DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS–0040–P]

RIN 0938–AQ13

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 ICD–10–CM and ICD–10–PCS Medical Data Code Sets

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 1104 of the Patient Protection and Affordable Care Act (hereinafter referred to as the Affordable Care Act) by establishing new requirements for administrative transactions that would improve the utility of the existing Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and reduce administrative burden and costs. It proposes the adoption of the standard for a national unique health plan identifier (HPID) and requirements or provisions for the implementation of the HPID. This rule also proposes the adoption of a data element that will serve as an other entity identifier (OEID), an identifier for entities that are not health plans, health care providers, or ''individuals,'' that need to be identified in standard transactions. This proposed rule would also specify the circumstances under which an organization covered health care provider must require certain noncovered individual health care providers who are prescribers to obtain and disclose an NPI. Finally, this rule proposes to change 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, 2013 to October 1, 2014.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on May 17, 2012.

ADDRESSES: In commenting, please refer to file code CMS–0040–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0040–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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

FOR FURTHER INFORMATION CONTACT: Kari Gaare (410) 786–8612, Matthew Albright (410) 786–2546, and Denise Buenning (410) 786–6711.

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*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also 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, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1–800–743–3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose of the Regulatory Action

a. Need for the Regulatory Action

This rule proposes the adoption of a standard unique health plan identifier (HPID) and the adoption of a data element that will serve as an other entity identifier (OEID). This rule also proposes an addition to the National Provider Identifier (NPI) requirements. Finally, this rule proposes to change the compliance date for the ICD–10–CM and ICD–10–PCS medical data code sets (hereinafter ''code sets'') from October 1, 2013 to October 1, 2014.

(1) HPID

Currently, health plans and other entities that perform health plan functions, such as third party administrators and clearinghouses, are identified in Health Insurance Portability and Affordability Act of 1996 (HIPAA) standard transactions with multiple identifiers that differ in length and format. Covered health care providers are frustrated by various problems associated with the lack of a

standard identifier, such as: improper routing of transactions; rejected transactions due to insurance identification errors; difficulty in determining patient eligibility; and challenges resulting from errors in identifying the correct health plan during claims processing.

The adoption of the HPID and the OEID will increase standardization within HIPAA standard transactions and provide a platform for other regulatory and industry initiatives. Their adoption will allow for a higher level of automation for health care provider offices, particularly for provider processing of billing and insurance related tasks, eligibility responses from the health plans, and remittance advice that describes health care claim payments.

(2) NPI

In January 2004, the U.S. Department of Health and Human Services (HHS) published a final rule establishing the standard for a unique health identifier for health care providers for use in the health care system and adopting the National Provider Identifier (NPI) as that standard. The rule also established the implementation specifications for obtaining and using the standard unique health identifier for health care providers. Since that time, pharmacies have encountered situations where they need to include the NPI of a prescribing health care provider in a pharmacy claim, but where the prescribing health care provider has been a noncovered health care provider who did not have an NPI because he or she was not required to obtain one. This situation has become particularly problematic in the Medicare Part D program. The proposed addition to the NPI requirements seeks to address this issue.

(3) ICD–10–CM and ICD–10–PCS Code Sets.

On January 16, 2009, HHS published a final rule (74 FR 3328) in which the Secretary of HHS (the Secretary) adopted the ICD–10–CM and ICD–10–PCS (ICD–10) code sets as the HIPAA standards to replace the previously adopted International Classification of Diseases, 9th Revision, Clinical Modification, Volumes 1 and 2, including the Official ICD–9–CM Guidelines for Coding and Reporting (ICD–9–CM Volumes 1 and 2) and the International Classification of Diseases, 9th Revision, Clinical Modification, Volume 3, including the Official ICD–9–CM Guidelines for Coding and Reporting (ICD–9–CM Volume 3) for diagnosis and procedure codes, respectively. The compliance date set by the final rule was October 1, 2013.

Since that time, some provider groups have expressed strong concern about their ability to meet the October 1, 2013 compliance date and the serious claims payment issues that might then ensue. Some providers' concerns about being able to meet the ICD–10 compliance date are based, in part, on difficulties they have had meeting HHS' compliance deadline for the adopted Associated Standard Committee's (ASC) X12 Version 5010 standards (Version 5010) for electronic health care transactions. Compliance with Version 5010 and ICD–10 by all covered entities is essential to a smooth transition to the updated medical data code sets, as the failure of any one industry segment to achieve compliance would negatively impact all other industry segments and result in returned claims and provider payment delays. We believe the change in the compliance date for ICD–10, as proposed in this rule, would give providers and other covered entities more time to prepare and fully test their systems to ensure a smooth and coordinated transition by all industry segments.

b. Legal Authority for the Regulatory Action

(1) HPID

This proposed rule implements section 1104(c) of the Affordable Care Act and section 1173(b)(1) of the Social Security Act (the Act) which require the adoption of a standard unique health plan identifier (HPID).

(2) NPI

This proposed rule would impose an additional requirement on covered organization health care providers under the authority of sections 1173(b)(1) and 1175(b) of the Act. It would also accommodate the needs of certain types of health care providers in the use of the covered transactions, as required by section 1173(a)(3) of the Act.

(3) ICD–10–CM and ICD–10–PCS

This proposed rule would set a new compliance date for the ICD–10 code sets, in accordance with section 1175(b)(2) of the Act, under which the Secretary determines the date by which covered entities must comply with modified standards and implementation specifications.

2. Summary of the Major Provisions

a. HPID

This rule proposes the adoption of the HPID as the standard for the unique identifier for health plans and definitions for ''Controlling Health Plan'' and ''Subhealth Plan.'' The proposed definitions of these two terms seek to differentiate between health plan entities that would be required to obtain an HPID, and those that would be eligible, but not required, to obtain an HPID. This rule also proposes to require all covered entities to use an HPID whenever a covered entity identifies a health plan in a covered transaction. Because health plans today have many different business structures and arrangements that affect how health plans are identified in standard transactions, these two proposed definitions also seek to enable health plans to obtain HPIDs to reflect differing business arrangements so they can be identified appropriately in standard transactions.

