| State | City/town/county | Source of flooding | Location | *Elevation in feet (NGVD) +Elevation in feet (NAVD) #Depth in feet above ground ∧Elevation in meters (MSL) Modified |
|---|---|---|---|---|
| | City of Newport News | Stoney Run-Colony Pines Branch. | Approximately 776 feet downstream of Richneck Road. | +27 |
| | | | Approximately 1,450 feet upstream of Windsor Castle Drive. | +40 |
| | City of Newport News | Stoney Run-Denbigh Branch. | Just downstream of Richneck Road ..... | +27 |
| | | | Just downstream of McManus Boulevard ..... | +33 |

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

**ADDRESSES**

**City of Newport News**

Maps are available for inspection at the Department of Engineering, 2400 Washington Avenue, Newport News, VA 23607.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: July 11, 2014.

**Roy E. Wright,**

*Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

[FR Doc. 2014–18364 Filed 8–1–14; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### 45 CFR Part 162

**[CMS–0043–F]**

**RIN 0938–AS31**

## Administrative Simplification: Change to the Compliance Date for the International Classification of Diseases, 10th Revision (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets

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

**ACTION:** Final rule.

**SUMMARY:** This final rule implements section 212 of the Protecting Access to Medicare Act of 2014 by changing the compliance date for the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding, including the Official ICD–10–CM Guidelines for Coding and Reporting, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, including the Official ICD–10–PCS Guidelines for Coding and Reporting, from October 1, 2014 to October 1, 2015. It also requires the continued use of the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2 (diagnoses), and 3 (procedures) (ICD–9–CM), including the Official ICD–9–CM Guidelines for Coding and Reporting, through September 30, 2015.

**DATES:** These regulations are effective on September 3, 2014.

**FOR FURTHER INFORMATION CONTACT:** Denesecia Green, (410) 786–8797. Geanelle G. Herring, (410) 786–4466. Kamahanahokulani Farrar, (410) 786–2155.

**SUPPLEMENTARY INFORMATION:**

### I. Executive Summary and Background

*A. Executive Summary*

1. Purpose

Prior to the enactment of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) on April 1, 2014, the health care industry was actively preparing to transition to the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding (herein collectively referred to as ICD–10) on October 1, 2014. Many in the health care industry had invested time and resources in system upgrades, testing, training, and undertaking the necessary changes to workflow processes. However, PAMA required the Secretary to adopt ICD–10 no sooner than October 1, 2015.

This final rule establishes October 1, 2015, as the new ICD–10 compliance date. This final rule also requires the continued use of the International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2 (diagnoses), and 3 (procedures), including the Official ICD–9–CM Guidelines for Coding and Reporting (herein collectively referred to as ICD–9–CM), through September 30, 2015.

a. Need for the Regulatory Action

This final rule establishes October 1, 2015 as the compliance date for ICD–10. It also requires the continued use of ICD–9–CM through September 30, 2015.

b. Legal Authority for the Regulatory Action

Section 212 of PAMA, titled ''Delay in Transition from ICD–9–CM to ICD–10 Code Sets'' is the legal authority for the regulatory action.

2. Summary of the Major Provisions

As noted previously, this final rule changes the compliance date for ICD–10 from October 1, 2014 to October 1, 2015 and requires covered entities to continue using ICD–9–CM through September 30, 2015.

3. Summary of Costs and Benefits

In the September 5, 2012 **Federal Register** (77 FR 54664), the Department of Health and Human Services (HHS) published a final rule titled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier

Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets'' (herein referred to as the 2012 ICD–10 Delay final rule) in which the Secretary changed the compliance date for ICD–10 from October 1, 2013 to October 1, 2014. In that rule, we estimated there would be a significant cost to industry from a delay of ICD–10 because commercial health plans, medium and large hospitals, and large physician practices were far along in their implementation and had devoted funds, resources, and staff to the effort. In our analysis, we estimated that a 1-year delay of the compliance date for ICD–10 would add a range of 10 to 30 percent to the total cost that these entities had already spent or budgeted for the transition to ICD–10 on October 1, 2013.

