will return to their pre-conversion levels and there will be no long-term impact on coding efficiency. After subtracting the $450,000 from each month's lost productivity, we add the residual monthly amount of lost productivity. The total cost due to reduced inpatient productivity resulting from introduction of the ICD–10–CM and PCS codes is projected to be $8.90 million incurred within the first year, with a low estimate of approximately $0 and a high estimate of approximately $55 million.

Further support for the view that long-term productivity will not be adversely affected came in a July 2007 conversation CMS had with AHIMA.[25] AHIMA further reiterated that long-term productivity losses would not be significant. The learning curve for ICD–10 in an inpatient setting may be longer due to the need for coders to learn both ICD–10–CM and ICD–10–PCS. However, ICD–10–PCS has proven to be easier for coders to learn than ICD–9–CM procedures with its many inconsistencies. Within 2 months, inpatient coders would understand ICD–10–CM and rapidly gain a proficiency in its use. Within 6 months, inpatient coders would be highly proficient in its use. After 6 months, there would be extremely small degrees of loss of productivity, if any at all.

ii. Outpatient

In analyzing the cost of productivity loss in the outpatient/ambulatory setting we had to determine the amount of additional time coders would need to code a claim with the ICD–10–CM codes, and the number of claims processed within a given period.

In selecting a source for the number of outpatient/ambulatory claims, we examined data from the National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical

[18] RAND, page 9.

[19] RAND, page 9.

[20] World Health Organization, *http://www.who.int/en/,* accessed 8–12–08.

[21] RAND, page 9.

[22] RAND, page 10.

[23] ICD–10 Field Testing Project Summary Report, September 23, 2003; AHIMA, p. 25.

[24] RAND, page 10.

[25] This was an informal conversation between Pat Brooks from the Hospital and Ambulatory Policy Group within the Centers for Medicare Management at CMS and Sue Bowman from AHIMA.

Care Survey and the Nolan report. These surveys collect data on patient visits to physicians and visits to hospital outpatient departments and emergency rooms. In 2005, the NAMCS reported 964 million physician visits. In the same year, the NHAMCS reported 115 million patient visits to emergency rooms and 90.4 million visits to hospital outpatient departments. The total number of patient visits to outpatient medical settings based on the two surveys was 1,169 million visits.

Because we are inclined to adopt a conservative approach to estimating the costs of converting to the ICD–10 codes, we are using the estimate of outpatient claims that the Nolan report used in its calculation. While the NAMCS and NHACS surveys probably accurately reflect the number of patient visits, the number of visits may understate the number of claims submitted. As we discuss below in section iv., Improper and Returned Claims, a certain percentage of claims will be processed more than once. We believe that the two billion claim estimate accounts for the multiple processing of claims in addition to the initial processing of claims.

For purposes of the analysis, we assume the average time to code an outpatient claim could take one-hundredth of the time for a hospital inpatient claim. The average time to code an outpatient claim takes into account the wide variety of outpatient settings and coding forms. For example, physician offices may use preprinted forms or touch-screens that require virtually no time to code. Clinics and hospital outpatient units using outpatient claim forms, however, may require more time and some may require as much time as inpatient claims.

Applying the estimate of 0.017 minutes per outpatient claim (one hundredth of 1.7 minutes for inpatient claims) to the monthly number of claims of 166.7 million and $50 per hour or $0.014 per claim, we estimate the first month's productivity loss will be $2.6 million. Applying a straight line assumption for the recovery or productivity over the next five months, we divided $2.6 million by six to arrive at $433,000. That is, productivity will recover from a low of $2.6 million at a rate of $433,000 per month for the next five months. Over the following 5 months, we expect productivity to return to its pre-conversion level.

In the same July 2007 CMS conversation referred to in the discussion of inpatient productivity loss, AHIMA noted that the productivity losses in an outpatient setting would be less than inpatient due to the need of coders to learn only ICD–10–CM rather than both ICD–10–CM and ICD–10–PCS. Within a few weeks, coders would understand most of the differences between ICD–9–CM and ICD–10–CM. Within 6 months, coders would be quite proficient in ICD–10–CM.

For purposes of this impact analysis, we estimate the cost associated with outpatient productivity losses with adopting ICD–10, is approximately $8.56 million with a range of a $0 minimum and a $55 million maximum.

iii. Physician Practices

We assume that physician practices will sustain an initial loss of productivity loss. Each practice will have to convert their current ''super-bills'' to an updated version that includes ICD–10 codes. AHIMA estimates that it will take approximately two hours for this conversion, with a one-time cost estimate of $55 per practice. Assuming there are 200,000 practices nationwide, this cost equates to a one-time total cost of approximately $10.98 million, with a low range of $5.5 million and a high range of $27 million. We consider this number to be high considering that some practices will have their specialty societies perform the ''super-bill'' conversion and supply it to their members.

iv. Improper [26] and Returned Claims

The implementation of the new code sets is expected to produce a temporary increase of coding errors especially on the part of physicians. To determine the effects of introducing code changes on the number of claims processing and the number of Medicare returned claims, we reviewed returned claims data for FYs 2004, 2005 and 2006. We found that there appears to be a pattern of a spike in Medicare returned claims 3 to 6 months following the introduction of ICD–9 annual code updates. The average percent increase in returned claims associated with the annual coding update is approximately three percent over the 3-year period.[27] Based on our findings and considering that the annual coding update affects a relatively small number of codes compared to the proposed ICD–10 conversion, which will affect all diagnostic and procedure codes, we anticipate that the percent of returned claims following the implementation could be more than double the previous years' increases. We expect that the percent of returned claims may peak at around 6–10 percent of the pre-implementation levels

Relying on RAND's estimate that the average overall cost of claims adjudication in the U.S. is roughly $22 billion nationwide per year,[28] this represents only a fraction of the $88 billion total health administrative claims adjudication costs.[29] If we assume that the average claim goes through two cycles, the overall cost of claims adjudication divided by the average number of cycles a claim makes, results in a cost of approximately $11 billion per cycle per year for all claims.[30] Based on our assumed cost of claims processing and the additional initial increase of 3 percent jump in erroneous claims, we estimate that the total cost for claims handling for plans and providers will be $543.29 million. We assume the annual cost of the increase in returned claims equals $329 million (3 percent of $11 billion). In the first year, we expect the full annual cost for added claims processing. In the second year, we expect added processing costs to equal 50 percent or $164 million. In the third year, we expect processing costs to equal 15 percent of the annual cost, or approximately $49.4 million. By the fourth year, however, we expect claims processing costs to begin to drop below their pre-conversion levels (see ''Fewer Rejected Claims'' and ''Fewer Improper Claims'' in the discussion of Benefits).

In the first year following implementation, claims processing costs for the added returned claims are estimated to be $329.29 million. The next year, we assume the number of returned claims will be half of the first year's level and will cost $164.64 million to process. By the third year following implementation, we assume that returned claims will be 15 percent of the first year's number and cost about $49.39 million.

With the transition to ICD–10, we assume that eventually there will be fewer returned claims due to the more detail and better structure that ICD–10 provides. Costs of returned claims may include improper claims that reflect an attempt on the part of suppliers and providers to ''game'' the system. That is, during the period following the transition, some suppliers and providers may attempt to abuse and possibly defraud the payment system, hoping that improperly coded claims may slip through plans' payment edits. In

[26] RAND defines improper claims as those claims that could be fraudulent.

[27] CMS Medicare Returned Claims Report for FYs 2004, 2005, and 2006; Office of Financial Management.

[28] RAND, page 25.

[29] The National Health Expenditure accounts for private health insurance cost of administering insurance are in claims adjudications.

[30] RAND defines a claim cycle as the process a claim goes through from provider to payer.

discussion of the benefits of implementing ICD–10, we have treated the benefits for fewer returned claims and fewer improper claims separately. In this section, we combine the cost of the initial increase in returned clams with the expected increase in improper claims. Therefore, for purposes of this impact analysis, we estimate that the lost productivity costs for improper and returned claims for transitioning to ICD–10, is $543.29 million with a range estimate of a $274 million minimum and a $1.1 billion maximum.

We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

*C. Systems Changes*

Although system change requirements may vary, all would need to support the expanded number of characters in ICD–10–CM and ICD–10–PCS, as well as the number of available codes. Trading partner agreements and reimbursement policies would also impact system changes.

In implementing the ICD–10–CM and PCS coding systems, large providers and institutions will probably need to make changes to their systems as well as perform software upgrades, while small providers may require only software upgrades.

i. Providers and Software Vendors

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. For example, mainframe-based systems will require changes to accommodate the longer diagnostic and inpatient procedure codes which, in turn, will require changes to interfaces with other systems such as accounting and medical records. The new codes may also require the redesign of standard and special reports. Small providers who rely on super-bills, 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 codes. Given the information above, we expect that system changes will incur costs in the range of $55 million to $220 million.[31] Factors that contribute to the range of costs include: The degree of system integration; the need for outside technical assistance; and the number of systems and system interfaces that must be updated.