This rule also proposes the adoption of a data element that would serve as an other entity identifier (OEID). The OEID would serve as an identifier for entities that are not health plans, health care providers, or ''individuals'' (as defined in 45 CFR 160.103), but that need to be identified in standard transactions (including, for example, third party administrators, transaction vendors, clearinghouses, and other payers). Under this proposed rule, these other entities would not be required to obtain an OEID, but they could obtain and use one if they needed to be identified in covered transactions. Because other entities are identified in standard transactions in a similar manner as health plans, we believe that establishing a data element to serve as an identifier for these entities will increase efficiency by encouraging the use of a uniform identifier.

The most significant benefit of the HPID and the OEID is that they will increase standardization within HIPAA standard transactions by establishing uniform identifiers.

b. NPI

This rule proposes that an organization covered health care provider require certain noncovered individual health care providers who are prescribers to: (1) Obtain NPIs and; (2) to the extent the prescribers write prescriptions while acting within the scope of the prescribers' relationship with the organization, disclose them to any entity that needs the NPIs to identify the prescribers in standard transactions. This addition to the NPI requirements would address the issue that pharmacies are encountering when the NPI of a prescribing health care provider needs to be included on a pharmacy claim, but the prescribing

health care provider does not have, or has not disclosed an NPI.

c. ICD–10–CM and ICD–10–PCS

This rule proposes that the compliance date for ICD–10–CM and ICD–10–PCS be changed from October 1, 2013 to October 1, 2014. We believe this change will give covered entities the additional time needed to synchronize system and business process preparation and changeover to the updated medical data code sets.

3. Costs and Benefits

a. HPID

The HPID is expected to yield the most benefit for providers, while health plans will bear most of the costs. Costs to all commercial and government health plans together (Medicare, Medicaid programs, IHS, VHA) are estimated to be $650 million to $1.3 billion. However, commercial and government health plans are expected to make up those costs in savings. Further, it is our understanding that the industry will not find that the HPID is overly burdensome. Many entities have indicated that they have delayed regular system updates and maintenance, as well as the issuance or adoption of new health plan identification cards, to accommodate the adoption of the HPID.

Health care providers can expect savings from two indirect consequences of HPID implementation: (1) The cost avoidance of decreased administrative time spent by providers interacting with health plans; and (2) a material cost savings through automation of processes for every transaction that moves from manual to electronic implementation. HPID's anticipated 10-year return on investment for the entire health care industry is expected to be between $1 to $4.6 billion. (This estimate includes savings resulting from the foundational effect of the HPID rather than a precise budgetary prediction.)

b. NPI

The addition to the requirements for the NPI would have little impact on health care providers and on the health industry at large because few health care providers do not already have an NPI. In addition, covered organization health care providers may comply by various means. For example, a covered organization could use a simple verbal directive to prescribers whom they employ or contract with to meet the requirements. Alternately, a covered organization could update employment or contracting agreements with the prescribers. For these reasons, we believe the additional NPI requirements do not impose spending costs on State government or the private sector in any 1-year of $136 million or more.

c. Change of Compliance Date of ICD–10

According to a recent survey conducted by CMS, up to one quarter of health care providers believe they will not be ready for the October 1, 2013 compliance date.[1] While the survey found no significant differences among practice settings regarding the likelihood of achieving compliance before the deadline, based on recent industry feedback we believe that larger health care health plans and providers generally are more prepared than smaller entities. The uncertainty about provider readiness is confirmed in another recent readiness survey in which nearly 50 percent of the 2,140 provider respondents did not know when they would complete their impact assessment of the ICD–10 transition.[2]

By delaying the compliance date of ICD–10 from October 1, 2013 to October 1, 2014, we would be allowing more time for covered entities to prepare for the transition to ICD–10 and to conduct thorough testing. By allowing more time to prepare, covered entities may be able to avoid costly obstacles that would otherwise emerge while in production.

Savings would come from the avoidance of costs that would occur as a consequence of significant numbers of providers being unprepared for the transition to ICD–10. In the Regulatory Impact Analysis (RIA) of this proposed rule, we estimate that there would be a cost avoidance of approximately $3.6 to nearly $8 billion in this regard. This range of estimates reflects the avoidance of two costly consequences that may occur should the compliance date remain October 1, 2013: (1) Both health care providers and health plans may have to process health care claims manually in order for claims to be paid; and (2) small health care providers may have to take out loans or apply for lines of credit in order to continue to provide health care in the face of delayed payments.

In terms of costs, commercial health plans, medium and large hospitals, and large physician practices are far along in their ICD–10 implementation planning, and therefore have devoted funds, resources, and staff to the effort. According to our estimates, a 1-year delay of the ICD–10 compliance date would add 10 to 30 percent to the total cost that these entities have already spent or budgeted for the transition—an additional cost to commercial entities of approximately $1 to $6.4 billion. Medicare and State Medicaid Agencies have also reported estimates of costs of a change in the compliance date in recent informal polls. Accordingly, the calculations in the RIA in this proposed rule demonstrate that a 1-year delay in the compliance date of ICD–10 would cost the entire health care industry approximately $1 billion to $6.5 billion.

We assume that the costs and cost avoidance calculated in the RIA will be incurred roughly over a 6- to 12-month period, from October 1, 2013 to October 1, 2014. For simplicity sake, however, both the costs and the cost avoidance that result from a change in the compliance date of ICD–10 are calculated over the calendar year, 2014.

We solicit comments on our assumptions and conclusions as described in the RIA.

