



**Analysis of the Final Rule:
HIPAA Administrative Simplification: Modification to Medical Data Code Set
Standards to Adopt ICD-10-CM and ICD-10-PCS**

January 2009

[AHIMA has developed this summary to assist the healthcare industry in beginning the transition to ICD-10-CM and ICD-10-PCS.]

On Friday, January 16, 2009, the Department of Health and Human Services (HHS) published a Final Rule for the adoption of ICD-10-CM and ICD-10-PCSⁱ code sets to replace the currently used ICD-9-CM code sets under rules, 45 CFR Parts 160 and 162, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). An electronic copy of this Final Rule can be accessed at <http://edocket.access.gpo.gov/2009/pdf/E9-743.pdf>. AHIMA's comments on the Proposed Rule can be accessed at: http://www.ahima.org/icd10/documents/comments_icd10_nprm.pdf.

HHS also published a final rule to change HIPAA transaction standards on the same date. AHIMA's analysis of this rule can be accessed at: <http://www.ahima.org/icd10>.

KEY HIGHLIGHTS OF THE FINAL RULE

- HHS is adopting the ICD-10-CM and ICD-10-PCS as medical data code sets under HIPAA, replacing ICD-9-CM Volumes 1 and 2, and Volume 3, with a single compliance date of October 1, 2013.
- The compliance date refers to all claims received for encounters and discharges occurring on or after October 1, 2013.
- ICD-10-CM (diagnoses) adoption will affect **all components** of the healthcare industry.
- ICD-10-PCS adoption will **only affect those** components of the healthcare industry that currently utilize ICD-9-CM volume 3 – **inpatient procedures**.
- After consideration of other alternatives, HHS concluded that the provisions in this Final Rule are the most cost-effective alternative for implementing HHS' statutory objective of administrative simplification.
- The three key issues HHS believes necessitates the need to update from ICD-9-CM to ICD-10-CM and ICD-10-PCS are:
 - ICD-9-CM is out of date and running out of space for new codes.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 US to adopt ICD-10-based classifications for reporting and surveillance.
 - ICD codes are core elements of many health information technology (HIT) systems, making the conversion to ICD-10-CM/PCS necessary to fully realize benefits of HIT adoption.
- Maps between ICD-9-CM and ICD-10-CM/PCS are already available and will facilitate conversion to the new code sets (maps provide links between code sets).
- HHS anticipates the estimated impact of ICD-10-CM/PCS transition costs on providers, suppliers, payers and software and system design firms is **\$1,878.68 million**.
- Benefits are estimated at **\$4,539.63 million** over 15 years.

AHIMA information on the adoption of ICD-10-CM/PCS can be found online at <http://www.ahima.org/icd10>.

NOTICE: *This review of the “Final Rule for HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS” is intended as an overview and not as a complete analysis of the rule.*

I. Background – Statutory and Regulatory (74FR3328)

HHS provides this initial section to summarize the statutory and regulatory background for adoption of code set standards. HIPAA, otherwise known as Public Law 104-191, was enacted on August 21, 1996. The HIPAA transactions and code sets final regulatory rule in 2000 (65FR50312) adopted standards for eight electronic transactions for use by covered entities. Several standard medical data code sets were adopted, including ICD-9-CM Volumes 1 and 2 and ICD-9-CM Volume 3. The 2000 Final Rule also adopted procedures for maintaining existing standards, for adopting modifications to existing standards, and for adopting new standards. The adoption of ICD-10-CM and ICD-10-PCS follows that procedure.

II. ICD-9-CM (74FR3329)

This section describes the ICD-9-CM code sets: volumes 1, 2 (diagnoses), and 3 (inpatient procedures), including the current development and maintenance processes and schedule. The ICD-9-CM Coordination and Maintenance Committee will be re-named the “ICD-10 Coordination and Maintenance Committee” at the point when ICD-10-CM/PCS become the new HIPAA standards. Until that time, the ICD-9-CM Coordination and Maintenance Committee will continue to update and maintain ICD-9-CM.

The limitations of ICD-9-CM are also discussed. It is 29 years old, the approximately 16,000 procedure and diagnosis codes are insufficient to continue to allow for the addition of new codes, and, because it cannot accommodate new procedures, its capacity as a fully functioning code set is diminished. The ICD-9-CM code set was never designed to provide the increased level of detail needed to support emerging needs, such as biosurveillance and pay-for-performance programs. A more detailed discussion of the shortcomings of ICD-9-CM can be found in the August 22, 2008 Proposed Rule at http://www.access.gpo.gov/su_docs/fedreg/a080822c.html

III. ICD-10 and the Development of ICD-10-CM and PCS (74FR3330)

This section describes the ICD-10-CM and ICD-10-PCS code sets. ICD-10-CM diagnosis codes have three to seven alphanumeric characters (whereas ICD-9-CM diagnosis codes have three to five alphanumeric characters). The ICD-10-CM code set provides much more information and detail within the codes than ICD-9-CM, facilitating timely electronic processing of claims by reducing requests for additional information. It reflects advances in medicine and medical technology, as well as accommodates the capture of more detail on socioeconomic, ambulatory care conditions, problems related to lifestyle, and the results of screening tests. It also provides for more space to accommodate future expansions, laterality for specifying which organ or part of the body is involved as well as expanded distinctions for ambulatory and managed care encounters.