We assumed that implementation of the system changes upgrades would begin as early as 2 years in advance of the ICD–10 implementation date. We expect that large providers especially would need to begin this far in advance and that spending on system change in 2009 would equal $20.58 million and would represent 15 percent of total provider system change costs. In the next year, spending would double to 30 percent of provider system change expenditures and equal $41.16 million. In FY 2012, the year ICD–10 is to be implemented, we anticipate spending for system changes to amount to 50 percent of provider spending on system changes and equal $68.60 million. The year following implementation, we expect providers and suppliers with small systems and some large organizations will still be implementing changes or refining their changes. In that year, we are assuming that about 5 percent of the provider system change costs will be expended or $6.86 million. Thus, for purposes of this impact analysis, we estimate that from 2009 through 2012, the cost of system changes to providers for transitioning to ICD–10, is approximately $137.20 million, with a low range estimate of $55 million minimum and a $220 million maximum.

For small providers that are PC-based or have client-server systems that rely on vendor-supplied software, the provider may not bear any immediate costs for the software upgrades. Based on CMS's own experience with the industry, most software maintenance contracts offer free upgrades to accommodate regulatory changes. Thus, the impact on providers that have such contracts will be postponed until the contract is renewed. Even if a provider were to pay for the software upgrade directly, an ambulatory provider would only require updating of the diagnostic codes.

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. In interviews RAND conducted with industry experts including association representatives, providers, payers, software and service vendors, and government officials, two major software vendors said it would take 10 percent of their labor force, one saying it would be spread out over a 3-year period. Another stated that it would take 50 to 100 person-years.[32] Several other software vendors that RAND interviewed, however, stated that they expect that adaptation to the ICD–10 codes would only take a few person-years. Thus, based on RAND, we estimate the cost of system changes for software vendors of transitioning to ICD–10, to be approximately $96.05 million with a range of $55 million minimum and $137 million[33] maximum because of the wide range of information and billing systems and the configurations of provider systems.

As in the case with provider and supplier system change costs, we assume that beginning in FY 2009, software vendors will begin developing new software and continue the development and refinement through FY 2013. In FY 2009, vendors are assumed to spend 15 percent of the cost of software development or $14.41 million. In FY 2010, we anticipate vendors will spend 30 percent of the cost of software development or $28.81 million and in FY 2012, the year of implementation, we project vendors will expend 50 percent or $48.02 million. In the next year, spending will continue mostly for refinement and last minute upgrades. The expenditures are calculated to be $4.81 million and represent 5 percent of the software development costs.

ii. Payers

We estimate that changing payer systems to ICD–10 may be one of the largest cost categories, but the cost is not clear and the range is variable as payers represent a widely varied group. System change costs for payers are based on interviews that RAND conducted with eight different payers. (However, the ''List of Interviewees'' in Appendix B of the RAND report lists seven different payers, with a total of nine interviews). RAND divides the eight payers into three groups, based on their approach and estimate for system change. RAND does not disclose which payers fall into which of the three groups. The first group, which consists of three payers, representing 4 percent of the market, expects their vendors to supply the updates. The second group, which consists of three payers, representing 12 percent of the market, notes they would invest 40 cents per member. The third group, which consists of two payers, representing 3 percent of the market, estimates costs to be $1 per member. Using RAND's basic findings, we estimate the cost of system changes to payers for transitioning to ICD–10, is approximately $164.64 million with a range of $110 million minimum to $274

[31] RAND, page xiv.

[32] RAND, page 5.

[33] RAND, page xiv and page 17.

million maximum, based on the groups' market share estimates from RAND.[34]

iii. Government Systems Costs

Government systems change estimates are expected to occur across a number of Federal and State agencies and include Federal transition costs. Also, to make costs comparable to those of the private sector system changes, only costs for logic and format changes are considered. The examples in this impact analysis are only illustrative in nature and are based on limited analysis. They are presented to illustrate the potential administrative costs to the Federal Government.

For purposes of this impact analysis, we gathered information from various government agencies to determine total government systems costs for implementing ICD–10. Estimates for State Medicaid Agencies were gathered from the Center for Medicaid and State Operations (CMSO) within CMS and were derived based on the state's need to design, develop and implement changes to their systems to accommodate ICD–10 codes. Some government agencies are continuing to work on their cost estimates. As this information is still in the process of being analyzed and compiled, it is not included for purposes of this impact analysis. The costs outlined in Table 8, represent our best estimate based on the information available from CMS, the Indian Health Service (IHS), State Medicaid Agencies, and the Department of Veteran's Affairs (VA).

For purposes of this impact analysis, we estimate costs for the impact on government systems in transitioning to ICD–10 include system modifications, payment modifications, updates to software applications and training for a total minimum cost of approximately $315 million, with a minimum estimate of $157.5 million and a maximum estimate of $630 million. Table 8 shows the cost breakouts by government agency.

TABLE 8—GOVERNMENT COSTS

| Change | Government agency | Cost (in millions) |
|---|---|---|
| Systems/Software Modifications and Updates: | | |
| | CMS | $105 |
| | IHS | 8 |
| | VA | 19.05 |
| Subtotal | | 132.05 |
| Training: | | |
| | CMS | 9.5 |
| | IHS | 1.3 |
| | VA | 47 |
| Subtotal | | 57.8 |
| Planning: | | |
| | CMS | 4 |
| | IHS | 3 |
| | VA | 2.5 |
| Subtotal | | 9.5 |
| Other | | 12.6 |
| State Medicaid Agencies | | 102 |
| Total | | 315 |

We invite public comment on our assumptions, as well as comments from affected government agencies herein identified or those not identified in this analysis, so they may provide any additional and/or updated data that may improve the accuracy of our analysis.

(d) Distribution of ICD–10 Transition Costs

In the Table 9, we show the distribution of the transition costs to the ICD–10 codes for providers, suppliers, payers and software and system design firms. Entities are grouped by the North American Industry Classification System (NAICS) and are presented at the firm level. The NAICS figures were adjusted based on the same medical inflation factor we used for all costs that are outlined above.

As indicated earlier in this analysis, data was collected primarily by inpatient and outpatient categories (see Table 9). To allocate the transition costs, we have to use an available base which can serve as a proxy for apportioning the transition costs to the sub-groupings of inpatient and outpatient providers and suppliers. For the task of allocating the transition costs, we are using the revenue-receipts reported in the Services Annual Survey and the National Health Expenditure Accounts.

The first step was to group providers and suppliers by inpatient and outpatient groups reflecting the level at which the data was available. Inpatient providers included:

- Hospitals,
- Nursing facilities.

The group of outpatient providers and suppliers included:

- Physicians and other practitioners (excluding dentists),
- Outpatient care centers,
- Medical and diagnostic imaging services,
- Home health services,
- Other ambulatory health care services,
- Durable medical equipment suppliers.

In column 3, we present the revenue-receipts for each type of provider-supplier, insurance carrier-third party administrator, and computer design firm expected to bear transition costs. We summed the revenue-receipts for each of the inpatient and outpatient.

Column 4 shows the percent of the two groups' revenue-receipts each

[34] RAND, page 14.

provider-supplier type comprises of the group's total.

In column 5, we apply the percentages to the total ICD–10 transition costs for each provider-supplier type. Total inpatient transition costs—including productivity losses—from Table 9 equal $228.55 million. Total transition costs—including productivity losses—for outpatient providers-suppliers (from Table 9) equal $165.36 million, including an adjustment for inflation. It should be noted that physician costs include a portion of the coding training costs and productivity losses in addition to costs directly allocated to physicians and practices expenses. This explains the high percent of implementation costs to receipts-revenues than for the other outpatient providers-suppliers.