B. Introduction

The following discussion presents a partial statutory and regulatory history related only to the statutory provisions and regulations that are relevant for purposes of this proposed rule. For additional statutory background and regulatory history, see the proposed rule entitled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,'' published in the **Federal Register** on August 22, 2008 (73 FR 49742); ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS: Proposed Rule,'' published in the **Federal Register** on August 22, 2008 (73 FR 49796) (hereinafter referred to as the ICD–10 proposed rule); and ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS,'' published in the **Federal Register** on January 16, 2009 (74 FR 3328) (hereinafter referred to as the ICD–10 final rule).

The Congress addressed the need for a consistent framework for electronic health care transactions and other administrative simplification issues through the Health Insurance Portability

[1] ''Version 5010 and ICD–10 Readiness Assessment: Conducted among health Care providers, payers and Vendors for the Centers for Medicare & Medicaid Services (CMS), December 2011 (OMB Approval No: 09938–1149). The assessment surveyed 404 providers, 101 payers, and 90 vendors, which represents 0.1% of all physician practices, 3% of hospitals, and 5% of health plans.

[2] An impact assessment for ICD–10 is performed by a covered entity to determine business areas, policies, processes and systems, and trading partners that will be affected by the transition to ICD–10. An impact assessment is a tool to aid in planning for implementation. ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

and Accountability Act of 1996 (HIPAA), (Pub. L. 104–191), enacted on August 21, 1996. HIPAA amended the Act by adding Part C–Administrative Simplification—to Title XI of the Act requiring the Secretary to adopt standards for certain electronic transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information exchange.

In the August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' (hereinafter referred to as the Transactions and Code Sets final rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards developed by standard development organizations (SDOs) for certain electronic health care transactions and medical code sets to be used in those transactions. We adopted the Accredited Standards Committee (ASC) X12 standards Version 4010/4010A1 and the National Council for Prescription Drug Programs (NCPDP) Telecommunication standard Version 5.1, which is specified at 45 CFR part 162, subparts K through R. All health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a covered transaction (referred to as covered entities) are required to comply with these adopted standards.

In the January 16, 2009 **Federal Register** (74 FR 3296), we published a final rule entitled, ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' (the Modifications final rule), that, among other things, adopted updated versions of the standards for the electronic health care transactions for which the Department originally adopted standards in the Transactions and Code Sets final rule. These updated standards for electronic health care transactions included ASC X12 Version 5010 and NCPDP Telecommunication Standard Implementation Guide, Version D. Release 0 (Version D.0), and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2). In the Modifications final rule, the Department also adopted the Medicaid pharmacy subrogation transaction, a new standard—the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0). Covered entities are required to conduct as standard transactions all electronic transactions for which the Secretary has adopted a standard. From March 17, 2009 through December 31, 2011, covered entities were required to comply either with the ASC X12 Version 4010/4010A1 and NCPDP Telecommunications standard Version 5.1 standards or the updated Version 5010 and NCPDP D.0 standards. Effective January 1, 2012, covered entities were required to comply with Version 5010 and NCPDP D.0, and (except for small health plans) the Version 3.0 standard for Medicaid pharmacy subrogation transactions. Small health plans must comply with Version 3.0 on or after January 1, 2013.

Also on January 16, 2009, we published a final rule entitled ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'' (74 FR 3328). In the ICD–10 final rule, we adopted the 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: (1) diseases; (2) injuries; (3) impairments; (4) other health problems and their manifestations; and (5) causes of injury, disease, impairment, or other health problems. We also adopted the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS), including the Official ICD–10–PCS Guidelines for Coding and Reporting, as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments of hospital inpatients reported by hospitals: (1) prevention; (2) diagnosis; (3) treatment; and (4) management.

Table 1 summarizes the full set of transaction standards adopted in the Transactions and Code Sets final rule and as modified in the Modifications final rule. The table uses abbreviations of the standards and the names by which the transactions are commonly referred, while the official nomenclature and titles of the standards and transactions related to the provisions of this proposed rule are provided later in this preamble.

TABLE 1—TRANSACTIONS STANDARDS ADOPTED UNDER HIPAA

Standard	Transaction
ASC X12 837 D.	Health care claims—Dental.
ASC X12 837 P.	Health care claims—Professional.
ASC X12 837 I	Health care claims—Institutional.
NCPDP D.0 and Version 1.2.	Health care claims—Retail pharmacy drug.
ASC X12 837 P and NCPDP D.0 and Version 1.2.	Health care claims—Retail pharmacy supplies and professional services.
NCPDP D.0 and Version 1.2.	Coordination of Benefits—Retail pharmacy drug.
ASC X12 837 D.	Coordination of Benefits—Dental.
ASC X12 837 P.	Coordination of Benefits—Professional.
ASC X12 837 I	Coordination of Benefits—Institutional.
ASC X12 270/271.	Eligibility for a health plan (request and response)—Dental, professional, and institutional.
NCPDP D.0	Eligibility for a health plan (request and response)—Retail pharmacy drugs.
ASC X12 276/277.	Health care claim status (request and response).
ASC X12 834	Enrollment and disenrollment in a health plan.
ASC X12 835	Health care payment and remittance advice.
ASC X12 820	Health plan premium payment.
ASC X12 278	Referral certification and authorization (request and response).
NCPDP D.0 and Version 1.2.	Referral certification and authorization (request and response)—Retail pharmacy drugs.
NCPDP D.0 and Version 1.2.	Retail pharmacy drug claims (telecommunication and batch standards).
NCPDP 3.0	Medicaid pharmacy subrogation (batch standard).