ICD-10-PCS codes have seven alphanumeric characters (ICD-9-CM procedure codes have three to four numeric characters). It is sufficiently detailed to describe complex medical procedures and has the capability to readily expand and capture new procedures and technologies. ICD-10-PCS can be used to identify resource consumption differences and outcomes for different procedures.

IV. Summary of Proposed Provisions and Analysis of and Responses to Public Comments (74FR3331)

Adoption of ICD-10-CM and ICD-10-PCS as Medical Data Code Sets Under HIPAA (74FR3331)

Commenters overwhelmingly supported HHS' proposal to adopt ICD-10-CM and ICD-10-PCS as code sets under HIPAA. None of the alternatives suggested by commenters adequately address the shortcomings of ICD-9-CM that were identified and discussed in the August 22, 2008 Proposed Rule. The majority of commenters supported HHS' analysis of these shortcomings.

Transition to ICD-10-CM/PCS will ultimately facilitate realizing the benefits of using interoperability standards specified by the Healthcare Information Technology Standards Panel (HITSP), including SNOMED-CT[®]. The benefits of using SNOMED-CT[®] increase if such use is linked to a classification system such as ICD-10-CM and ICD-10-PCS. Mapping would be used to link SNOMED-CT[®] to these new code sets, and plans are underway to develop these maps.

The use of ICD-10-CM will offer greater detail and granularity and will greatly enhance HHS' capability to measure quality outcomes, such as the quality performance outcome measures used in the hospital pay-for-reporting program. The greater detail and granularity of ICD-10-CM/PCS will also provide more precision for claims-based, value-based purchased initiatives such as the hospital-acquired condition (HAC) payment policy.

Maps that allow the industry to convert ICD-9-CM codes into ICD-10-CM and ICD-10-PCS codes (and vice versa) are already in existence. These maps and others that are developed during the implementation period will allow the industry to convert payment systems, HAC payment policies, and quality measures to ICD-10-CM/PCS.

Compliance Date (74FR3333)

The compliance date for implementation of ICD-10-CM and ICD-10-PCS is October 1, 2013. In establishing the compliance date, HHS sought to select a date that achieves a balance between the industry's need to implement ICD-10-CM/PCS within a feasible amount of time, and HHS' need to begin reaping the benefits of the use of these code sets; stop the hierarchical deterioration and other problems associated with the continued use of the ICD-9-CM code sets; align with the rest of the world's use of ICD-10 to achieve global health care data compatibility; plan and budget for the transition to ICD-10-CM/PCS appropriately; and mitigate the cost of further delays. HHS believes that an October 1, 2013 ICD-10-CM/PCS compliance date achieves that balance.

Implementation Period (74FR3335)

A minority of commenters disagreed with HHS' proposal to establish a single compliance date for ICD-10-CM/PCS. HHS concluded that it would be in the health care industry's best interests if all entities were to comply with the ICD-10-CM/PCS code set standards at the same time to ensure the accuracy and timeliness of claims and transaction processing. A single compliance date will reduce the burden on both providers and insurers who will be able to edit on a single new coding system for claims received for encounters and discharges occurring on or after October 1, 2013.

Maintenance of two code sets for a significant span of time such that, on any specific date of service in that time frame one could submit, process and/or receive payment on a claim based on ICD-9-CM or the ICD-10-CM and ICD-10-PCS code sets would raise considerable logistical issues and add to the complexity of ICD-10-CM/PCS implementation.

Date of Admission Versus Date of Discharge Coding (74FR3336)

Several commenters requested that inpatient hospital facilities use the code set version in effect at the date of admission instead of the date of discharge because this would benefit inpatient facilities that use interim billing. HHS noted that it is a longstanding practice for inpatient facilities to use the version of ICD codes in effect on the date of discharge. HHS does not agree that changing this practice would be of benefit to hospitals, and maintains that the opposite would be true, and is counter to the implementation of a single, consistent ICD-10-CM/PCS implementation date. Also, using the date of admission for some types of claims coding, and date of discharge for other types of claims coding, would greatly disrupt national data and create problems in analyzing what has been a consistent approach to coding medical records. HHS will not change the current practice followed by inpatient facilities of coding based on the date of discharge.