TABLE 9—ESTIMATED IMPACT OF ICD–10 TRANSITION COST ON INPATIENT AND OUTPATIENT PROVIDERS AND SUPPLIERS (ADJUSTED FOR INFLATION)

| NAICS | Provider/supplier type | Firms | Revenue/ receipts ($ mil.) | Percent of revenue receipts | ICD–10 costs ($ mil.) | 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 | 186.16 | 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 | 42.40 | 0.03 |
| | Subtotal | 27,276 | 801,749 | 100 | 228.55 | 0.03 |
| 6211 | Office of Physicians (firms) | 189,542 | 330,889 | 61.60 | 137.62 | 0.04 |
| 6214 | Outpatient Care Centers (Family Planning Centers, Outpatient Mental Health and Drug Abuse Centers, Other Outpatient Health Centers, HMO Medical Centers, Kidney Dialysis Centers, Freestanding Ambulatory Surgical and Emergency Centers, All Other Outpatient Care Centers). | 13,624 | 73,966 | 13.80 | 9.93 | 0.01 |
| 6215 | Medical Diagnostic and Imaging Services. | 7,811 | 37,253 | 6.93 | 5.00 | 0.01 |
| 6216 | Home Health Services | 14,512 | 47,007 | 8.75 | 6.31 | 0.01 |
| 6219 | Other Ambulatory Care Services (Ambulance and Other). | 5,872 | 24,593 | 4.58 | 3.30 | 0.01 |
| N/A | Durable Medical Equipment [3] | 404,293 | 23,709 | 4.41 | 3.18 | 0.01 |
| | Subtotal | 636,654 | 537,417 | 100 | 165.36 | 0.03 |
| 524114, 524292 | Health Insurance Carriers and Third Party Administrators [4]. | 4,578 | 723,412 | 100 | 164.54 | 0.023 |
| 5415 | Computer System Design and Related Services [6]. | 97,556 | 200,695 | 100 | 96.50 | 0.048 |
| | Subtotal | 102,134 | 924,107 | | 261.00 | 0.044 |
| | Total | 575,522 | 2,263,273 | | 655 | 0.031 |

Table notes: Most of the 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_Compendium.asp#TopOfPage.* Revenue data comes from the National Health Expenditures tables, 1960–2006, available at *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 subtotaled by ambulatory provider plus DME suppliers (NAICS 62111–6219) and inpatient providers (NAICS 622, 623) and the percent of the subtotaled revenue/receipts for the provider/supplier was computed and applied to the total ICD–10 implementation costs for each of two subtotaled 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.

In calculating the impact on provider/suppliers, payers, third party administrators and computer design and related service firms we compared the total expected costs to the one-year revenues for each class of entities. By

doing so, we deliberately overstate the expected annual impact of the transition. In part, we did this because we cannot be certain that we have properly allocated implementation costs to each entity category or that we accounted for all costs.

The impact on revenue-receipts of the transition to ICD–10 is shown. For inpatient providers, the impact will be an average increase against revenues of 0.03 percent. For outpatient providers and suppliers, the average increase against revenues is projected to be 0.03 percent.

The impact on insurance carriers and third party administrators is expected to be an increase against revenues of 0.023 percent. For system design firms, the impact against revenues is projected to be 0.048 percent.

Because we are not able to determine the exact number of third party administrator firms or system design firms that will be involved or have to implement the ICD–10 codes, we used the number of firms and revenues-receipts shown for the applicable NAICS. To the degree that fewer firms are actually involved in the transition to ICD–10, our estimate of the impact is understated. The fewer firms implementing ICD–10, the smaller number firms over which to spread the implementation costs. Therefore, we are specifically requesting comments on this estimate and how many third party administrators and computer design firms will be implementing ICD–10.

Table 10 outlines the approximate total estimated costs as outlined in the above sections. Table 10 shows both the minimum and maximum ranges for each cost as well as their corresponding primary estimates. We solicit comments from industry and other stakeholders on other potential entities that may be affected by the transition from ICD–9 to ICD–10 code sets.

TABLE 10—SUMMARY OF TOTAL ESTIMATED COSTS

[In millions]

| | Minimum | Maximum | Primary estimate |
|---|---|---|---|
| Training: | | | |
| Full-time Coders (Inpatient) | $110 | $165 | $137.51 |
| Part-time Coders (Outpatient) | $55 | $165 | $98.50 |
| Code Users | $27 | $55 | $37.50 |
| Physicians | $0 | $165 | $82.20 |
| Productivity Losses: | | | |
| Coders (Inpatient) | $0 | $55 | $8.90 |
| Coders (Outpatient) | $0 | $55 | $8.56 |
| Physician Practices | $5.5 | $27 | $10.98 |
| Improper and Returned Claims | $274 | $1,100 | $543.29 |
| Systems Changes: | | | |
| Providers | $55 | $220 | $137.20 |
| Software Vendors | $55 | $137 | $96.05 |
| Payers | $110 | $274 | $164.64 |
| Government Systems | $157.5 | $630 | $315.00 |

7. Projected Benefits

We identified six benefits of transitioning to ICD–10: [35]

- More accurate payments for new procedures:
- Fewer rejected claims;
- Fewer improper claims;
- Better understanding of new procedures;
- Improved disease management;
- Better understanding of health conditions and health care outcomes (no monetary estimate made); and
- Harmonization of disease monitoring and reporting world-wide (no monetary value was included in the analysis).

In our analysis, benefits begin to appear in the year following the implementation date. Therefore, our total estimated benefits differ slightly from RAND estimates, which assumed phased-in benefits prior to implementation. All benefit estimates, in addition to having a point estimate also have a wide high to low range because of the uncertainties inherent in these estimates. We have also adjusted benefit figures for the projected growth in the population using the growth in national health care expenditures for years 2005–2007. Year 2007 is an estimated growth rate of which we used an adjusted growth factor of 21.2 percent. For the growth projections for 2012 and beyond, we used the compounded growth in the U.S population which is projected to grow at 0.8 percent per year.

a. More Accurate Payments for New Procedures [36]

The transition to ICD–10–PCS codes will allow for more accurate payments for new procedures. Under the current ICD–9 Volume 3 procedure codes there is little room for additional codes. It has been estimated that at the current rate of adding additional codes, the capacity of ICD–9 Volume 3 will reach its maximum by 2009. The result is that new and possibly more complex and expensive procedures are being grouped in with less expensive procedures. With introduction of the PCS codes, it is more likely that such new procedures will receive a separate code and more appropriate payment. We assume that new procedures that could receive a separate code under the PCS system are so expensive they would be unlikely to be performed unless, through the new coding, the hospital received adequate payment.[37]

Of the approximately 20 million procedures performed each year, roughly one percent or 200,000 procedures are new. We estimate that 100,000 of the new procedures would be paid for by CMS based on the fact that Medicare pays for approximately one half of all inpatient procedures. Examining the historical trend for the number of new codes assigned each year, we determine that about one percent of new procedures received separate codes. Using this one percent assumption, the 200,000 new procedures would be represented by approximately 36 new codes (one percent of the 3,600 current procedure

[35] RAND, page 19.

[36] RAND, page 21.

[37] RAND, page 21.

codes in the ICD–9 Volume 3). We assume that three procedures would be performed frequently enough to be given their own codes. We also assume the three procedure codes would represent about 40 percent of the annual number of new procedures.[38]

Subtracting out 40 percent of the procedures from 100,000 new procedures that CMS would pay for each year leaves 60,000 procedures represented by 33 codes that, under the current coding structure, may be inappropriately grouped and paid an inappropriate amount. For purposes of this analysis, we recognize that the odds that hospitals would not perform a procedure that was seen to have therapeutic value in spite of being underpaid are low. For this reason, we assume that in 10 percent or 6,000 of the cases involving new inpatient procedures that are not adequately reimbursed, hospitals may be disinclined to admit patients requiring the procedure.

Finally, we estimate the opportunity cost of foregoing those procedures that would be undervalued under the current coding structure (and presumably would be properly paid under the PCS codes). Of 33 procedures that are undervalued, some may yield significant health benefits while the majority will yield small health benefits. Hospitals are more likely to perform the high benefit procedures even though they may be underpaid for the procedures.

We assume that the average procedure costs approximately $12,120 and has a net benefit yield of $6,060. Multiplying the amount by the 6,000 procedures yields a benefit of approximately $36 million.[39] We also expect that the effects of the benefit are cumulative for each year and that every year, 6,000 procedures will be added.

Based on a growth rate of 6,000 per year, the growth in benefits would equal 50 fold or $1.8 billion in 10 years. This may overstate the benefits because of cost reduction over time due to the learning curve and the introduction of lower cost alternative procedures. Rather than an increase of 50 times, a factor of 25 is used, resulting in an estimate of $909 million. For purposes of this impact analysis, we make a more conservative assumption. After the third year following implementation of the code conversion we assume an opportunity cost that increases $12 million every year, with the fourth year showing approximately $62 million benefit (see Table 13b). For purposes of this impact analysis, we estimate that the benefit of more accurate payments for new procedures would equal approximately $1,032 million with a minimum range estimate of $121 million and a maximum estimate of $1,455 million.

We recognize that many assumptions underlie our estimates of more accurate payments and we invite comments on this analysis.

b. Fewer Rejected Claims

The Workgroup for Electronic Data Interchange (WEDI) has stated that ''[The] greater detail [of ICD–10–CM and ICD–10–PCS] may help reduce the number of cases where copies of the medical record need to be submitted for clarification for claims adjudication.'' [40] For example, in ICD–10–CM, the injury codes provide excellent detail in identifying the fracture site of a malunion or non-union; the ICD–9–CM codes for malunion and non-union do not identify fracture site. If the payer required this information to adjudicate the claim, the provider would need to send a claims attachment. Also, in ICD–10–CM, the injury codes provide excellent detail in identifying bilateral fractures. If a patient fractured both wrists, two codes could be assigned; one code identifying the left wrist fracture and a separate code identifying the right wrist fracture could be reported. ICD–9–CM does not provide this detail and if a provider wanted to report fractures of both wrists and reported the diagnosis code twice, the claim would be rejected.