In the July 8, 2011 **Federal Register** (76 FR 40458), we published an interim final rule with comment period, ''Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions'' (Eligibility and Claim Status Operating Rules IFC). That rule adopted operating rules for two HIPAA covered transactions: (1) Eligibility for a health plan; and (2) health care claim status. The Eligibility and Claim Status Operating Rules IFC also defined the term, ''operating rules,'' revised the definition for ''standard transaction,'' revised specific related regulatory provisions, and described the relationship between operating rules and standards.

In general, the transaction standards adopted under HIPAA enable electronic data interchange (EDI) using a common interchange structure, thus minimizing the industry's need to rely on multiple formats. The standards significantly decrease administrative burden on covered entities by creating greater uniformity in data exchange, and reducing the amount of paper forms needed for transmitting data, which remains an obstacle to achieving greater health care industry administrative simplification.

Section 1172(a) of the Act states that ''[a]ny standard adopted under [Part C—Administrative Simplification—of Title XI of the Social Security Act, as amended by section 262 of HIPAA] shall apply, in whole or in part, to the following persons: (1) A health plan; (2) A health care clearinghouse; and (3) A health care provider who transmits any health information in electronic form in connection with a [HIPAA transaction].''

Section 1173(b) of the Act directs the Secretary to adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In the May 31, 2002 **Federal Register** (67 FR 38009), we published a final rule entitled, ''Health Insurance Reform: Standard Unique Employer Identifier,'' which adopted the standard for a unique employer identifier in HIPAA electronic health care transactions. In the January 23, 2004 **Federal Register** (69 FR 3434), we published a final rule entitled, ''HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers'' (the 2004 NPI final rule), in which the Secretary adopted the National Provider Identifier (NPI) as the standard unique health care provider identifier and the requirements for obtaining and using the NPI. Health care providers that transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard (known as ''covered health care providers''), are required to obtain NPIs and use them according to the NPI regulations at 45 CFR part 162, subpart D. Specifically, under the requirements for health care providers at 45 CFR 162.410, a covered health care provider must obtain an NPI for itself and some of its subparts, use the NPI in standard transactions it conducts, and disclose its NPI to any entities that need it for standard transactions. The Secretary has not adopted a standard patient identifier.

Under section 1172(c)(2)(B) of the Act, if no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under the Administrative Simplification provisions of HIPAA, then the Secretary may adopt a standard, relying upon recommendations of the NCVHS. In such a case, the Secretary shall publish in the **Federal Register** any recommendation of the NCVHS regarding the adoption of a standard under the HIPAA Administrative Simplification provisions. Further, the Secretary must consult with 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), other appropriate private organizations, and appropriate Federal and State agencies regarding such standard adoption.

In this proposed rule, we address the adoption of a unique health plan identifier, the adoption of a data element that would serve as an identifier for other entities, an addition to the NPI requirements, and a change to the compliance date for the ICD–10–CM and ICD–10–PCS code sets.

C. The Unique Health Plan Identifier (HPID) and the Affordable Care Act

Section 1104(c)(1) of the Affordable Care Act, enacted on March 23, 2010, directs the Secretary to promulgate a final rule establishing a unique health plan identifier that is based on the input of a Federal advisory committee, the National Committee on Vital and Health Statistics (NCVHS). Section 1104 of the Affordable Care Act authorizes the Secretary to promulgate the rule on an interim final basis and indicates that such rule shall be effective not later than October 1, 2012.

Health plans are currently identified for different purposes using different identifiers that have different sources, formats, and meaning. A health plan may have multiple identifiers, each assigned by a different organization for a different purpose. The following discussion focuses on the types of identifiers that currently may be used to identify health plans in standard transactions. State regulators, for instance, use the National Association of Insurance Commissioners' (NAIC) Company code to identify health plans when a health plan is licensed to sell or offer health insurance in a particular State. The U.S. Department of Labor (DOL) and the Internal Revenue Service (IRS) use the 9-digit Employer Identification Number (EIN) and a 1-digit alphabetic or a 3-digit plan number to identify health plans. Employers, sole proprietorships, corporations, partnerships, non-profit associations, trusts, estates of decedents, government agencies, certain individuals, and other business entities, use EINs to identify health plans for a host of purposes and transactions. The IRS uses the EIN to identify taxpayers that are required to file various business tax returns. Health care clearinghouses assign proprietary identifiers to health plans for use in standard transactions. Multiple clearinghouses may identify the same health plan using different proprietary identifiers in different covered transactions. Health plans may use other existing identifiers, such as a tax identification number (TIN) or an EIN, to identify themselves in the standard transactions, to more easily integrate into existing proprietary systems, or for use on health insurance cards that they issue to health plan enrollees.

Not only are health plans identified using a variety of identifiers, but these identifiers have different formats. For instance, some identifiers are alphanumeric while other identifiers are only numeric. Identifiers also differ in length; for example, NAIC codes are typically five digits while an EIN is nine digits.

The current versions of the adopted standards (ASC X12N and NCPDP) allow health plans to use these and other identifiers in standard transactions. Therefore, for the covered transactions there is no requirement for consistency in the use of identifiers for health plans. Health care providers, health plans, and healthcare clearinghouses may use EINs, TINs, NAIC numbers, healthcare clearinghouse, or health plan assigned proprietary numbers to identify health plans in standard transactions. Industry stakeholders, especially health care providers, have indicated that the lack of a standard unique health plan identifier has resulted in increased costs and inefficiencies in the health care system. Health care providers are frustrated by problems with: the routing of transactions; rejected transactions due to insurance identification errors; difficulty determining patient eligibility; and challenges resolving errors identifying the health plan during claims processing.

The Affordable Care Act specifically calls for the establishment of a unique identifier for health plans. There are however, other entities that are not health plans but that perform certain health plan functions and are currently identified in the standard transactions in the same fields using the same types of identifiers as health plans. For

example, health care clearinghouses, third party administrators (TPAs), and repricers often contract with insurance companies, self-funded employer health care plans, and provider- or hospital-run health plans to perform claims administration, premium collection, enrollment, and other administrative functions. In some cases, TPAs or other entities are identified in the same fields as health plans in the transactions, depending on the contractual relationships. As explained later in this proposed rule, we propose to adopt a data element—an other entity identifier—to serve as an identifier for these other entities.