We use the same rationale and methodology in our analysis of costs and benefits in the Regulatory Impact Analysis (RIA) of this final rule, and conclude that a delay of 1-year, as opposed to a longer delay, will be the least costly and most fiscally responsible way to implement the requirements of section 212 of PAMA. We estimate the cost of a 1-year delay to HIPAA covered entities will be $1.1 to $6.8 billion.

*B. Background*

In the January 16, 2009 **Federal Register** (74 FR 3328), HHS published a final rule (herein referred to as the 2009 ICD–10 final rule) in which the Secretary adopted ICD–10 as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard code set to replace ICD–9–CM. The 2009 ICD–10 final rule established an October 1, 2013 compliance date for ICD–10. For more background on the adoption of ICD–10, see the 2009 ICD–10 final rule and the August 22, 2008 proposed rule titled ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'' (herein referred to as the 2008 ICD–10 proposed rule) (73 FR 49796).

In late 2011 and early 2012, three issues emerged that led the Secretary to reconsider the compliance date for ICD–10: (1) The industry transition to ASC X12 Version 5010 did not proceed as effectively as expected; (2) providers became concerned that other statutory initiatives were stretching their resources; and (3) there was a lack of readiness for the ICD–10 transition, as indicated by industry surveys and polls. As a result, HHS published the 2012 ICD–10 Delay final rule in which the compliance date for ICD–10 was delayed from October 1, 2013 to October 1, 2014.

**II. Provisions of the Final Rule**

Section 212 of PAMA provides that the Secretary may not adopt ICD–10 under HIPAA prior to October 1, 2015. We interpret this provision as requiring the Secretary to delay the October 1, 2014 implementation of ICD–10, and we believe the provision gives the Secretary discretion to choose a new compliance date of October 1, 2015, or later. We are establishing October 1, 2015 as the new compliance date.

All segments of the health care industry have invested significant time and resources in financing, training, and implementing necessary changes to systems, workflow processes, and clinical documentation practices in order to prepare for ICD–10. The American Academy of Professional Coders (AAPC) provides training and education to medical coders, physicians and their practice management staff. In a June 2014 survey [1] of 5,000 AAPC members, nearly 75 percent of the survey respondents reported that they are making significant progress toward preparing for ICD–10 implementation. The survey also indicated that about 25 percent of those surveyed had completed all of the necessary ICD–10 training; 13 percent indicated that they were prepared for the October 1, 2014 implementation date; and 23 percent were actively testing with their ICD–10 vendors when PAMA was signed into law. The industry has made significant progress toward ICD–10 compliance and has gained momentum in its efforts. A delay of longer than 1 year would slow or even stop progress towards ICD–10 implementation. In order to preserve this momentum and encourage continued compliance efforts, we are establishing the shortest delay permitted by law, which is 1 year.

Additionally, we believe it is important to require implementation of ICD–10 as soon as the law permits because it will allow the industry to begin reaping the benefits of ICD–10 as soon as possible. ICD–10 provides greater specificity of diagnosis-related groups; improves quality measurement and reporting capabilities; improves tracking of illnesses; and reflects greater accuracy of reimbursement for medical services. ICD–10's granularity will improve data capture and analytics of public health surveillance and reporting, national quality reporting, research and data analysis, and provide detailed data to inform health care delivery and health policy decisions.

ICD–10 reflects the advances in medicine and medical technology that U.S. physician specialty groups called for as they provided extensive input into the development of the ICD–10–CM code-set to capture more precise codes for the conditions they treat. ICD–10 includes significant improvements over ICD–9–CM in coding primary care encounters, external causes of injury, mental disorders, and preventive health. For example, ICD–10 reflects improved diagnosis of chronic illness and identifies underlying causes, complications of disease, and conditions that contribute to the complexity of a disease, and captures the severity and stage of diseases such as chronic kidney disease, dementia, and asthma.