Based on the WEDI assumption, we estimate the average cost per cycle of processing a claim at a total of $12 billion per year for all claims. RAND makes the assumption that using ICD–10 code sets would decrease the amount of claims sent back by one percent. This gives a $120 million annual benefit (0.01 x 12 billion).[41]

For purposes of this impact analysis, we estimate approximately $100 million per year in benefits after phased-in benefits for the first four years, compounded annually by a 0.8 percent growth in the population. We assume an extended phase-in for this benefit because of the lag time in receiving claims data showing the effects of the new system that will lead to delays in taking advantage of the improved and more precise data.

We also assume that returned claims will temporarily increase in the initial years. We discussed the temporary increase of returned claims in section b. iv., above, under Productivity Losses.

For purposes of this impact analysis, we estimate that the benefit of fewer rejected claims would equal approximately $1,015.41 million with a minimum range estimate of $242 million and a maximum estimate of $3,031 million. We invite the public to comment on our assumptions and to provide any data that will improve the accuracy of our analysis.

c. Fewer Improper Claims

The distinction that we are seeking to make in this section is between claims that would be returned because of mistakes in coding resulting from confusion about the new codes, lack of training and experience with the new codes, and those claims that appear to be deliberately miscoded in an attempt to defraud or abuse the payment system. WEDI states that, despite an initial expectation of increased improper claims, ''In the longer term, it is possible that fraud could be reduced since ICD–10–CM and ICD–10–PCS are more specific and there are fewer 'gray' areas in the coding.'' [42] The amount of improper claims due to abuse is estimated to be $3.03 billion annually, approximately 20 percent of the $15.8 billion that GAO estimates are improperly paid each year.[43] GAO acknowledges that this number may not represent all improper payments. Given this, we assume that eight percent of payment system abuse is perpetrated by people who capitalize on the ambiguity of the ICD–9–CM codes.[44] We also assume that half of that eight percent would feel that the new codes would eliminate the ambiguity, eliminating half of these abuses, assuming that new ambiguities are not created.

We estimate that after phased-in benefits in the first four years after implementation, which compounded annually by an 0.8 percent population growth factor, 100 percent of the benefit will be reached in the fifth year after implementation. We assume an extended phase-in for this benefit because of the lag time in receiving claims data showing the effects of the new system that would lead to delays in taking advantage of the improved and more precise data.

For purposes of this impact analysis, we estimate that the benefit of fewer

[38] RAND, page 22.

[39] RAND, page 23.

[40] ''Issues Surrounding the Proposed Implementation of ICD–10.'' WEDI MHHSh 2000, page 9.

[41] RAND, page 23.

[42] RAND page 26.

[43] RAND, page 26 and GAO, Federal Budget, ''Opportunities for Oversight and Improved Use of Taxpayer Funds,'' Statement of David M. Walker, Comptroller General of the United States, GAO–03–922T, *http://www.gao.gov/new.items/d03922t.pdf*, accessed 8–12–08.

[44] RAND, page 26.

improper claims will equal approximately $508.22 million, with a range minimum estimate of $121 million and a maximum estimate of $1,455 million.

As with rejected claims, this benefit is also expected to be an initial cost as people take advantage of the ambiguity during transition to ICD–10 code sets. For purposes of this impact analysis, there may be a greater number of returned claims as well as an increase in the percentage of initial improper payments. In Table 13a, we show the expected effects of the initial impact of rejected and improper claims. We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

d. Better Understanding of New Procedures [45]

Benefits are also anticipated due to better understanding of new procedures with ICD–10. The rationale is that ICD–10's granularity would aid statistical analysis and provide more information on disease treatments and outcomes. We estimate the number of procedures that would be identified only in ICD–10–PCS and would provide statistically significant differences in outcomes. That is, identification of procedures through the use of the ICD–10 codes could presumably enable statistical analysis of procedures that would not otherwise be possible and thereby become the subject of research. Through a series of assumptions regarding 200,000 occurrences of the ''significant'' new procedures that would be added each year (see the discussion above regarding more accurate payment for new procedures), we pare the number of procedures that would actually be changed as a result of research down to 16,000 procedures.[46] The assumptions apply to the elimination of high volume procedures (again, see the discussion on more accurate payment for new procedures), the probability that anomalies would be discovered only through the application of ICD–10 codes and that finally such anomalies would result in the change in medical practice. The results of the research could indicate that procedures that were considered appropriate are now found to be inappropriate for the patients that underwent the procedure. Similarly, the research may find that procedures that were believed to be inappropriate may now be thought to be appropriate.

Finally, applying the same net benefits used in the analysis of more accurate payments of new procedures, we conclude after phased-in benefits in the first three years following implementation, which compounded annually by an 0.8 percent growth in the population, 100 percent of the benefit will be realized in the fourth year.

For purposes of this impact analysis, we estimate that the benefit of a better understanding of new procedures with implementing ICD–10, would equal approximately $812.54 million with a minimum range estimate of $121 million and a maximum estimate of $1,819 million. We invite the public to comment on our assumptions and to provide any data that may improve the accuracy of our analysis.

e. Improved Disease Management [47]

Disease management programs are generally used for managing chronic diseases to prevent or delay serious complications. The increased granularity of ICD–10–CM would allow case management organizations to better identify candidates for disease management programs, and to better adapt the disease management program to the individual once enrolled. To estimate improvements in disease management that the ICD–10 conversion could bring about, we follow RAND's use of diabetes as the sample disease and their assumption that two-thirds of all the benefit would come from better management of this disease.

For purposes of this analysis we follow the RAND model that divides diabetics into Type I and Type II not currently in a disease management plan and who could benefit from participating in such a plan; and those in a disease management plan and who could benefit from improved management of their disease. RAND makes the following assumptions:

- 60 percent of diabetics are currently enrolled in plans with disease management programs;
- 50 percent of the patients in such plans are not in a disease management program (30 percent);
- 50 percent of plans use a system other than ICD to identify and classify their patients. Of the remaining half, 2/3 use (1/3 of the total) use ICD classifications;
- Use of ICD–10 reveals new information on 20 percent of Type II diabetics in plans using ICD classifications;
- 50 percent of these patients elect to participate in the disease management program;
- 20 percent of those newly enrolled in a disease management program, achieve sufficient improvement to increase their life expectancy by six months.
- For patients already in a disease management program, using ICD–10 will result in an improved program in 50 percent of the patients.
- 10 percent of Type I and Type II will achieve improvements to the point of Type I achieving two additional years of full quality life and Type II six additional months of full quality life.

We estimate the number of both Type I and Type II diabetics at 1.2 million and 22.8 million,[48] respectively. Using these numbers as a base, we can arrive at an annual estimate of benefits. Applying RAND's formulas in this case, we determine that approximately 45,144 Type II individuals per year who would gain six months of full quality of life valued at $100,000 per year.[49] This yields a benefit of $2.257 billion ($50,000 × 45,144) for those Type II diabetics not currently enrolled in a disease management plan but who would be enrolled as a result of the conversion to the ICD–10 codes.[50]

The benefit of the greater granularity that use of ICD–10 codes may offer for those who are currently enrolled in a disease management plan is greatly dependent upon how much the additional detail helps the enrollee, and how many enrollees are helped. We could create an assumption for the percentage of people who would be enrolled in a better plan based on the new information that ICD–10 codes may provide, and the percentage of those whose treatment would be adjusted in response to the new information.[51]

We could potentially conclude that adding someone to a diabetes management program has twice the benefit of adjusting treatment for someone already enrolled in a disease management program. As a result of the code conversion, it is possible that, for example, 1,188 individuals with Type I diabetes would gain 2 years of life while 22,572 individuals with Type II diabetes

[45] RAND, page 28.

[46] This is an absolute value concept which applies to both procedures done and not done. RAND, page 9.

[47] RAND, page 30.

[48] *http://www.cdc.gov/media/pressrel/2008/r080624.htm*, accessed 8–12–08

[49] Based on research that Viscoosy and others have done on the value of a statistical value of life, $50,000 for a year of full quality of life appears to be conservative. We have updated the estimated a statistical life year based on inflation since RAND examined the issue based on the value that HHS has used in a number of regulations.

[50] RAND, page 30.

[51] This is different from RAND's parameter of 0.1, but was confirmed through discussions with the authors.

would gain 6 months of full quality life. We attribute the difference in longevity to the fact that Type I diabetes usually manifests itself in younger persons. Changes made earlier in a person's life will have a longer deterioration curve by about two years than changes made later in a person's life.