D. The National Committee on Vital and Health Statistics (NCVHS)

In section 1104 of the Affordable Care Act, the Secretary is directed to conduct its rulemaking to establish a unique health plan identifier based on input of the NCVHS. Congress created the NCVHS to serve as an advisory body to the Secretary on health data, statistics, and national health information policy. The NCVHS has been assigned a significant role in the Secretary's adoption of all standards, code sets, and operating rules under HIPAA, including the unique health plan identifier. In section 1104(c)(1) of the Affordable Care Act, Congress reiterated that the NCVHS would retain its role in providing input on the establishment of the health plan identifier.

The NCVHS Subcommittee on Standards fulfilled these duties by conducting public hearings on the health plan identifier on July 19 through 21, 2010. Industry stakeholders, including representatives from health plans, health care provider organizations, health care clearinghouses, pharmacy industry representatives, standards developers, professional associations, representatives of Federal and State public programs, the Workgroup on Electronic Data Interchange (WEDI), the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), and individuals with health plan identifier proposals provided in-person and written testimony. Stakeholder testimony at the hearings focused on the use and need for an HPID to: facilitate the appropriate routing of transactions; reduce the cost of managing financial and administrative information; improve the accuracy and timeliness of claims payment; and reduce dissatisfaction among health care providers and patients/members by improving communications with health plans and their intermediaries. Stakeholders provided suggestions on the types of entities that need to be identified in standard transactions, those that should be eligible to obtain an HPID, and the level of enumeration for each plan (for example the legal entity, product, benefit package etc). We discuss the specifics of key issues in more detail later in this proposed rule.

1. Eligibility for an HPID

There was substantial testimony on the types of entities that should obtain an identifier and a request that HHS clearly indicate the organizations that would be required to obtain and use an identifier in standard transactions. Testifiers also offered extensive input on the need to provide an identifier for entities that do not meet the definition of health plan under HIPAA, but have a need to be identified in standard transactions. The majority of those testifying recommended that these entities, such as TPAs and health care clearinghouses, be eligible to obtain an identifier for use in the standard transactions.

2. HPID Enumeration Level

Stakeholders offered extensive input on the appropriate level of health plan enumeration. Testifier suggestions ranged from requiring health plans to enumerate at the highest level (that is the parent company), to enumerating every health plan benefit package (for example ''HMO Gold''). Some testifiers proposed that there be two types of health plan identifiers, and they used the term ''plan'' to mean both the health plan products and health plan organizations—Type 1 and Type 2 identifiers, respectively. As reflected in written testimony submitted to the NCVHS, they proposed that the Type 1 identifier identify patient-specific health plan products, for instance, a particular health insurance product, or an employee health benefit plan or other product defining the patient's coverage. The Type 2 identifier would identify organizations that perform health plan functions, such as entities issuing long-term care policies, plan organizations paying for the cost of medical care for specified populations, or entities responsible for funding high risk pools offering coverage to eligible individuals. Some testifiers also suggested that the Type 2 identifier also identify entities other than health plans that perform certain administrative or contracting functions on behalf of health plans, such as TPAs or health care clearinghouses. In addition, some of these testifiers recommended the creation of a fee schedule identifier so health care providers could download the appropriate fee schedule, just as the entity that is administering the claims transaction must do to price the claim.

Other testifiers opined that enumeration should occur at a health plan organization level and should support the ability to obtain and utilize a more granular enumeration scheme if there is a business need for further differentiation to appropriately route transactions. This proposal was based on the premise that the purpose of the HPID is to identify entities that meet the regulatory definition of health plan and are conducting the covered transactions. The HPID will be used to identify a health plan that sends or receives the covered transactions. These testifiers cautioned that requiring fee schedule, reimbursement information, or product level information in the HPID would create a level of complexity that would greatly increase the number of identifiers needed, resulting in significant health plan maintenance requirements, increased cost, and inefficiencies. These testifiers recommended that associating product information with particular identifiers should not be a goal of the HPID, although it could be addressed in future versions of the standards, implementation guides, or operating rules.

3. Timing

Stakeholders at the NCVHS hearings also stressed the importance of a smooth transition from current plan identifiers to the HPID during the enumeration process, given its potential impact on the industry. For example, they noted that health plan and health care provider information systems will need to be reprogrammed to accommodate the HPID, including the possible expansion of data fields and the creation of crosswalks between existing proprietary identifiers and the HPID. Health care clearinghouses and health IT vendors will need to update their systems to accommodate the new identifiers, and may also need to create identifier crosswalks to match current health plan identifiers to the HPID and vice versa. Health plans will need to conduct an analysis of their organizations and structure to determine, if they have subsidiaries, which of their entities qualify as health plans and need to be enumerated. The HPID may also impact information systems that involve Health Level 7 (HL7) standard protocols. Testimony from the HL7 SDO noted that it is likely that the HPID may require changes to existing scheduling, registration, pre-admission, admission, and other information systems and their screens,

work flows, and data elements collected, stored, displayed, and processed by those applications. In addition, testifiers pointed out other regulatory requirements with similar, converging compliance dates, such as: January 1, 2012 for complying with Version 5010, Version D.0 and Version 3.0; October 1, 2013 for complying with the ICD–10–CM and ICD–10–PCS medical code sets requirements; January 1, 2013 for implementing the first set of operating rules for two of the standard transactions; and other changes under the Affordable Care Act all require limited industry resources.