Coding Guidelines (74FR3336)

Several commenters expressed the need for ICD-10-CM/PCS coding guidelines to be developed and maintained. HHS agrees that it is important to have an official set of ICD-10-CM coding guidelines and that they be properly maintained. At the time of publication of the Final Rule, ICD-10-CM guidelines were posted on the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) web sites. The Cooperating Parties (CMS, CDC's National Center for Health Statistics, American Hospital Association, and the American Health Information Management Association) will finalize a 2009 version of the official ICD-10-CM coding guidelines which will be posted on the CDC's web site in January 2009. Updated coding guidelines for ICD-10-PCS are included in the Reference Manual posted on CMS' web site at:

http://www.cms.hhs.gov/ICD10/Downloads/pcs_refman.pdf.

ICD-10 Mappings and Crosswalks (74FR3337)

Authoritative, detailed bi-directional mappings, referred to as General Equivalency Mappings (GEMs), have been developed between ICD-9-CM Volumes 1 and 2 and ICD-10-CM and between ICD-9-CM Volume 3 and ICD-10-PCS. These mappings were developed with stakeholder input into their creation and maintenance and discussed at public meetings of the ICD-9-CM Coordination and Maintenance Committee.

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

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

The use of the GEM mappings to convert the MS-DRGs from ICD-9-CM to ICD-10-CM/PCS codes demonstrates that the GEM mappings are extremely accurate and useful. These mappings will be of great assistance to the industry in converting payment, quality and other types of systems from ICD-9-CM to ICD-10-CM and ICD-10-PCS and vice versa. There may be value in annually revising these bi-directional mappings to allow for conversions between ICD-9-CM codes and the ICD-10-CM and ICD-10-PCS codes as ICD-10-CM/PCS are updated annually after their adoption. The ICD-9-CM Coordination and Maintenance Committee (to be re-named the "ICD-10 Coordination and Maintenance Committee" after ICD-10-CM/PCS implementation) will discuss the need to continue updating these mappings for a minimum of three years after the ICD-10-CM/PCS final compliance date.

HHS encourages anyone who has particular concerns about possible errors in the mappings to share them with CMS and CDC through the ICD-9-CM Coordination and Maintenance Committee so that mappings can be updated.

It is expected that CMS will have converted all MS-DRGs to ICD-10-CM and ICD-10-PCS by October 2009, and they will share those results with payers and providers at a future ICD-9-CM Coordination and Maintenance Committee meeting. The adoption of the final ICD-10-CM/PCS version of MS-DRGs will be subject to rulemaking.

CDC intends to produce a crosswalk between the World Health Organization's ICD-10 and ICD-10-CM, addressing the need for international data comparability, and this crosswalk will be completed and made available one year prior to the ICD-10-CM compliance date. CDC already uses ICD-10 to report cause of death.

ICD-10 Education and Outreach (74FR3338)

With publication of the Final Rule, HHS will begin to proactively conduct outreach and education activities which include, but are not limited to, roundtable conference calls with industry stakeholders, development of FAQs, fact sheets, and other supporting education and outreach materials for industry partner dissemination. HHS will work closely with industry stakeholders to make subject matter experts available to them and to expeditiously help stakeholders disseminate relevant information at the national, regional, and local level that will be useful to them in educating their respective members.

HHS will continue to collaborate with other stakeholder organizations on outreach and education on the transition from ICD-9-CM to ICD-10-CM/PCS, taking into consideration the contextual and timing needs of different industry segments, including hospitals, providers, coders, etc., in a way that will ensure all affected entities have the resources needed to properly code.

Testing (74FR3339)

In response to comments stating that ICD-10-CM and ICD-10-PCS needed more testing prior to implementation, HHS indicated that there has been successful, independent field testing of the utility and functionality of ICD-10-CM and ICD-10-PCS, and that no additional testing of this nature is necessary. Any pilot testing of ICD-10-CM and ICD-10-PCS would demonstrate its integration into business processes and/or systems, and not the appropriateness of its adoption as a HIPAA standard.

ICD-10 Code Set Development and Utility (74FR3339)

Several commenters stated that countries such as Canada and Australia have not developed such extensive clinical modifications to medical code sets compared to those used in the US. Commenters recommended undertaking a process to streamline and/or significantly reduce the number of ICD-10-CM/PCS codes to make adoption easier. HHS noted that the level of detail in the US' clinical modification of ICD-10 is commensurate with the complexities of the multi-payer healthcare system in the US. The US' clinical modifications have been derived in part with the input of clinical specialty groups that have requested this level of specificity. If the US is moving toward an electronic healthcare system and increasingly using codes for quality purposes, there is a need to capture more precise information, not less. ICD-10-CM and ICD-10-PCS will greatly support these efforts.