When we combine the parameters, we could realize an annual benefit of $237.6 million for Type I diabetes and $1.1286 billion for Type II diabetes already in a plan for a total of $1.3662 billion. We could potentially show an annual benefit for better management of diabetes to be $3.6234 billion ($2.2572 billion from new Type II patients enrolled in disease management + $1.3662 billion from improved disease management of Type I and Type II patients already in a plan).

Finally, we could share RAND's assumption that the diabetes benefit is about two-thirds of the total benefit for improved case management attributable to converting to ICD–10. Under RAND's assumption the total annual benefit for improved disease management would be $5.4351 billion. We assume a phase-in of benefits prior to the fourth year of implementation where 100 percent of the benefit is realized in the fourth year after implementation.

The aforementioned scenario is based upon our interpretation of RAND's scenario that the benefit of improved disease management could conceivably be expected from ICD–10–CM and ICD–10 PCS code sets applied to the sample disease, diabetes. However, although we agree that the potential benefits of disease management could be large, we do not necessarily agree with the calculations used in RAND's theory because we believe they assume much greater benefits than can be directly attributable to the ICD–10 code set alone, such as the development of new and improved diabetes drugs or improved patient outreach, monitoring and communications. RAND also does not take into account disease management benefits from across the full clinical spectrum. For purposes of this analysis, we very conservatively claim a one percent benefit of our total disease management calculations based on RAND's formulas, and solicit feedback from the industry on this assumption.

Therefore, for purposes of this impact analysis, we estimate that the total benefit of improved disease management may equal approximately $582.57 million with a minimum range estimate of $291 million and a maximum estimate of $1,165 million.

f. Better Understanding of Health Conditions and Health Care Outcomes

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. For quality improvement programs to effectively result in meaningful clinical outcomes, improved practice management processes that document and measure patient care, and sustain provider investment in services that improve quality of care, the ability to modify or add to a list of treatments, diseases and conditions is essential. The ICD–10 code sets provide a standard coding convention that is flexible, providing unique codes for all substantially different procedures or health conditions and allowing new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols.

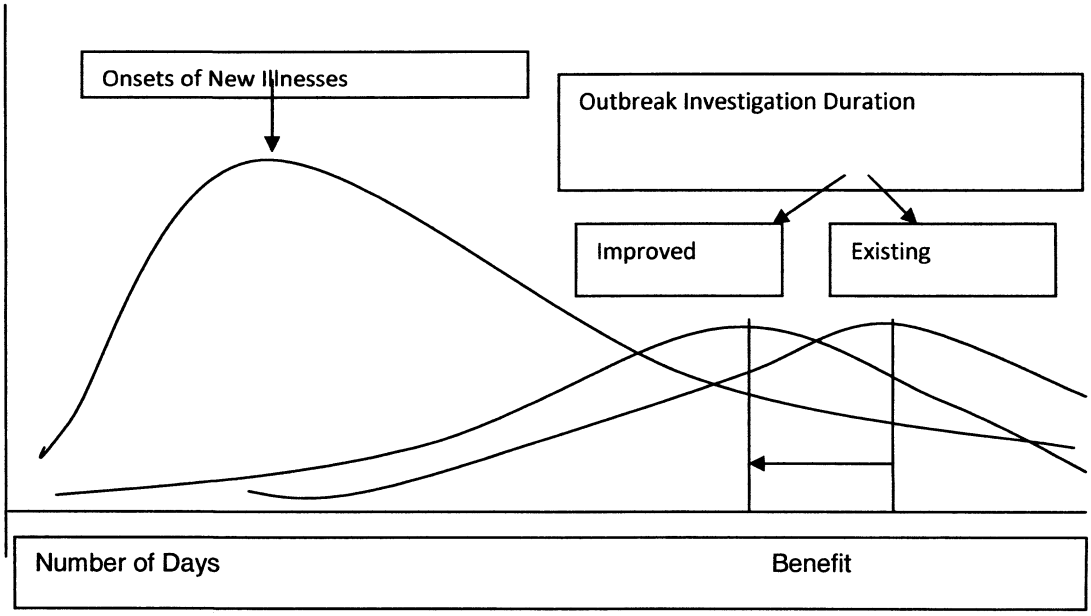
g. Harmonization of Disease Monitoring and Reporting World-Wide

Another benefit we expect will be achieved with the implementation of the ICD–10–CM codes is better coordination of disease outbreak reporting with other countries. Most industrialized countries have adopted the ICD–10 code structure and, with the United State's adoption of the codes, the time to identify and respond to cross-border disease outbreaks will be reduced. We will be able to process public health warnings coming from other countries faster and be able to respond more accurately to the threats because of the greater precision of the coding compared to ICD–9.

Below is a chart that illustrates the reduction in response time we expect to achieve from the implementation of ICD–10–CM codes. After the outbreak of an illness occurs, as represented by the large curve on the left of the chart, there is a reporting lag and a further delay for the processing and analyzing of reports and the mounting of a response. The sooner outbreaks are reported to public health officials and the more accurate the information that is reported, the faster officials can respond. The two smaller curves on the right side of the chart represent the time between outbreak and response under the current coding and the enhanced response time. The shift to the left of the response time represents the benefit in terms of the short response time and outbreak.

The following chart was originally published in an FDA rule, ''Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' It was published in the **Federal Register** on December 9, 2004 (Vol. 69, No. 236; Rules and Regulations 71615) and was adapted for use in this regulation.

**Table: 11 Improvement in Response Time to Cross-Border Public Health Warnings of Disease Threats as a Result of ICD-10 Implementation**




Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods

These benefits would expand communication and interoperability capabilities for biosurveillance and disease reporting at an international level. As noted in a recent report, *The Effectiveness of ICD–10–CM in Capturing Public Health Diseases,* ''* * * the use of ICD–10–CM has great implications for our entire nation since public health diseases, which include epidemic and other diseases related to bioterrorism, are generally able to be captured in a more specific way when using the ICD–10–CM system.'' [52] BioSense, CDC's early event detection system, currently uses ICD–9–CM. Improved clinical detail would be a benefit to a national system designed to improve the nation's capabilities for disease detection, monitoring, and real-time health situational awareness.

As noted in the May 2004 NCVHS Workgroup on Quality Report, titled ''Measuring Health Care Quality: Obstacles and Opportunities'', most other industrialized nations have already transitioned to ICD–10, requiring a painstaking crosswalk of United States diagnosis codes to make international comparisons.

However, even with a crosswalk, comparisons are problematic given that changes to ICD–10 which represent a new understanding of disease (such as the myeloproliferative disorders and myelodysplastic syndrome now being recognized as hematologic malignancies which are classified as neoplasms of uncertain behavior in ICD–9–CM) affect data analysis at the State, national and international level.

Because the U.S. does not currently use ICD–10–CM and ICD–10–PCS, there is insufficient data to quantify the results of these benefits. For additional discussion of biosurveillance, refer to section III.

Table 12 below outlines the total estimated benefits as outlined in the above sections. The table shows both the minimum and maximum ranges for each benefit as well as their corresponding primary estimates.

TABLE 12—SUMMARY OF TOTAL ESTIMATED BENEFITS

| | Minimum | Maximum | Primary estimate |
|---|---|---|---|
| More accurate payments for new procedures | $121 | $1,455 | $1,032 |
| Fewer rejected claims | 242 | 3,031 | 1,015.41 |
| Fewer improper claims | 121 | 1,455 | 508.22 |
| Better understanding of new procedures | 121 | 1,819 | 812.54 |
| Improved disease management | 291 | 1,165 | 582.57 |

[52] ''The Effectiveness of ICD–10–CM in Capturing Public Health Diseases.'' AHIMA, *Perspectives in Health Information Management 2007* (June 12, 2007), *http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_036019.html*, accessed 8–12–08.

*C. Alternatives Considered*

As discussed in detail in section VII of the preamble of this proposed rule, we considered a number of options for replacing ICD–9. We considered extending the life of ICD–9–CM by utilizing unassigned codes, use of CPT–4 for coding inpatient hospital procedures, and waiting to adopt ICD–11 as alternatives to the adoption of ICD–10–CM and ICD–10–PCS. We determined that adopting ICD–10–CM and ICD–10–PCS was the only viable alternative that would meet the long-term coding needs of the health care industry.