Finally, there was testimony related to the use of health plan identifiers in the retail pharmacy transactions, and we address this topic later in this proposed rule. (For transcripts and testimony of the July 19 and 20, 2010 NCVHS Subcommittee on Standards hearings, go to *http://www.ncvhs.hhs.gov*.)

E. The NCVHS Recommendation to the Secretary on HPID

On September 30, 2010, following the July 2010 NCVHS Subcommittee on Standards hearing, the NCVHS sent a letter to the Secretary with its recommendations for the adoption of a standard for a health plan identifier. The nine NCVHS observations addressed the following topics: (1) The definitions and types of entities eligible for enumeration with an HPID; (2) the level of entity enumeration; (3) the format and content of the HPID; (4) the directory database to support the HPID enumeration system and process; (5) the implementation of the HPID in retail pharmacy; (6) the implementation process and timing; (7) applicable testing of the HPID enumeration process; (8) the use of the HPID on health plan identification cards, and (9) the improvement in the use of standards and operating rules. The specific recommendations are as follows:

''HHS should:

• 1.1 clarify the definition of health plan as specified in the HIPAA regulations (45 CFR 160.103) for purposes of HPID eligibility and enumeration, including that property and casualty insurers and workers' compensation plans could be eligible for such enumeration even though they are not covered entities.

• 1.2 work with stakeholders to reach consensus on names and definitions for intermediary entities. Consider making these intermediary entities eligible to obtain an HPID where there is a clear use case for them to be enumerated.

• 1.3 request stakeholder input through groups such as Workgroup on Electronic Data Interchange (WEDI), America's Health Insurance Plans (AHIP), National Association of Insurance Commissioners (NAIC), and the Designated Standards Maintenance Organizations (DSMO) Committee for definitions of products to be used in plan enumeration by October 31, 2010 (or other date as deemed feasible by CMS).

• 1.4 collaborate across Federal agencies and departments to develop or identify consensus definitions affecting the identification of health plans, including Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Defense (DoD), and the Federal Employee Health Benefit Program (FEHBP).

• 1.5 coordinate, to the maximum extent feasible, the development and implementation of the HPID with other plan related requirements in the Affordable Care Act, including, for example, the consumer health insurance web portal, the health insurance exchanges and the regulatory requirements for health plans.

• 2.1 initially enumerate all health plan legal entities as defined in the HIPAA legislation and further clarified in regulations at 45 CFR 160.103.

• 2.2 determine at what level, including product (benefit package) level or other categorization, a health plan should also be enumerated, using input from stakeholders, and identify these in regulation.

• 3.1 adopt an HPID that follows the ISO Standard 7812, with Luhn check-digit as the tenth digit.

• 3.2 adopt an HPID that contains no embedded intelligence.

• 4.1 establish an HPID enumeration system and process supported by a robust online directory database.

• 4.2 direct CMS to work with stakeholders including other Federal agencies to identify the minimum necessary data elements for the directory database. Consideration should be given to including the Employer Identification Number (EIN), Taxpayer Identification Number (TIN), National Association of Insurance Commissioners (NAIC) identifier, Source of Payment Typology, and other identifiers that may assist in supporting the need to appropriately identify health plans in administrative transactions and in the updating, development and/or effective use of standards and operating rules. The database should be sufficiently flexible to enable additional information to be added initially at the discretion of the entity, and potentially in the future, as a requirement by HHS.

• 4.3 require the entity enumerated to maintain all information according to a published schedule of updates or more often as appropriate, to maintain accuracy. If there are no changes at the time of a scheduled update, the date information was validated should signify that the entity has reviewed and is confirming the data as being current.

• 4.4 make available appropriate information from the HPID directory database to support the efficient and accurate exchange of information.

• 4.5 consider, for the future, requiring that the HPID system enable electronic transactions with the directory database for users or their systems to obtain information and route transactions more efficiently and effectively.

• 5.1 not require the HPID to be used in place of the existing RxBIN/PCN identifier in retail pharmacy business and transactions.

• 5.2 require the use of HPID on the HIPAA-named standard transactions for retail pharmacy, where appropriately defined by industry through the ASC X12 and NCPDP processes.

• 6.1 consider that the effective date of October 1, 2012 be interpreted as the date to begin registering for an HPID. As such, subsequent phases should include time for enumeration and testing before a final implementation date when the HPID must be used in compliant transactions. This will ensure sufficient time for publication of the regulation and development of the enumeration system and process. Phases should include:

• October 1, 2012—March 31, 2013: Enumeration

• April 1, 2013—September 30, 2013: Testing

• October 1, 2013: Implementation

• 6.2 describe in regulation the potential purposes and uses of the HPID, including its uses in standard transactions, potential uses for health information exchange, and others. While purposes should not be restricted, the initial focus should be on enumerating entities for use in the financial and administrative transactions required under HIPAA.

• 6.3 accommodate bulk enumeration of HPID as applicable.

• 7.1 provide sufficient time and guidance for testing the HPID in transactions prior to use.

• 7.2 allow for a period during which dual use of legacy health plan identifiers and the new HPID is permitted in the transactions as appropriate.

• 8.1 encourage the use of the HPID in health plan identification cards.

• 9.1 strongly encourage the industry to collaborate to enhance operating rules for the financial and

administrative transactions to support the use of the HPID.''

For the complete text of the NCVHS' observations and recommendations, go to *http://www.ncvhs.hhs.gov/100930lt1.pdf.*

We agree in principle with the spirit and intent of the NCVHS' recommendation to the Secretary for a health plan identifier standard as relayed in the September 30, 2010 letter. In this proposed rule, we propose to adopt a health plan identifier based in large part upon the NCVHS' recommendations, with some minor departures. In section II. of this proposed rule, we itemize our proposals and, where necessary, explain the differences between the HHS proposal and the NCVHS' recommendations.