An increased number of codes does not necessarily result in increased complexity in using the coding system. Though training would be required in order to make full use of the increased number and granularity of the codes, greater specificity can mean the correct code is easier to determine because there is less ambiguity. Also, not all HIPAA covered entities will use all of the ICD-10-CM/PCS codes.

Commenters, including AHIMA, stated that the annual ICD-9-CM code set updates should cease one year prior to the implementation of ICD-10-CM/PCS. They indicated that such a “freeze” on code set updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and/or purchases. HHS indicated that the ICD-9-CM Coordination and Maintenance Committee has jurisdiction over any action impacting the code sets. Therefore, the issue of consideration of a moratorium on updates to the ICD-9-CM, ICD-10-CM, and ICD-10-PCS code sets in anticipation of adoption of ICD-10-CM/PCS will be addressed through this Committee at a future public meeting.

V. Provisions of the Final Regulations (74FR3341)

HHS notes that for the most part, the Final Rule incorporates the provisions of the August 22, 2008 Proposed Rule. The provisions that differ in the Final Rule are the compliance date (October 1, 2013 in the Final Rule versus October 1, 2011 in the Proposed Rule) and replacement of the word “classification” with “coding” throughout the regulation.

VI. Collection of Information Requirements (74FR3341)

HHS indicates that the burden associated with the implementation and continued use of ICD-10-CM/PCS is the time and effort required to update information systems for use with updated HIPAA transaction and code set standards. Specifically, the entities must comply with the ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards, which accommodate the use of the ICD-10-CM and ICD-10-PCS code set. The burden associated with meeting the ICD-10-CM and ICD-10-PCS code set standards is not discussed in this final rule; however, it is accounted for in the Version 5010 Final Rule.

VII. Regulatory Impact Analysis (RIA) Statement of Need (74FR3341)

The objective of the 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 healthcare environment. The RAND and Nolan reports are considered to be the benchmark studies for the transition from ICD-9-CM to ICD-10-CM/PCS, and both reports were analyzed by HHS prior to their development of their own assumptions and conclusions.

The three key issues HHS believes necessitates the need to update from ICD-9-CM to ICD-10-CM/PCS are:

- 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 US to adopt an ICD-10-based classification for reporting and surveillance.
- ICD codes are core elements of many health information technology (HIT) systems, making the conversion to ICD-10-CM/PCS necessary to fully realize benefits of HIT adoption.

Overall Impact (74FR3341)

HHS examined the impacts of the Final Rule as required by:

- Executive Order (EO) 12866 on Regulatory Planning and Review
- Regulatory Flexibility Act
- Business Regulatory Enforcement Fairness Act of the SSA
- Unfunded Mandates Reform Act
- EO 13132 on Federalism
- Congressional Review Act

The regulatory impact analysis (RIA) explains calculations for costs and benefits and impact analysis focusing on savings projections and cost estimates. An RIA must be completed on major rules with economically significant effects--\$100 million in any one year, updated annually for inflation. The threshold level is approximately \$130 million. Based on HHS' analysis, HHS anticipates that the private sector would incur costs exceeding \$130 million per year beginning 3 years after publication of the final rule and ending 3 years after implementation.

The objective of the 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 healthcare environment.

A summary of estimated costs, annualized at 3 percent and 7 percent, is shown in Table 4 on page 74FR3360 of the Final Rule. A summary of estimated benefits, also annualized at 3 percent and 7 percent, is shown in Table 5 on page 3360 of the Final Rule.

Training (74FR3343)

HHS retained their estimate of 229,267 coders in total from the proposed rule, but increased their estimate of hospital coders from 50,000 to 60,000 coders. This shift decreases the number of outpatient coders as shown in the proposed rule by 10,000, to 169,267, but still accounts for a total number of 229,267 coders. The basis for these revised assumptions is derived from HHS' research of the US Bureau of Labor Statistics data. HHS noted that their estimate of total number of coders is higher than the estimates from the Nolan report and commenters. They considered reducing their estimate accordingly, but decided to retain the higher number to assure this cost has been adequately addressed.

Based on industry feedback regarding the need for more time than the 40 hours of training HHS estimated for inpatient coders to learn both ICD-10-CM and ICD-10-PCS, HHS increased their estimate of the number of hours of training that inpatient coders will need to learn ICD-10-CM and ICD-10-PCS from 40 hours to 50 hours. The cost of training is estimated to be \$3,218.75 per inpatient coder. This figure includes \$2,500 for lost productivity and \$718.75 in training costs.