1. Relation to and Impact on Other HIT Initiatives

Both Federal and private-sector stakeholders prefer synchronization of related Federal HIT initiatives to permit adequate planning, resources, and implementation. Because implementation of ICD–10 is a massive undertaking, these initiatives should be queued up as rationally as possible. Most of the initiatives related to the adoption of ICD–10 involve promulgation of regulations and compliance dates. In this respect, there is minimal flexibility when some regulations may be promulgated and related compliance dates. Under sections 1860D–4(e)(1), 1860D–4(e)(3) and 1860D–4(e)(4)(D) of the Act, we were required to promulgate uniform standards for e-prescribing not later than April 1, 2008. Not later than one year after promulgation of such final standards, prescriptions and other prescription-related information for drugs covered under Medicare Part D and for individuals eligible for Part D benefits must be transmitted only in accordance with such standards. We anticipate that most of this regulatory activity will take place in 2008. At the same time, there are a number of related Departmental and private sector initiatives that will be ongoing during this time period, although specific dates are not available at this time. During the next several years, for instance, we anticipate that the Certification Commission for Healthcare Information Technology (CCHIT) will be completing and updating certification criteria for ambulatory EHRs, inpatient EHRs, and health information networks. CCHIT has already developed certification criteria for ambulatory EHRs and inpatient EHRs and has already begun certifying both types of products. CCHIT has also begun developing certification criteria for networks. Once CCHIT has established the certification criteria, it plans to update them on a yearly basis to align its efforts with the standards harmonization efforts of the Healthcare Information Technology Standards Panel (HITSP).

HITSP seeks to achieve widely accepted and readily implemented consensus-based standards that will enable and support widespread interoperability among health care information technology users, especially as they would interact in a Nationwide Health Information Network (NHIN) for the United States. On October 31, 2006, HITSP presented three sets of ''interoperability specifications'' to the American Health Information Community (AHIC), a Federal advisory committee chartered to make recommendations to the Secretary on methods for accelerating the development and adoption of health information technology. The AHIC considered HITSP's presentation, and after reaching consensus, recommended to the Secretary that he recognize certain interoperability specifications. On March 1, 2007, the Department published a Notice of Availability (72 FR 9339), identifying the recommended specifications, and indicating the Secretary's acceptance and anticipated recognition of the interoperability specifications. In January 2008, following a one-year period of implementation testing, the Secretary announced his formal recognition of HITSP interoperability specifications (*http://www.hitsp.org/government.aspx*, accessed 8–12–08.)

Both CCHIT and HITSP have developed processes that build industry consensus and support voluntary adoption of health information technology standards. By ''recognizing'' interoperability standards, the Secretary is also advancing the adoption of health IT standards within the Federal government and among many of its contractors (See Executive Order 13410—Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs), and for certain entities seeking to donate EHR software and training services in compliance with the Stark EHR Exception and the Anti-Kickback EHR Safe Harbor (See 71 FR 45140 and 71 FR 45110). Finally, trial implementations of the Nationwide Health Information Network (NHIN), including specifications and testing of interoperable health information exchange, are proceeding.

The implementation of ICD–10 will promote the use of HIT and increase the overall value of EHRs. Updating a coding system to a more rigorous and exact coding system such as ICD–10 results in the ability to more accurately understand changes in medical technology, treatment patterns, disease spread, and outcomes of quality measures. The detail and precision of the ICD–10 codes will allow for any necessary updates to quality measures, payment systems, fraud prevention and clinical decision support mechanisms. ICD–10 is already included in the HITSP electronic health record (EHR) use case, and as an administrative standard it will drive change as it will be required for use on all claims.

ICD–10 impacts on HIT initiatives might come in the form of the industry needing time to become comfortable with the new codes, resulting in benefits being reaped 1–2 years after implementation. While there will be resource impacts on other HIT initiatives as a result of the ICD–10 implementation, there will be greater impacts if ICD–10 is delayed and more EHR systems need to be retrofitted.

CMS solicits industry and stakeholder comments on the direct and indirect impacts to current Health Information Technology initiatives.

Tables 13a and b below outline the total estimated benefits and costs as outlined in the above sections. The table illustrates in which years we believe each cost and benefit will be realized.

**Table 13a: Estimated Annual Costs for Years 2009-2023 (in millions and adjusted for inflation)**

| Estimate Costs for Years 2009 - 2023 (in millions) | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | Total |
| **Training** | | | | | | | | | | | | | | | | |
| Full-time Coders/Inpatient | 0.00 | 20.63 | 103.13 | 13.75 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 137.51 |
| Part-time Coders/Outpatient | 0.00 | 9.85 | 78.76 | 9.85 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 98.50 |
| Code Users | 0.00 | 3.75 | 30.00 | 3.75 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 37.50 |
| Physicians | 0.00 | 8.22 | 65.76 | 8.22 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 82.20 |
| **Productivity Losses** | | | | | | | | | | | | | | | | |
| Coders-- Inpatient | 0.00 | 0.00 | 8.90 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 8.90 |
| Coders--Outpatient | 0.00 | 0.00 | 8.56 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 8.56 |
| Physician Practices | 0.00 | 0.00 | 10.98 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 10.98 |
| Improper and Returned Claims | 0.00 | 0.00 | 0.00 | 329.29 | 164.64 | 49.39 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 543.29 |
| **System Changes** | | | | | | | | | | | | | | | | |
| Providers | 20.58 | 41.16 | 68.60 | 6.86 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 137.20 |
| Software Vendors | 14.41 | 28.81 | 48.02 | 4.81 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 96.05 |
| Payers | 24.70 | 49.39 | 82.32 | 8.23 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 164.64 |
| Government | 47.09 | 94.18 | 156.98 | 15.70 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 315.00 |
| **Total** | 106.78 | 255.99 | 662.01 | 400.46 | 164.64 | 49.39 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 1640.33 |

**Table 13b: Estimated Benefits for Years 2009 - 2023 (in millions and adjusted for inflation)**

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| More accurate payments for new procedures | 0.00 | 0.00 | 0.00 | 0.00 | 18.30 | 49.16 | 61.94 | 72.85 | 83.92 | 95.16 | 106.58 | 118.18 | 129.95 | 141.91 | 154.05 | 1032.00 |
| Fewer Rejected Claims | 0.00 | 0.00 | 0.00 | 0.00 | 25.40 | 51.21 | 82.60 | 104.06 | 104.90 | 105.74 | 106.58 | 107.43 | 108.30 | 109.16 | 110.03 | 1015.41 |
| Fewer improper Claims | 0.00 | 0.00 | 0.00 | 0.00 | 13.21 | 25.60 | 41.30 | 52.03 | 52.45 | 52.87 | 53.29 | 53.72 | 54.15 | 54.58 | 55.02 | 508.22 |
| Better understanding of new procedures | 0.00 | 0.00 | 0.00 | 0.00 | 12.19 | 32.77 | 82.60 | 83.25 | 83.92 | 84.59 | 85.27 | 85.95 | 86.64 | 87.33 | 88.03 | 812.54 |
| Improved Disease Management | 0.00 | 0.00 | 0.00 | 0.00 | 16.57 | 44.53 | 56.11 | 56.56 | 57.01 | 57.47 | 57.93 | 58.40 | 58.86 | 59.33 | 59.80 | 582.57 |
| Total | 0.00 | 0.00 | 0.00 | 0.00 | 85.67 | 203.27 | 324.55 | 368.75 | 382.20 | 395.83 | 409.65 | 423.68 | 437.90 | 452.31 | 466.93 | 3950.74 |

**Table 14: Net Benefits and Cumulative Net Benefits (in millions and adjusted for inflation)**

| | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Net Benefits | (106.78) | (255.99) | (662.01) | (400.46) | (78.97) | 153.88 | 324.55 | 368.75 | 382.20 | 395.83 | 409.65 | 423.68 | 437.90 | 452.31 | 466.93 |
| Cumulative Net Benefits | (106.78) | (362.77) | (1024.8) | (1425.24) | (1504.21) | (1350.33) | (1025.78) | (657.03) | (274.83) | 121.00 | 530.65 | 954.33 | 1392.23 | 1844.54 | 2311.47 |

*D. Regulatory Flexibility Analysis*

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires that the Secretary certify that a proposed regulation will not have a significant economic impact on a substantial number of small entities. In the health care sector, a small entity is one with between $6.5 million and $31.5 million in annual revenues or is a nonprofit organization. For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of the proposed regulation.

Because most medical providers are either nonprofit or meet the SBA's size standard for small business, we treat all medical providers as small entities.

1. Alternatives Considered

As mentioned in section VII of the proposed rule, we considered various policy alternatives to adopting ICD–10–CM and ICD–10–PCS. One alternative that was considered included the use of unassigned codes. Although it may be possible to extend the life of ICD–9–CM by assigning codes to new diagnoses and procedures without regard to the hierarchy of the code set, it does not represent a long-term solution and will only be effective as long as there are empty code slots. Moreover, it does not address the remaining shortcomings of ICD–9–CM such as the critical lack of detail that is required to support evolving business needs and advanced technology.

Another alternative that was considered included the use of CPT–4 for coding hospital inpatient procedures. Both the National Committee on Vital and Health Statistics (NCVHS) and GAO found structural problems and serious flaws with CPT–4 for coding inpatient hospital procedures since the system could not capture all services in all health care settings.