F. Definition of Health Plan

The regulatory definition of health plan at 45 CFR 160.103 was initially adopted in the Transactions and Code Sets final rule. The basis for the additions to, and clarifications of, the statutory definition of health plan is further discussed in the preamble to the December 28, 2000 final rule (65 FR 82478 and 82576) entitled ''Standards for Privacy of Individually Identifiable Health Information'' (hereinafter referred to as the Privacy Rule). The term ''health plan'' is defined at 45 CFR 160.103.

This definition of ''health plan'' references group health plans, health insurance issuers, and health maintenance organizations that are also defined in 45 CFR 160.103. These definitions are included here:

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg–91(b)(2) and used in the definition of health plan in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of health plan in this section) means a Federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

II. Provisions of the Proposed Rule To Adopt a Standard for a Unique Health Plan Identifier (HPID)

This rule proposes an HPID as the standard for the unique identifier for health plans. We are also proposing instructions and guidance concerning how health plans may obtain an HPID. We further propose requirements that covered entities will have to meet to use the unique health plan identifier in standard transactions. This proposed rule would add provisions specific to the HPID in a new subpart (subpart E) to 45 CFR part 162.

A. The Health Plan Identifier

1. Definition of ''Controlling Health Plan'' and ''Subhealth Plan''

Health plans today have many different business structures and arrangements that affect how health plans are identified in standard transactions. There is often a ''parent'' corporation that meets the definition of health plan, which may be controlled by entities, such as holding companies, that do not meet the definition of health plan. This ''parent'' health plan may own and operate several other entities and organizations, which may also meet the definition of a health plan. While these individual health plans that are owned by the same ''parent'' corporation may have their own EIN or NAIC number, they may all use a single identifier in covered transactions because of data processing arrangements. In these situations, some health plans may not need to be identified separately in covered transactions, and may not need their own health plan identifier. To differentiate between health plan entities that would be required to obtain an HPID, and those that would be eligible, but not required, to obtain an HPID, we are proposing definitions for controlling health plan (CHP) and subhealth plan (SHP) in proposed 45 CFR 162.103 as follows.

a. Controlling Health Plan (CHP)

We would define a CHP as a health plan (as defined at 45 CFR 160.103) that—(1) controls its own business activities, actions, or policies; or is controlled by an entity that is not a health plan (2) and if it has a subhealth plan(s) (SHPs) (see definition of SHP in subpart b), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

The following factors would need to be considered when determining if an entity is a CHP:

- Does the entity itself meet the definition of health plan at 45 CFR 160.103?
- Does either the entity itself or a non health plan organization control the business activities, actions, or policies of the entity?

If the answer to both questions is ''yes,'' then the entity meets the definition of CHP. We propose that an entity that meets the definition of CHP would be required to obtain a health plan identifier.

b. Subhealth Plan (SHP)

A SHP would mean a health plan (as defined in 45 CFR 160.103) whose business activities, actions, or policies are directed by a CHP. The following considerations may be helpful in determining whether an entity is a SHP:

- Does the entity meet the definition of health plan at § 160.103?
- Does a CHP direct the activities, actions, or policies of the health plan entity?

If the answer to both questions is ''yes,'' then the entity meets the definition of SHP. We propose that a SHP would not be required to obtain an HPID, but may choose to obtain an HPID, or its CHP may obtain an HPID on its behalf.

2. Proposed Use of the HPID

In proposed 45 CFR 162.510, we propose HPID usage requirements for all covered entities. We propose to require all covered entities to use an HPID wherever a covered entity identifies a health plan in a covered transaction. Covered entities would obtain the HPIDs of health plans from the health plans themselves or from the Enumeration System, which we describe later in this proposed rule. If a covered entity uses a business associate to conduct standard transactions on its behalf, the covered entity must require that its business associate use an HPID in each field where the business

associate identifies a health plan in all covered transactions.

The HPID may also be used for any other lawful purpose that requires the identification of health plans.

Some examples of permitted uses include the following:

- Health plans may use HPIDs in their internal files to facilitate processing of health care transactions.
- A health plan may use an HPID on a health insurance card.
- The HPID may be used as a cross-reference in health care fraud and abuse files and other program integrity files.
- Health care clearinghouses may use HPIDs in their internal files to create and process standard and non-standard transactions, and in communications with health plans and health care providers.
- HPIDs may be used in patient medical records to help specify patients' health care benefit package(s).
- HPIDs may be used to identify health plans in electronic health records (EHRs).
- HPIDs may be used to identify health plans in Health Information Exchanges (HIEs).
- HPIDs may be used to identify health plans in Federal and State health insurance exchanges.
- HPIDs may be used to identify health plans for public health data reporting purposes.

3. Proposed Health Plan Identifier Requirements for Health Plans

In 45 CFR 162.512, we propose HPID implementation specifications for health plans. We propose to require all CHPs, as defined in 45 CFR 162.103, to obtain HPIDs from the Enumeration System in accordance with the enumeration process, which is described later in this proposed rule. In addition, CHPs could obtain HPIDs from the Enumeration System on behalf of their SHPs, as defined in 45 CFR 162.103, or direct their SHPs to obtain HPIDs directly from the Enumeration System. Any SHP would be eligible to obtain an HPID regardless of whether or not its CHP directs it to obtain an HPID. A CHP could only obtain one HPID for itself.

We propose to require each health plan to disclose its HPID to any entity, upon request, that needs the HPID to identify that health plan in a standard transaction. We propose to require each health plan to ensure that its own data in the Enumeration System is correct and that each health plan submits changes (updates, corrections, etc.) to its own data to the Enumeration System within 30 days of the date the change took place. A SHP would ultimately be responsible for submitting updates for its own data in the Enumeration System regardless of whether it obtained its HPID independently or the CHP obtained the HPID on its behalf. We are requesting comments on whether a SHP should be responsible for submitting updates to its own data if a CHP obtained the HPID on its behalf.