Finally, a 1-year delay, as opposed to a longer delay, is the least expensive option for the industry. As estimated in the 2012 ICD–10 Delay final rule [2] and repeated in this final rule, a 1-year delay increases costs for covered entities by a range of 10 to 30 percent. We conclude that a delay beyond 1 year would be significantly more costly and have a damaging impact on the healthcare industry. For example, extending the delay beyond 1 year could render current ICD–10 system updates and releases obsolete, which would diminish the investments stakeholders have already made to prepare for the ICD–10 transition. Stakeholders would need to restart their system preparation and would not be able to leverage past system investments.

In order to implement section 212 of PAMA, we are changing the compliance date for ICD–10 from October 1, 2014 to October 1, 2015 in 45 CFR 162.1002(c) by changing ''October 1, 2014'' to ''October 1, 2015'' to read, ''[f]or the period on and after October 1, 2015.''

Our regulations at 45 CFR 162.1002(b) currently require compliance with ICD–9–CM through September 30, 2014. We are changing our regulations to require the continued use of ICD–9–CM through September 30, 2015. Accordingly, we are revising 45 CFR 162.1002(b) by

[1] ICD–10 Monitor: Exclusive: ICD–10 Implementation—Where Do We Really Stand? *http://icd10monitor.com/enews/item/1220-exclusive-icd-10-implementation-where-do-we-really-stand?utm_source=Real%20Magnet&utm_medium=Email&utm_campaign=42358626.*

[2] Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets; Final Rule. *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf* pages 50–53.

changing ''September 30, 2014'' to ''September 30, 2015'' to read, ''[f]or the period on and after October 16, 2003 through September 30, 2015.''

## III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), we are required to publish a notice of proposed rulemaking (NPRM) in the **Federal Register**. Section 553(b) of the APA provides an exception to this requirement. Section 553(b)(B) of the APA authorizes HHS to waive normal rulemaking requirements if it finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. We believe waiving normal notice and comment rulemaking requirements is justified because covered entities need to know how to proceed with respect to ICD–9–CM and ICD–10 now, or they will not have adequate time to prepare to accurately submit, process, and pay for health care claims.

The October 1, 2014 compliance date for ICD–10 was established in the 2012 ICD–10 Delay final rule. Section 212 of PAMA was enacted on April 1, 2014, six months prior to the October 1, 2014 ICD–10 compliance date, at a critical time when most health care entities had already configured and tested systems and business processes, and devoted staff and financial resources in preparation for compliance on October 1, 2014. IT systems were changed to align with new payment policies and rules, staff was trained on new workflow processes, and trading partner agreements were updated to begin using ICD–10 on October 1, 2014.

After section 212 of PAMA was enacted, many industry stakeholders asked the Secretary to clarify which ICD version could or must be used and when. Many interpreted section 212 of PAMA as requiring a delay of ICD–10 to October 1, 2015, while others interpreted the law as allowing the Secretary to postpone implementation of ICD–10 for longer than a year. Other industry stakeholders suggested that section 212 of PAMA permitted covered entities to use either ICD–9–CM or ICD–10 on October 1, 2014. These widely different interpretations reflected the industry's uncertainty about when it would be required to use specific versions of the ICD coding system, and we recognized a growing apprehension among stakeholders in light of this uncertainty.

There are also a number of important business and implementation decisions that industry stakeholders have to make now. For example, budgeting, project management, and systems planning for the continued use of ICD–9–CM on October 1, 2014 and for the delayed implementation of ICD–10 on October 1, 2015, must begin as soon as possible for all covered entities. Both large and small providers and health plans generally develop budgets and allot resources for transitions far in advance and particularly for those transitions that impact IT systems, business policies, and processes. Most covered entities have allocated funds, assigned human resources, and have employed contractors to assist with or manage various aspects of the transition to ICD–10 based on an October 1, 2014 compliance date. These resources, trading partner agreements, vendor systems, and maintenance contracts will have to be reconsidered and reallocated within a very short period of time to accommodate the delay. Many covered entities have also begun to train their staff for ICD–10 implementation and must decide immediately whether to continue this training. The absence of a firm implementation date impedes decision-making for budgetary development, projecting planning, and systems preparation. If covered entities are unable to make these decisions timely, some may choose to slow or even suspend ICD–10 preparations.