A final alternative that was considered was waiting and adopting ICD–11, which is not a feasible option since the WHO is in their earliest stages of development with the earliest projection of the completion being 2016. However, based on past experience with the development of ICD–10 being several years late, it is anticipated that this date will slip. The U.S version would then need to be developed requiring additional analysis, which could take a minimum of 3–5 years (optimistically). It is not expected that ICD–11 will be available for use in the U.S. until at least 2020.

We considered a number of options for implementing the transition to ICD–10 but rejected them as being too costly and too burdensome. One of the options we considered included phasing in the implementation of the new codes either by geographic region as Canada and Australia did, or by provider/supplier category. We rejected these alternatives because it 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 the ICD–9 and ICD–10 coding systems for an extended period of time. Code users in national payer

plans would have to learn the new ICD–10 codes at the same time work with the old ICD–9 codes, which would increase the chance of errors in payments, create confusion and uncertainty in the providers/supplier community and result in delays in processing claims. We believe the cost of maintaining two systems running concurrently would impose a very significant burden on plans and providers/suppliers.

Another option for implementing the transition to the new coding system is to maintain both the ICD–9 and ICD–10 systems for a period of time. We rejected this alternative for many of the same reasons we rejected phasing in the ICD–10 code sets. Maintaining two systems imposes a significant burden on payers and providers/suppliers as well as creates conditions for increased coding errors and payment delays. In addition, because Medicare updates the ICD codes on October 1 of each year, implementation of any new codes must take place on that date. Given the risks for error and the added costs, there seems to be little benefit to be gained from providing the opportunity for parallel coding systems beyond the October 1 deadline being proposed in this rule.

A third option that was considered and rejected was to delay implementation for small entities. However, because we treat all heath care providers/suppliers as small entities, we did not see any benefit to be gained from delaying implementation of the ICD–10 code sets beyond the four-year implementation period being proposed in the rule. Delaying implementation would only have an adverse effect on implementation of other standards that use the ICD codes. Those standards and the systems built around those standards would either have to be pushed off further into the future or have to be revised and redesigned to accommodate the ICD–10 code sets. The costs of such delays could be substantial. Therefore we rejected this option for ICD–10 implementation.

2. Number of Small Entities

Two hundred nonprofit health care organizations that offer 213 plans are considered small entities because of their nonprofit status. Practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $6.5 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*, accessed 8–12–08) lists 97 billing companies on its Web site. It notes that these are the only companies with Web sites. The Statistics of U.S. Businesses data shows that there are 97,556 firms involved in system design and related services (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 9 above (see section XI.B.6.d) presents the impact of the ICD–10 implementation costs on all entities we anticipate will be affected by the rule. Because we consider all health care provider-suppliers as small entities, Table 9 shows that the proposed rule will not have a significant impact on a substantial number of small health care entities. The following table (Table 15) summarizes the results from Table 9 for inpatient and outpatient providers/suppliers.

TABLE 15—IMPACT ON INPATIENT AND OUTPATIENT PROVIDER-SUPPLIERS

| Providers/suppliers | Firms | Revenue-receipts ($ millions) | ICD–10 costs (million $) | % ICD–10 cost of revenue receipts |
|---|---|---|---|---|
| Inpatient | 27,276 | 801,749 | 228.55 | 0.03 |
| Outpatient | 635,654 | 537,417 | 165.36 | 0.03 |

To determine the impact on small insurance carriers, third party administrators and system design and related services 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.

Using the Statistics for U.S. Businesses for firm sizes by number of employees for 2005 (the latest year for which the Census Bureau reports payroll), we combined total annual payroll reported for NAICS 524114 and 524292 for a total of $32.5 billion (*http://www.census.gov/epcd/susb/2005/us/US—.HTM*, accessed 8–21–08) Taking the total premium payments made to health insurers reported for 2006 (the latest year for which CMS has insurance premium data) in the National Health Expenditure Report of $723.4 billion (*http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp*, accessed 8–12–08), we divided total insurance premiums by total payroll to arrive at a ratio of annual health insurance receipts to annual payroll of 22.3.

Applying the ratio to the reported annual payroll for the employee size categories and dividing by the number of firms in each category, we found that firms with between 10 and 19 employees had average annual receipts of $8.3 million.

Based on the method for computing annual receipts for firms by the number of employees, we estimate that 71 percent of insurers and third party administrators account for 2.5 percent of annual receipts. Applying this percent to the projected costs of system changes for payers found in Table 13a, the costs to small insurers and third party administrators is expected to be a total of $4 million for the anticipated four-year implementation period. Thus, the annual cost is expected to be approximately $1 million or 0.01 percent of revenues.

We applied the same approach for system design and related computer services firms and used 2006 receipt data from the Statistics of U.S. Businesses Annual Survey for NAICS 5415 in place of the National Health Expenditure data, *http://www.census.gov/svsd/www/services/sas/sas_data/sas54.htm*, accessed 8–12–08). Dividing total annual receipts by total annual payroll, we applied a ratio of 2.4468 to the annual payrolls of the various employee size categories and

found that firms with between 100 and 499 employees had average annual receipts of $27.7 million. Total annual receipts for all small entities equal $107 billion which represents 53.3 percent of total annual receipts for the NAICS category. By comparison, the number of small entities represents 99.3 percent of all firms in this category.

Taking the small entity receipt ratio to total receipts and applying it to the expected ICD–10 implementation costs, we find that the cost to small entities equals $51.5 million over the four year implementation period or $12.9 million per year. As a percent of receipts, this equals 0.1 percent.

As we pointed out in discussing the effects of the total costs on third party administrators and system design computer firms, we do not know how many firms will actually be involved in implementing the ICD–10 coding system. For purposes of the analysis, we assume that all firms reported in the Statistics of U.S. Businesses for the NAICS codes we are examining will be participating in the implementation of the codes. Since it is possible we could be including more firms than will be implementing the codes, our impact estimate on small entities may be understated. To test the sensitivity of the impact of the implementation costs on small firms, we assumed that burden would equal three percent of revenues. HHS policy states that if a rule imposes a burden equal to or greater than three percent of a firm's revenues, it is significant (see: ''Guidance on Proper Consideration of Small Entities in Rulemakings of the U. S. Department of Health and Human Services'' at *http://www.hhs.gov/execsec/smallbus.html*, accessed 8–12–08). We assumed that the small business share of the market would remain constant at 53 percent and that the $12.8 million costs we expect small firms to incur will be distributed equally. Using these assumptions, we computed the amount of small entity revenue such that the ICD–10 small entity share would equal three percent—$429 million. We then calculated the percent of $429 million that is the small entity share of the revenue and multiplied the results by the number of small entities (see Table 16). From this analysis we estimate that if only 389 or fewer small firms provide computer and software services, the burden could be significant.

We note that the regulation would not impose any compliance requirements on system design and related services firms and, while the firms may have to wait for some period of time before they are compensated for their services because of contract agreements, they should eventually be able to pass on some or all of their costs on to their customers. In order to determine if these estimates are accurate, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the ICD–10 code sets.

Table 16 below summarizes the impact of the rule on small insurance carriers, third party administrators, and system design and related computer design firms.

TABLE 16—PAYERS AND COMPUTER DESIGN AND RELATED SERVICES

| NAICS | Payers and system design and related services | Firms | Small entities | Revenue/ receipts ($ millions) | Small entity receipts (in millions $) | % Small entity receipts of total receipts | Annual ICD–10 costs (in millions) | Small entity share of ICD–10 Costs (in millions $) | % Small entity implementation cost/ revenue receipts |
|---|---|---|---|---|---|---|---|---|---|
| 524114, 524292. | Health Insurance Carriers and Third Party Administrators. | 4,578 | 3,449 | 723,412 | 18,309 | 2.53 | 41.13 | 1.04 | 0.01 |
| 5415 ..... | Computer Systems Design and Related Services. | 97,556 | 96,948 | 200,695 | 107,048 | 53.34 | 24.13 | 12.87 | 0.01 |

It is evident that the conversion to ICD–10 would have a wide-ranging impact, affecting almost every health entity. At minimum, personnel will have to adjust to the new diagnostic codes when submitting bills. For a small enterprise that does business in a relatively narrow range of services or supplies relies primarily on paper records, the change may be minimal involving no more than a software upgrade for its billing system and new super bill forms. Based on a survey published in the June 18, 2008 *New England Journal of Medicine* (Catherine M. DesRoches, Eric G. Campbell, Sowmya R. Rao, et al.) found that 83 percent of doctors did not have electronic records systems (N Engl J Med 2008;359:50–60). Thus, we expect that the vast majority of physicians and practitioners will need to make relatively small changes in their record billing systems.

In the same survey the authors found that only 4 percent of physicians surveyed had fully functional electronic health records systems and 13 percent had a basic electronic health records system. Of the physicians with fully functioning electronic health records, 28 percent belong to group practices with six or more physicians. Nine percent of physicians with access to electronic health record systems practice in hospitals, clinics, and medical centers. Although the cost to transition to the ICD–10-CM codes will be more costly for providers/suppliers with electronic health records systems, the data suggests that large practices and hospitals and medical centers have invested in the sophisticated record systems rather than the average medical practice.