Based on similar feedback from the industry expressing concern about the complexity of ICD-10-CM due to its size and structural changes, and coder unfamiliarity, HHS also increased from 8 to 10 hours the time that outpatient coders will need for ICD-10-CM training. The cost of training is estimated to be \$644 per outpatient coder. This figure includes \$500 in lost productivity and \$143.75 in training costs.

HHS considered reducing the coder training estimates in recognition of the fact that almost half of the total number of coders is likely to receive some ICD-10-CM/PCS training as part of their continuing education requirements for maintaining certification. However, they elected to retain the higher number to ensure this cost has been adequately addressed.

HHS noted that there appears to be a wide variance of opinions across all industry segments as to how many physicians would need and/or want ICD-10-CM/PCS code set training and the length of that training. Based on feedback from commenters, HHS concluded that the RAND estimate of only 10 percent of physicians interested in training may be too low. They decided to accept the Nolan estimate of 754,000 physicians seeking a midpoint of 8 hours of ICD-10-CM/PCS training, at a cost of \$157.55 per hour. HHS assumes the remainder of physicians will either not seek training or will need less intensive "awareness training," which is anticipated to be available through continuing medical education opportunities of which they likely would have availed themselves absent the transition from ICD-9-CM to ICD-10-CM/PCS.

HHS estimated that, based on RAND data, there are approximately 250,000 code users, and of this total number, only 150,000 work directly with codes and would require 8 hours of training.

Productivity Losses (74FR3346)

HHS anticipates that the percent of returned claims following ICD-10-CM/PCS implementation may peak at around 6-10 percent of pre-implementation levels. They estimated a cost range from between \$274 million to \$1,100 million.

HHS acknowledged that coders' productivity will be directly affected because of the need to learn new codes and definitions. They maintain their assumptions and productivity loss estimates as outlined in the proposed rule. For outpatient productivity losses, they assume the average time to code an outpatient claim could take one-hundredth of the time for a hospital inpatient claim, taking into account the wide variety of outpatient settings and coding forms. They adjusted the cost estimate for outpatient productivity losses from the estimate shown in the proposed rule to update to 2007 dollars, for a revised total of \$9.40 million in 2014, the year after ICD-10-CM/PCS implementation. The cost estimate for inpatient productivity losses has been adjusted from the estimate shown in the proposed rule to update to 2007 dollars, for a revised estimate of \$9.77 million.

HHS received several comments that the use of ICD-10-CM/PCS would cause physicians to order unnecessary medical tests to provide more precise diagnoses or require more documentation to the medical record. HHS disagrees that physicians will be pressured to perform unnecessary medical tests or include additional medical documentation because they are using ICD-10-CM and ICD-10-PCS codes. Patient care and treatment are not pre-determined by diagnostic coding; in fact, diagnostic coding is determined from best practice patient care. There are substantial benefits to be derived from the greater detail of ICD-10-CM when a coder selects the most accurate code based on the available documentation. HHS noted that this is true whether one is using ICD-9-CM codes or ICD-10-CM codes. If one cannot assign a precise code, it is because the medical record documentation is not available or because a clear diagnosis has not been made and in that case, a more general, non-specific code would be selected.¹

HHS noted that a poorly documented medical record can be problematic for a number of reasons, but such deficient medical records are an issue of and by themselves, and not contingent upon whether the code assigned is an ICD-9-CM or an ICD-10-CM code. Improved medical record documentation is not predicated on the change from ICD-9-CM to ICD-10-CM. Rather, improved documentation is being driven by initiatives such as quality measurement reporting, value-based purchasing and patient safety.

System Changes (74FR3348)

System Changes – Providers and Vendors

HHS stated that the costs of updating provider systems will depend on the degree of system integration; the need for outside technical assistance; and the number of systems and system interfaces that must be updated. They assume that large provider groups, chain providers, and institutions, such as large hospitals, are most likely to require changes to their billing systems, patient record systems, reporting systems and associated system interfaces. Small providers, who rely on superbills as well as their homegrown systems for capturing patient information and claims submission, may only need to update their systems to

¹ Field testing of ICD-10-CM conducted by AHIMA and the American Hospital Association demonstrated that ICD-10-CM codes can be applied to today's health records in a variety of healthcare settings without having to change documentation practices, although improved documentation would result in higher coding specificity, and therefore higher data quality, in some cases. The report of this field testing project can be accessed at: <http://www.ahima.org/icd10>.

accommodate the length of the new code fields.² For small providers that are PC-based or have client-server systems, the provider may not bear any immediate costs for the software upgrades. Practice management systems will need to be revised to accommodate ICD-10-CM codes, but this change will take place as a part of the migration to the Version 5010 standards.