Covered entities will also have to accomplish systems and business process changes in a relatively short period of time. Many providers have programmed their IT systems to submit ICD–10 codes on October 1, 2014, and have implemented changes in business processes to accommodate these changes. Most health plans have programmed their claims processing systems to accept and process ICD–10 codes on October 1, 2014. These systems will have to be reconfigured to process ICD–9–CM coded claims for an additional year while also preparing to process ICD–10 coded claims on and after October 1, 2015. It is imperative that covered entities know the new compliance dates now so they can begin immediately to take the necessary steps to comply.

A seamless industry transition to a required code set is necessary in order to avoid payment disruptions. If covered entities are not prepared to accept and process ICD–9–CM codes on October 1, 2014, there could be significant disruptions in health care payments. The inability of health plans to successfully process claims directly impacts the timeliness of provider reimbursements for services rendered. Many providers, especially small and rural providers, rely on the timeliness of payments in order to continue to do business. A risk to a provider's economic well-being is a risk to patient care.

In order to minimize industry disruption, it is important for the Secretary to announce the new compliance dates as soon as possible. Even with the extra few months this final rule affords, time is short. If we were to engage in full notice and comment rulemaking, covered entities would be left with uncertainty until a final rule could be published, which would be unlikely to happen prior to October 1, 2014. And even if the process could be expedited, a final rule would be issued too close to October 1, 2014 to give most covered entities sufficient time to comply with the requirements of the rule. Accordingly, we find there is good cause to waive the normal notice and comment rulemaking procedures, as they are impracticable and contrary to the public interest.

## IV. Collection of Information Requirements

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

## V. Regulatory Impact Analysis

### *A. Statement of Need*

As stated previously, section 212 of PAMA specifies that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.'' This final rule establishes a new ICD–10 compliance date of October 1, 2015. It also requires the continued use of ICD–9–CM through September 30, 2015.

### *B. Overall Impact*

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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 Orders 12866 and 13563 direct 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million in 1995 dollars or more in any one year). We estimate that this rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that presents the costs and benefits of this rule.

In determining the costs of this final rule, we needed to establish, as a baseline, what costs would likely be incurred absent this final rule, and then compare this baseline to the costs of the ICD–10 delay announced in this final rule. The costs estimated in this RIA include costs to industry and government entities for an October 1, 2015 compliance date. For the RIA in this final rule we have also relied largely on the estimates in the RIA of the 2012 ICD–10 Delay final rule because that rule also estimated the cost of a 1-year delay in the compliance date for ICD–10.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This final rule contains a mandate that would likely impose spending costs on the healthcare industry of more than $141 million. Therefore, in this RIA we illustrate the costs of the 1-year delay in compliance date for ICD–10.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State laws, or otherwise has Federalism implications. We do not anticipate that the 1-year delay in the compliance date for ICD–10 will have a significant impact on State and local governments, preempt State laws, or otherwise have Federalism implications.

### *C. Anticipated Effects on Impacted Entities*

ICD codes are used in nearly every sector of the health care industry. All HIPAA covered entities will be affected by a delay in the compliance date of ICD–10. Covered entities include all health plans, 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.

While covered entities are required to transition to ICD–10, many other entities not covered by HIPAA also use ICD codes for a variety of purposes because their operational and business needs often intersect with those of covered entities. For practical and business purposes, we expect these non-covered entities will voluntarily transition to ICD–10. Entities that are not considered covered entities, but that may be affected by the transition to ICD–10, include: Workers' compensation programs and automobile and personal liability insurers, hardware and software vendors for health care practice management systems and electronic health record systems, researchers, public health organizations, educational institutions, and coding entities.