Based upon the previously cited survey, we assume that in many small provider practices, electronic health record systems likely are not used. Some may use practice management systems (most likely for billing purposes) and these will need to be updated. However, the costs for these updates can be attributed to the implementation of Version 5010, and not to ICD–10. Very small provider practices without practice management systems likely use only paper. In these instances, there will be minimal costs, such as revision to their paper records and the updating of their printed super bills. We invite industry and stakeholder comment regarding these assumptions.

At the other extreme are large teaching hospitals and health plans that will not only have to transition to the new diagnostic codes, but also to the new procedure codes. The changes entailed for such large organizations may involve the reconfiguration of entire data systems that will require

hundreds of staff hours in addition to training time and lost productivity. Although the previous analysis indicates that the overall impact on the health care sector of the economy will be very small, we acknowledge that these entities may incur a significant economic impact. However, we believe these organizations comprise a small minority of the total number of health care entities. We solicit industry and stakeholder input on this issue.

To further illustrate the impact we anticipate the rule will have, we developed a scenario for a typical community hospital in the Mid-West. The data for this illustration is drawn from the American Hospital Directory (*http://www.AHD.com*). While based on an actual hospital in a mid-western state, the data has been altered to make calculations simpler. The hospital has 100 beds, 4,000 discharges annually, and gross revenues of $200 million. Using the factors presented in the impact analysis, we estimated training costs (including the cost of the actual training as well as lost time away from the job), productivity loss for the first 6 months resulting from becoming familiar with the diagnostic and procedure codes, and the cost of system changes. For our scenario, we assumed that the hospital employs three full-time coders who will require eight hours of training at $500 per coder for $1,500 ($500 × 3). While they are in training, the hospital will have to substitute other staff either by hiring temporary coders if possible or shifting staff. The estimated cost at $50 per hour is $1,200 (8 hours × 3 staff × $50 per hour).

In estimating the productivity loss, we are only looking at the initial 6 months after implementation. Therefore we divided the annual number of discharges of 4,000 by 2 to equal 2,000. We assume that 3/4 of the discharges are surgical, giving us 1,500 discharges requiring use of PCS codes. Dividing this by 6 months yields an average monthly discharge rate of 250.

We perform a similar calculation for outpatient claims. Of the 13,000 outpatient claims, the monthly average is 1,083 (we do not distinguish between medical and surgical outpatient claims).

Applying the 1.7 extra minutes per discharge, we estimate it would take an extra 425 minutes (1.7 × 250) to code the discharges in the first month. At $50 per hour, the cost per minute is $0.83 ($50/60 minutes) and the cost per claim is $1.41 ($0.83 × 1.7). For the first month, the productivity loss for inpatient coding is $353 ($1.41 × 250). Assuming for simplicity's sake that the resumption of productivity over the 6-month period would increase in a straight line, we divide the $353 by six to come up with $59. We reduce the productivity loss by this amount each month through the sixth month. The total loss for the 6-month period is $1,233.

We apply the same method to determine the outpatient productivity loss. Based on our assumption that outpatient claims will require one-hundredth of the time for hospital inpatient claims, we applying the .017 extra minutes per claim, we estimate it would take an extra 18.41 minutes (0.017 × 1083) to code the discharges in the first month. At $50 per hour, the cost per minute is $0.83 ($50/60 minutes) and the cost per claim is $0.014 ($0.83 × 0.017). For the first month, the productivity loss for inpatient coding is $15.28 ($0.014 × 1083). Assuming for simplicity sake that the resumption of productivity over the 6-month period would increase in a straight line, we divide the $15.28 by six; to come up with $2.55. We reduce the productivity loss by this amount each month through the sixth month. Thus the total loss for the first 6 months will equal $53.

In estimating the cost of system changes and software upgrades, we deliberately chose a value that we think overstates the cost. We assumed that hospital will have to spend $300,000 on its data infrastructure to accommodate the new codes. Summing the training costs, productivity losses, and system upgrades, we estimate the total cost to the hospital will equal approximately $303,990. Finally, in order to determine the percent of the hospital's revenue that would be diverted to funding the conversion to the ICD–10 we compared the estimated cost associated with the conversion to ICD–10 to the total hospital revenue of $200 million. The costs amount to 0.15 percent of the hospital's annual revenues.

We note that although the impact in our scenario of 0.15 percent is significantly larger than the estimated impact of 0.03 percent for inpatient facilities in the Table 15 above, it is still significantly below the threshold the Department considers a significant economic impact. As expressed in the Department guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus based on the foregoing analysis, we conclude that some health care providers or suppliers may encounter significant burdens in the course of converting to the ICD–10 codes. However, we are of the opinion that, for most providers and suppliers, payers and computer firms involved in facilitating the transition, the costs will be relatively small.

3. Conclusion

Based on the foregoing analysis, we could certify that this proposed regulation would not have a significant economic impact on a substantial number of small entities. However because of the substantial uncertainty in the data and our assumptions we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the rule.

*E. Accounting Statement*

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a–4.pdf*) (accessed 8–12–08), in Table 12 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the costs and benefits associated with the implementation of ICD–10–CM and ICD–10–PCS in 2011 as HIPAA standard code sets to replace ICD–9–CM. All exclassified as implementation for HIPAA covered entities.

TABLE 17—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2009 TO FY 2023

[In millions]

| Category | Primary estimate (millions) | Minimum estimate (millions) | Maximum estimate (millions) | Source citation (RIA, preamble, etc.) |
|---|---|---|---|---|
| **Benefits** | | | | |
| Annualized Monetized benefits: | | | | |
| 7% Discount | $212.1 | $72.3 | $233.6 | RIA. |
| 3% Discount | 241.0 | 82.2 | 265.4 | RIA. |
| Qualitative (un-quantified) benefits | Improved biosurveillance and global disease management. | ..... | ..... | RIA. |
| **Costs** | | | | |
| Annualized Monetized costs: | | | | |
| 7% Discount | $144.9 | $40.1 | $159.4 | RIA. |
| 3% Discount | 124.8 | 34.4 | 137.3 | RIA. |
| Qualitative (un-quantified) 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 | |

*F. Conclusion*

Because ICD–9 is the official system of assigning codes to medical diagnoses and procedures associated with hospital and ambulatory utilization, the changeover to ICD–10 codes will have a major impact on the entire health care industry. This transition is needed due to the space and granularity deficiencies inherent in the almost three-decade-old ICD–9 code set, and the increased procedure and diagnosis detail that ICD–10 offers, allowing for more accurate payment of claims.

For hospitals, ambulatory centers, physician offices, and health plans, this transition will be multifaceted, but once adopted, ICD–10 would allow for better coding of complex conditions and procedures as well as a more uniform measure of reimbursement. Providers and payers are likely to need a cross-walk of ICD–9 codes to ICD–10 codes in the beginning of the transition, but as our analysis has shown, in the long-term, the benefits of ICD–10 outweigh its costs.

This impact analysis references two reports that outline the costs and benefits of transitioning from ICD–9 to ICD–10. These reports include ''The Costs and Benefits of Moving to the ICD–10 Code Sets'' by the RAND Corporation, and ''Replacing ICD–9–CM with ICD–10–CM and ICD–10–PCS Challenges, Estimated Costs, and Potential Benefits'' by the Robert E. Nolan Company. For purposes of this impact analysis, we also reference field studies and interviews done by AHIMA, which detail first-hand accounts of the benefits of using the ICD–10 code sets.

If we do not implement ICD–10 codes, we could continue to use ICD–9 codes; however, as mentioned in previous sections of this impact analysis, ICD–9 codes do not capture new technologically-advanced procedures, there would be an increased need to add new codes in illogical locations which would cause more confusion and inaccuracy when assigning codes, and there would possibly be improper payments for inaccurate diagnoses and procedures.

Because of the considerable uncertainty in the data and our assumptions we invite public comments regarding whether this proposed regulation would have a significant economic impact on a substantial number of small entities. We request any additional data that would help us determine more accurately the impact on the various categories of entities affected by the rule.

We have considered the alternatives specified in section XI of the preamble of this proposed rule. We welcome comments on ways to lessen any burdens from our proposal, on alternatives that might be more effective or less costly, and/or any other improvements we can make before issuing a final rule.

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

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

Administrative practice and 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 proposes to amend 45 CFR subtitle A, subchapter C, part 162 as follows:

## PART 162—ADMINISTRATIVE REQUIREMENTS

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

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

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, 2011:

* * * * *

(c) For the period on and after October 1, 2011:

(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 Classification 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)

Approved: March 12, 2008.

**Michael O. Leavitt,**

*Secretary.*

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