HHS did not receive substantial information or data during the proposed rule's public comment period that would lead them to revise their cost analysis for system changes for providers. They have adjusted their cost estimate shown in the proposed rule to update to 2007 dollars, for a revised cost of \$150.64 million over 4 years.

It may be difficult to initially account for all changes to vendor systems because of the varying needs of individual providers. Also, a portion of these costs will take place as part of the migration to the Version 5010 standards. However, based on comments indicating the proposed rule did not account for all of the vendor systems that will need to be updated to accommodate the new code set, HHS increased their cost estimate for software vendor systems by 20 percent, resulting in an estimate of \$115.29 million over a 4-year period.

System Changes – Plans

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

HHS acknowledged that the estimated payer systems costs may exceed those identified in the proposed rule. Recognizing that these payer system costs may be difficult to ascertain, and considering the comments submitted that expressed concern regarding underestimation of payer system costs, HHS increased their estimate of payer system costs by 20 percent, resulting in an estimate of \$197.64 million over 4 years.

It was stated in the Final Rule that there are multiple ways for entities to integrate the ICD-10-CM/PCS code sets into their business settings. As the codes are incorporated into systems and processes, some providers, plans, and vendors may decide to populate the new codes throughout their entire system all at once, or translate the codes on a flow basis as they are used. Integration of the codes in many cases will be determined by the extent to which the available granularity is needed in transactions.

System Changes – Government

ICD-10-CM/PCS Medicaid cost estimates were understated in the proposed rule because they were based on a very limited State survey. HHS had anticipated that State Medicaid agencies would respond with more accurate and complete data, but they were unable to do so with some citing current State budget

² For examples of physician superbills converted to ICD-10-CM, see AHIMA's ICD-10 web page: <http://www.ahima.org/icd10>.

uncertainties. The ICD-10-CM/PCS compliance date of October 1, 2013 addresses State Medicaid agencies' concerns about not being able to be ready to accept claims with the new codes by the proposed October 1, 2011 date. State Medicaid agencies can approach the transition from ICD-9-CM to ICD-10-CM/PCS either through installation of a new Medicaid Management Information System (MMIS) that would already accommodate the ICD-10-CM and ICD-10-PCS codes or through remediation of their current systems. Either way, States are reimbursed by the Federal government for 90 percent of the cost of ICD-10-CM and ICD-10-PCS modification to the State's Medicaid system design, development, installation or enhancement, leaving 10 percent as the state's share of the expense. Based on updated information and discussions with Medicaid experts, HHS revised their estimates of the States' Medicaid program cost of ICD-10-CM/PCS implementation to a range of between \$200 million to \$400 million. Using the midpoint of this range, the average ICD-10-CM/PCS cost per State Medicaid program is estimated to be \$588,235 for their share of the cost. The remaining 90 percent cost share to the Federal Medicaid program is estimated to be an average of \$5,294 million per state.

Commenters recommended that:

- CMS consider suspending Medicare Administrator Contractor and Recovery Audit Contractor auditing for at least 12 months following the ICD-10-CM/PCS compliance date.
- During the transition from ICD-9-CM to ICD-10-CM/PCS, provider coding errors should not be used as a basis for prosecution under the False Claims Act.
- CMS should not unfairly penalize providers if the agency adopts a prospective budget neutrality adjustment.

HHS noted that these comments relate specifically to ICD-10-CM/PCS implementation issues that will impact the Medicare program. These comments will be taken under consideration, the industry and other interested stakeholders will be informed through normal CMS communication channels of any decisions made relative to these issues as HHS plans for the transition from ICD-9-CM to ICD-10-CM/PCS.

Impact on Clinical Laboratories (74FR3351)

A few commenters stated that the proposed rule did not address the impact of ICD-10-CM adoption on clinical laboratories. HHS responded that the impact of the adoption of ICD-10-CM on clinical laboratories was addressed in the proposed rule in two areas, part-time coders and laboratories as small entities. Since clinical laboratories utilize ICD-9-CM codes for reimbursement and submit claims to various payers, it is imperative that they implement ICD-10-CM at the same time as the rest of the healthcare industry.

Impact on Pharmacies (74FR3352)

Commenters stated that the ICD-10-CM/PCS- Proposed Rule did not account for the impact that the transition to ICD-10-CM and ICD-10-PCS would have on the pharmacy industry. HHS noted that the National Committee on Vital and Health Statistics (NCVHS) held multiple hearings and solicited comments from all industry segments regarding the potential impacts of ICD-10-CM on their respective business processes and systems. During the ongoing NCVHS process, representatives of the pharmacy industry did not indicate that the transition from ICD-9-CM to ICD-10-CM codes would be problematic and, therefore, HHS did not identify pharmacies as an impacted industry segment in the proposed rule's regulatory impact analysis.