### *D. Scope and Methodology of the Impact Analysis for ICD–10*

This RIA estimates the costs of a delay of compliance with ICD–10. In this RIA we are analyzing only the impact of a delay, not the impact of ICD–10 implementation, which we addressed in the 2008 ICD–10 proposed rule (73 FR 49476) and the January 2009 ICD–10 final rule (74 FR 3328). For purposes of this analysis, we reference estimates made in the RIA of the 2012 ICD–10 Delay final rule because it also delayed compliance with ICD–10 by 1 year.

While we assume that a delay of the implementation of ICD–10 will affect a broad range of health care providers, as illustrated in Table 1, we only examine the costs and benefits of a delay on two types of health care providers: Hospitals and small providers. We do not analyze the impact on other providers, including, but not limited to, nursing and residential care facilities, dentists, or durable medical equipment (DME) suppliers, though we understand that there is likely to be an impact on most of these providers. As was the case for our impact analysis in the 2008 ICD–10 proposed rule, there continues to be very little publicly available data on the use of electronic data interchange (EDI) among dentists, DME suppliers, nursing homes, and residential care facilities. The lack of data for these types of health care providers has been noted in other studies on administrative simplification.[3]

We do not include an analysis of costs or benefits to health care clearinghouses and transaction vendors in this RIA. Transaction vendors are entities that process claims or payments for entities such as health plans. Not all transaction vendors meet the HIPAA definition of a health care clearinghouse, which constitute a subset of transaction vendors. Payment vendors also would be a type of transaction vendor—a transaction vendor that ''associates'' or ''re-associates'' health care claim payments with the payments' remittance advice for either a health plan or provider. For our purposes, transaction vendors do not include developers or retailers of computer software or entities that are involved in installing, programming or maintaining computer software. However, we did not calculate costs and benefits to health care clearinghouses and transaction vendors in this RIA because, as in our previous impact analyses in the August 2008 ICD–10 proposed rule and the 2012 ICD–10 Delay final rule, we assume that any associated costs and benefits will be passed on to the health plans or providers and will be included in the costs and benefits we apply to health plans and providers.

Although self-insured group health plans meet the HIPAA definition of ''health plan,'' we did not include them in this impact analysis. While self-insured group health plans will be required to implement ICD–10, we assume that, with a few exceptions, such plans do not send or receive HIPAA electronic transactions because

[3] ''Excess Billing and Insurance-Related Administrative Costs,'' by James Kahn, in *The Healthcare Imperative; Lowering Costs and Improving Outcomes: Workshop Series Summary,* edited by Pierre L. Yong, Robert S. Saunders, and Leigh Anne Olsen, Institute of Medicine of the National Academies, the National Academies Press, Washington, DC: 2010.

most are not involved in the day-to-day activities of a health plan, and outsource those services to third party administrators (TPAs) or transaction vendors.

We do delineate a cost to TPAs in this RIA. Although TPAs do not meet the definition of ''health plans,'' and therefore are not required by HIPAA to use code sets such as ICD–10, as a practical matter they will need to make the transition in order to continue to conduct electronic transactions on behalf of self-insured group health plans. The impact of a delay of the compliance date of ICD–10 on TPAs will be similar to the commercial insurer cost/benefit impact profile as TPAs serve a similar function and will have to implement and test their systems in the same manner as health plans. Therefore, when we refer to ''commercial health plans'' in this RIA, we are including TPAs in the category of ''small health plans'' in the RIA.

In the 2012 ICD–10 Delay final rule (77 FR 22991) and in this RIA, we do not include the costs for software vendors, including software vendors for practice management and EHR systems, as they ultimately pass their costs to their clients.

*E. Cost of a 1-Year Delay of Implementation of ICD–10 for Health Plans*

1. Cost of a 1-Year Delay to Commercial Health Plans and TPAs

Health plans are a varied group in terms of size, and the cost of a delay is calculated using a range that reflects this variance. In terms of costs, commercial health plans are far along in their ICD–10 implementation and have devoted funds, resources, and staff to the effort. When PAMA was enacted, the majority of commercial health plans were in the external testing phase of their ICD–10 implementation plans.[4] A 1-year delay of ICD–10 compliance will allow entities more time to thoroughly test, but the testing and the continued maintenance of contracts and personnel required for the transition will be 1-year longer than was budgeted.

Continued training, testing, and retention of personnel, and contracts are expected to be the primary costs associated with a 1-year delay for commercial health plans. Commercial health plans will perform additional work in preparing their systems to process ICD–9 coded claims for an additional year while also converting their systems to process ICD–10 coded claims on and after October 1, 2015. We estimate the costs of the delay for commercial health plans and third party administrators to be between $547 million and $2,786 million.

2. Cost of a 1-Year Delay to Medicare

We believe many government health programs were prepared to be ICD–10 compliant on October 1, 2014, and, like commercial payers, will incur costs from a 1-year delay. As an example, components affected by a 1-year delay at the Centers for Medicare & Medicaid Services (CMS), in particular, Medicare Fee-for-Service (herein referred to as Medicare), estimate that there will be additional costs. Like other government payers, Medicare has programmed its claims processing systems to accept and process ICD–10 codes on October 1, 2014. These systems will have to be reconfigured to process ICD–9–CM-coded claims for an additional year while also preparing to process ICD–10-coded claims on and after October 1, 2015. Therefore, costs include expenditures like extending contracts and reprogramming work for the ICD–9–CM systems and ICD–10 systems while continuing to test ICD–10 in the new 2015 systems environment. Other additional costs include an increased need for outreach and education claims processing manual updates, technical assistance, and training.

It was estimated in the 2012 final rule that a 1-year delay of ICD–10 compliance would be reflected by additional work at an estimated total cost of $5 to $10 million for the Medicare program. Because the Medicare program was so far along in its ICD 10 implementation when PAMA was enacted, we now estimate that the cost of a 1 year delay will be $21 to $32 million for the Medicare program spread across FYs 2014 and 2015.

3. Cost of a 1-Year Delay to State Medicaid Agencies

State Medicaid Agencies (SMAs) completed a cost impact assessment for a 1-year delay in April of 2014. SMAs face similar costs as commercial health plans as a result of the 1-year delay of ICD–10. SMAs will incur costs due to contractual obligations which may require modifications, extensions, or procurements. Other costs to SMAs include the need to test ICD–10 codes in the new 2015 systems environment, which will be needed even by SMAs that have successfully tested to date. SMA resources will need to be maintained at full pre-implementation and go-live levels through 2015 in order to prepare for the October 1, 2015 implementation. These will likely affect planning and implementation of other IT initiatives for SMAs, potentially resulting in additional costs and delays for those initiatives. SMAs report the total cost for both state and federal of a 1-year delay for all SMAs is $169 to $182 million.

*F. Cost of a 1-Year Delay to Providers*

1. Hospitals and Large Providers

We expect that many hospitals and large provider organizations have already spent funds in preparation for the ICD–10 transition. As with health plans, a delay of the compliance date will add to their costs because large providers must maintain personnel staffing levels, make significant system changes; renegotiate the contracts necessary to extend preparations an extra year, and retest systems in the new 2015 systems environment. Likewise, large providers must maintain technological resources for an extra year.

According to our estimates in the 2012 ICD–10 delay final rule, the cost of a 1-year delay to hospitals and large physician practices will be $409 million to $3.7 billion.

2. Small Providers

There are some surveys that estimate the associated costs for providers transitioning to ICD–10, and we referenced some of these studies in the 2012 ICD–10 Delay proposed rule (77 FR 22997). In that proposed rule, we did not estimate the cost to small providers of the 1-year delay because these costs were negligible.