HHS now understands that ICD-9-CM codes are currently used in pharmacy settings when the patient's drug benefit plan may require a diagnosis code for purposes of prior authorization. However, the pharmacist does not assign the diagnosis code; it must be obtained by the pharmacist from the prescriber, just as it would be if ICD-9-CM codes were still in use. HHS does not anticipate that the use of the National Council of Prescription Drug Plans' Telecommunications Standard Version D.0 or the ICD-10-

CM code set in pharmacy settings will cause an increase in the requirement to use codes to report supplies/services in e-prescribing transactions and that, in fact, the use of such standards will enhance retail pharmacy transactions through their greater specificity, reducing pharmacy call-backs to physicians, and improving the efficiency of pharmacy claims submissions and accurate payments.

Commenters recommended that there be a one year staggered transition period for pharmacies to implement ICD-10-CM so that authorized prescription medication refill orders can complete the reorder cycle uninterrupted. While there will be a single compliance date of October 1, 2013 for all covered entities, HHS anticipates that pharmacies will be able to use the reimbursement mappings posted to the CMS web site to translate ICD-9-CM codes into ICD-10-CM.

Contract Renegotiation

HHS did not account for the costs of contract renegotiations because they share RAND's assumption that providers and payers must regularly renegotiate contracts in response to new policies. They do not anticipate that the ICD-10-CM and ICD-10-PCS data that would constitute the basis for changes in reimbursement will be available until sometime after the initial implementation of the new code sets. HHS believes that any cost of renegotiating contracts will be spread out over time, be undertaken at the time of the regularly scheduled contract renewal, and should be accounted for as a cost of doing business.

Impact on Electronic Medical Records (74FR3353)

HHS agrees with commenters that there will be costs associated with reprogramming electronic medical record (EMR) systems to accommodate the use of ICD-10-CM/PCS. However, as both commenters and the proposed rule noted, the rate of adoption of EMRs among providers is currently very low, and the transition to ICD-10-CM and ICD-10-PCS would affect only those providers who now employ EMRs. For those providers who anticipate purchasing EMR systems, they should verify with their vendors that the systems they are considering can accommodate ICD-10-CM and ICD-10-PCS codes.

General Benefits (74FR3353)

Most commenters agreed with the benefit categories outlined in the proposed rule. Not all of the benefits that could potentially be realized through the use of ICD-10-CM and ICD-10-PCS were accounted for in the proposed rule. Commenters suggested additional benefits, including:

- Improvement in medical knowledge and technology;
- The ability to substantiate the medical necessity of diagnostic and therapeutic services;
- The ability to demonstrate the efficacy of using technology for particular clinical conditions; and
- The ability to identify complications and adverse effects through the use of technology.

The benefit estimate was updated to reflect 2007 dollars in the Final Rule, resulting in a benefit estimate of \$4,539.63 million over 15 years.

Education and Outreach (74FR3354)

HHS intends to provide ICD-10-CM/PCS education and outreach to a wide variety of healthcare entities, including Medicare contractors; Fiscal Intermediaries, Carriers, and Medicare Administrative Contractors; hospitals; physicians; other providers; and other stakeholders. A host of tools will be developed and made publicly available. HHS is beginning to post educational materials to these web sites:

<http://www.cms.hhs.gov/MedLearn> and <http://www.cms.hhs.gov/ICD10>.

Impacts on Training Programs (74FR3354)

In response to a comment noting that implementing ICD-10-CM/PCS will exacerbate the shortage of clinical coders, HHS stated that they have received no indication from industry, and have no reason to believe, that the changeover from ICD-9-CM to ICD-10-CM/PCS codes might contribute to the existing

shortage of coders. In fact, increased marketplace demand for coders as a result of adoption of ICD-10-CM and ICD-10-PCS may lead to more enrollment in coding curriculums, and, in turn, the graduation of more and better qualified coders.

Industry trade and technical school representatives have indicated [to HHS] their readiness to adapt to any needed curriculum changes as a result of the adoption of ICD-10-CM/PCS, and anticipate that they will be able to produce “ICD-10-CM/PCS ready” clinical coders upon graduation from their respective institutions.

Impact on other HIT Initiatives (74FR3355)

Commenters stated that there are too many other HIT initiatives that they are being asked to embrace, creating too much competition for scant resources and time. HHS noted that they took other HIT initiatives into consideration in establishing the proposed ICD-10-CM/PCS compliance date to sequence compliance in a manner that would allow covered entities to concentrate their efforts on ICD-10-CM/PCS implementation during the relevant period. With the new ICD-10-CM/PCS compliance date of October 1, 2013, there will be ample time for providers to prepare for the changeover from ICD-9-CM to ICD-10-CM/PCS. HHS will not consider implementing a new HIPAA standard for claims attachment transactions until after the compliance date for ICD-10-CM/PCS.