Given the lack of statistically valid data regarding the resources small providers have expended, as well as their state of readiness for an October 1, 2014 compliance date as compared to an October 1, 2015 compliance date, we do not estimate the cost or benefits to small providers in this RIA. However, based on other relevant areas of the health care industry, we assume that the change in compliance date will negatively impact some percentage of small providers in terms of cost. Nonetheless, the 1-year delay may also give relief to small providers that were not prepared by affording them another year in which to spread costs and resources.

*G. Summary of Costs of a 1-Year Delay of the Compliance Date of ICD–10*

Except for estimates of the impact on Medicare and State Medicaid agencies, we are using the cost estimates from the 2012 ICD–10 Delay final rule to

[4] Twenty of the top 25 health insurance companies indicated that they were prepared to test with trading partners, according to a scan of their Web sites. The top 25 health insurance companies were identified by US News (*http://health.usnews.com/health-news/health-insurance/articles/2013/12/16/top-health-insurance-companies*).

conclude that a 1-year delay of the ICD–10 compliance date would add a range of 10 to 30 percent to the total cost that these entities have already spent or budgeted for an October 1, 2014 implementation date, for an additional cost to commercial entities of approximately $1 billion to $6.8 billion.

We summarize the range of low and high estimates of a 1-year delay of the compliance date for ICD–10 in Table 1.

TABLE 1—SUMMARY OF COSTS IN 2015 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

| | Low (in millions) | High (in millions) | Mean (average) (in millions) |
|---|---|---|---|
| Cost to Commercial Health Plans | $547 | $2,786 | $1,667 |
| Cost to Medicare | 21 | 32 | 27 |
| Cost to State Medicaid Agencies | 169 | 182 | 176 |
| Cost to Hospitals and Large Provider Organizations | 422 | 3,849 | 2,136 |
| Total Costs | 1,161 | 6,850 | 4,007 |

* In 2014 Dollars.

*H. Considered Alternatives to a 1-Year Delay of the ICD–10 Compliance Date*

Section 212 of PAMA states that ''the Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.'' We interpret the statute as mandating a delay of the compliance date of ICD–10, and permitting the Secretary discretion to select the length of the delay, as long as implementation is required no sooner than October 1, 2015. This final rule adopts a compliance date of October 1, 2015.

We considered a number of delays of different durations before establishing October 1, 2015 as the compliance date for ICD–10. However, we concluded that a delay beyond 1 year would be significantly more costly and have a damaging impact on industry. For example, extending the delay beyond 1 year could render current ICD–10 system updates and releases obsolete, which would diminish the investments stakeholders have already made to prepare for the ICD–10 transition. All segments of the health care industry have invested significant time and resources in financing, training, and implementing necessary changes to systems, workflow processes, and clinical documentation practices. Stakeholders would need to restart their system preparation and would not be able to leverage past system investments.

As estimated in the 2012 ICD–10 Delay final rule [5] and repeated in this final rule, a 1-year delay increases costs for covered entities by a range of 10 to 30 percent. As indicated in the RIA in this final rule, we estimate little to no benefit or cost savings in delays of ICD–10 beyond the minimum 1-year delay required by PAMA. Although industry readiness has not been studied, stakeholders representing a significant majority of the industry have reported that they invested significant time and resources and were prepared for the October 1, 2014 ICD–10 compliance date. A delay of longer than 1 year would slow or stop progress towards ICD–10 implementation, delay the efficiencies that can be achieved through ICD–10 implementation, and create wasteful spending. Therefore, we believe that an October 1, 2015 compliance date is the most appropriate alternative.

*I. Regulatory Flexibility Analysis: Impact on Small Providers of a Delay in the Compliance Date of ICD–10*

The Regulatory Flexibility Act (RFA) of 1980 (Pub. L. 96–354) requires agencies to describe and analyze the impact of the final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. According to the Small Business Administration's size standards, a small entity is defined as follows according to health care categories: Office of Physicians are defined as small entities if they have revenues of $11 million or less; most other health care providers (dentists, chiropractors, optometrists, mental health specialists) are small entities if they have revenues of $7.5 million or less; hospitals are small entities if they have revenues of $38.5 million or less. (For details, see the SBA's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*. Refer to Sector 62—Health Care and Social Assistance).

As in the 2012 Delay final rule, we continue to assume for purposes of the RFA, that all physician practices are small entities. We conclude that a 1-year delay in implementation of the ICD–10 will affect a ''substantial number'' of small entities. However, we assert in this final rule, that the 1-year delay of the compliance date of ICD–10 will be more beneficial to small entities than it will be burdensome. The benefits are derived from the additional time that small entities will have for ICD–10 implementation. Therefore, we certify that the provisions in this final rule will not have a significant economic impact on a substantial number of small entities.

*J. Accounting Statement and Table*

The total costs of a 1-year delay of the compliance date will likely be incurred over a 12-month period. However, due to the range of impacted entities, including educational institutions, those 12 months may span different dates and different budget periods. Given the diverse approaches to budgeting in the industry, there is no precise way of calculating how much of the cost and cost avoidance falls outside of the October 1, 2014 to October 1, 2015 timeframe. For simplicity's sake, we calculate costs of a delay of the compliance date for ICD–10 as occurring in calendar year 2015.

As required by OMB Circular A–4,[6] Table 2 is an accounting statement showing the classification of the expenditures associated with the

[5] Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets; Final Rule. *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf* pages 50–53.

[6] ''Circular A–4,'' September 17, 2003, Office of Management and Budget (OMB), *http://www.whitehouse.gov/omb/circulars_a004_a-4/*.

provisions of this final rule. Table 2 provides our best estimates of the costs and benefits associated with a 1-year delay of the compliance date of ICD–10.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE FROM FY 2014 TO FY 2015

[In millions of dollars]

| Category | Primary estimate (millions) | Minimum estimate (millions) | Maximum estimate (millions) | Source citation (RIA, preamble, etc.) |
|---|---|---|---|---|
| **COSTS** | | | | |
| Annualized Monetized costs: | | | | |
| 7% Discount | $4,007.0 | $1,161.0 | $6,850.0 | RIA. |
| 3% Discount | 4,007.0 | 1,161.0 | 6,850.0 | RIA. |

**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 the preamble, the Department of Health and Human Services amends 45 CFR Part 162 as follows:

## PART 162—ADMINISTRATIVE REQUIREMENTS

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

**Authority:** Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat 2021–2031, sec. 105 of Pub. L. 110–233, 122 Stat. 881–992, and sec. 264 of Pub. L. 104–191, 110 Stat 2033–2034 (42 U.S.C. 1320d–2 (note)), secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat 146–154 and 915–917.

**§ 162.1002 [Amended]**

■ 2. Section 162.1002 is amended as follows:

■ A. In paragraph (b) introductory text by removing the date ''September 30, 2014'' and adding in its place the date ''September 30, 2015''.

■ B. In paragraph (c) introductory text by removing the date ''October 1, 2014'' and adding in its place the date ''October 1, 2015''.

Dated: July 17, 2014.

**Marilyn Tavenner,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: July 25, 2014.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2014–18347 Filed 7–31–14; 4:15 pm]

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## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### 49 CFR Part 214

### Railroad Workplace Safety

*CFR Correction*

■ In Title 49 of the Code of Federal Regulations, Parts 200 to 299, revised as of October 1, 2013, on page 189, in § 214.315, paragraph (b) is reinstated to read as follows:

**§ 214.315 Supervision and communication.**

* * * * *

(b) A job briefing for on-track safety shall be deemed complete only after the roadway worker has acknowledged understanding of the on-track safety procedures and instructions presented.

* * * * *

[FR Doc. 2014–18425 Filed 8–1–14; 8:45 am]

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