Impact on Other Entities (74FR3355)

In the proposed rule, HHS addressed the adoption of ICD-10-CM and ICD-10-PCS as medical data code sets under HIPAA and, therefore, did not specifically address the potential impacts of ICD-10-CM/PCS adoption on non-HIPAA entities. Commenters noted that certain non-HIPAA covered entities would be impacted by the change from ICD-9-CM to ICD-10-CM/PCS, such as worker’s compensation programs, life insurers, and third party administrators. These commenters did not offer any quantitative data that could be used to refine the impact analysis calculation of their costs associated with the adoption of ICD-10-CM/PCS. From a benefits perspective, HHS noted that Chapter 20 of ICD-10-CM, External Causes of Morbidity, provides for the classification of environmental events and external circumstances as the cause of injury and other adverse effects. These codes are more precise and describe a wider range of causes of injuries, which should be helpful to worker’s compensation programs in determining the exact cause of an injury.

With regard to the Outcome and Assessment Instrument Set (OASIS), the inpatient rehabilitation patient assessment instrument (IRF-PAI), and the post-acute care payment reform demonstration project, the business process and systems impacts of ICD-9-CM, and subsequently ICD-10-CM and ICD-10-PCS, on these and similar instruments have already been identified. The costs associated with the implementation of ICD-10-CM/PCS relative to these instruments will be accounted for through CMS’ ongoing ICD-10-CM and ICD-10-PCS internal planning and analysis activities and will be shared with the industry once these costs have been projected.

HHS acknowledged that many uncertainties exist regarding the transition to ICD-10-CM and ICD-10-PCS, and that the costs and benefits associated with the transition as outlined in the Final Rule may not fully capture all of the impacts to the industry. In order to account for this uncertainty, HHS included low, high and primary estimates of transitioning to ICD-10-CM and ICD-10-PCS.

Regulatory Flexibility Analysis (74FR3356)

Section 604 of the Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities if a Final Rule has a significant impact on a substantial number of small entities. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit status or by qualifying as small businesses under the Small Business Administration’s size standards.

In the ICD-10-CM/PCS Proposed Rule, HHS showed the distribution of the transition costs to the ICD-10-CM/PCS codes for providers, suppliers, payers and software and system design firms. The cost estimates in the Final Rule have been revised to reflect changes in the estimates for ICD-10-CM and ICD-10-PCS training, productivity loss, and systems changes as well as changes to account for inflation. The estimated impact of ICD-10-CM/PCS transition costs on providers, suppliers, payers and software and system design firms is \$1,878.68 million. A summary can be found in Table 2 on page 3357 of the Final Rule.

A phased-in approach to ICD-10-CM/PCS implementation to allow more time for small entities to transition to the new code sets is not feasible because the use of dual coding systems would result in burdensome costs to industry, confusion as to which code set was being used in claims submission, and which payers are capable of accepting the new codes. The result would be massive claims processing delays and lagging reimbursements to providers.

HHS noted that there are multiple ways for small entities to integrate the ICD-10-CM/PCS code sets into their business settings, either populating the new codes throughout their entire system all at once, or integrating the codes on a flow basis as they are used. Additionally, any small practices may continue to submit paper claims, using preprinted forms that include all of the appropriate codes required for use in such practices. The use of ICD-10-CM/PCS is not predicated on the use of electronic hardware and software. The ICD-10-CM/PCS code sets have already been produced in book version. For physician practices that have already migrated to electronic systems and wish to purchase software, a CD of the ICD-10-CM/PCS code sets will be made available through the US Government Printing Office. The ICD-10-CM code set is available at no charge on the National Center for Health Statistics (NCHS) web site at <http://www.cdc.gov/nchs/about/otheract/icd9/icd10cm.htm>. The *ICD-10-PCS* code set is available at no charge on the CMS web site at http://www.cms.hhs.gov/ICD10/02_ICD-10-PCS.asp.

Conclusion (74FR3360)

HHS did not receive any data or information to substantiate arguments that their impact analysis of the potential effects of ICD-10-CM/PCS implementation on small entities was flawed. Therefore, they maintain their small entity ICD-10-CM/PCS impact assumptions outlined in the proposed rule. The Secretary certified the Final Rule will not have a significant economic impact on a substantial number of small entities.

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ⁱ "ICD-10-CM/PCS" is used throughout this document to refer to both ICD-10-CM and ICD-10-PCS.