This proposed rule provides a discussion on how CHPs and SHPs will obtain an HPID from the Enumeration System. Health plans would be able to begin to apply for an HPID on or after the effective date of the final rule, which we expect to be October 1, 2012, and must use it in standard transactions by the compliance date of the final rule.

a. Requirements and Options for Obtaining and Using a Health Plan Identifier

While a CHP would be required to obtain a health plan identifier, there would be different options available for the enumeration of SHPs based on a CHP's organizational structure and business needs. The CHP may analyze its organizational structure to determine if and which of its SHPs need a HPID based on whether the SHP needs to be identified in covered transactions. The CHP may obtain HPIDs on behalf of its SHP, or it may direct the SHPs to obtain the HPIDs. While a CHP could only obtain 1 HPID for itself, a CHP could use the HPID of its SHPs for any lawful purpose, including in the transactions.

Self-insured group health plans are included in the definition of health plan in § 160.103. Because of this, self-insured group health plans will need to obtain a health plan identifier if they meet the definition of a CHP. We specifically mention self-insured group health plans as there was industry discussion about whether these health plans should be required to obtain HPIDs because they do not always need to be identified in the standard transactions. As discussed, the primary purpose of the HPID is for use in the standard transactions. Many self-insured group health plans contract with third party administrators or other entities to perform health plan functions on their behalf and those entities, not the self-insured group health plans, may be identified in the standard transactions. Some in the industry thus suggested not requiring self-insured group health plans to obtain HPIDs as they may not need to be identified in the standard transactions, while others recommended requiring these plans to obtain HPIDs as they may be the financially responsible party. Given that self-insured group health plans are included in the definition of health plan and there is a potential need to be identified in the standard transactions, we propose that they be required to obtain a HPID if they meet the definition of a CHP. We are soliciting comment on this issue.

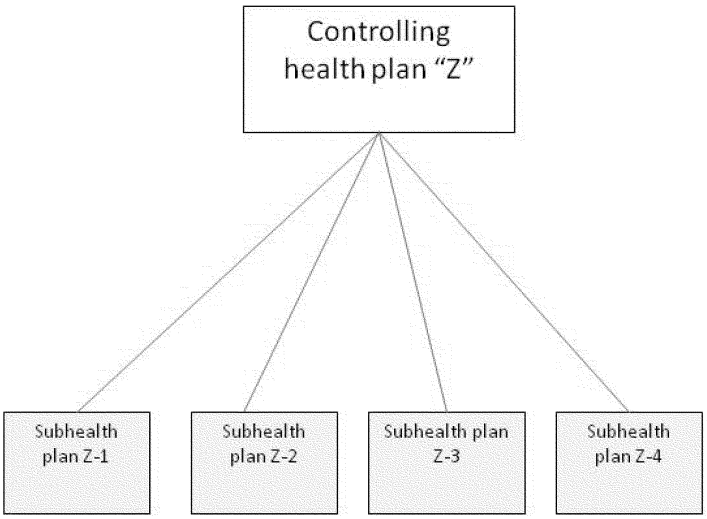
A SHP would be able to obtain an HPID even if its CHP does not obtain one on its behalf or does not direct the SHP to obtain an HPID. We encourage CHPs and SHPs to coordinate their HPID applications to prevent duplicative and unnecessary numbers. See Table 2 for a comparison of requirements for obtaining an HPID.

TABLE 2—PROPOSED ENUMERATION REQUIREMENTS AND OPTIONS FOR CHPS AND SHPS

Entity	Enumeration requirements	Enumeration options
CHPs	Must obtain an HPID for itself	May obtain an HPID(s) for its SHP(s). May direct its SHP(s) to obtain an HPID(s).
SHPs	Not required to obtain an HPID	May obtain an HPID at the direction of its CHP. May obtain an HPID on its own initiative.

Using Illustration A and B, we provide examples of enumeration options to demonstrate the ways a CHP could choose to enumerate itself and its SHPs, if applicable. For these options, we are assuming that CHP ''Z'' and the SHPs Z–1, Z–2, Z–3, and Z–4 each meets the definition of health plan at 45 CFR 160.103.

Illustration A



(1) Illustration A. Enumeration Option 1: CHP and Each SHP Obtain HPIDs

CHP ''Z'' meets the definition of a health plan and controls its own business activities, actions, and policies. Therefore CHP ''Z'' would be required to obtain an HPID. CHP ''Z'' would then analyze its organizational structure and business needs to determine if and which of its SHPs need an HPID for use in standard transactions. CHP ''Z'' may determine that SHPs Z–1, Z–2, Z–3, and Z–4 each need their own HPID for use in the standard transactions as CHP ''Z'' and each of its SHPs may have separate data processing centers or arrangements. Thus, CHP ''Z'' would obtain an HPID, and each of the SHPs, from Z–1 to Z–4 would obtain their own HPIDs. SHPs could obtain HPIDs in one of two ways as described in the following scenarios:

- Scenario 1—CHP ''Z'' obtains all the HPIDs. It obtains one HPID for itself and it obtains an HPID on behalf of each SHP. In total there are five HPIDs.
- Scenario 2—CHP ''Z'' directs its SHPs to obtain HPIDs: CHP ''Z'' obtains its own HPID and each of the SHPs would obtain their own HPIDs individually. Ultimately, the result would be the same as scenario 1: The CHP and each of the four SHPs would have their own HPIDs and there would be a total of five HPIDs.

Other possible scenarios would involve CHP ''Z'' obtaining fewer than all five HPIDs, or directing fewer than all four SHPs to obtain an HPID. Each of the SHPs may also decide on its own to obtain an HPID without direction from the CHP to do so.

(2) Illustration A. Enumeration Option 2: CHP Obtains HPID. SHPs Do Not Obtain HPIDs

As in the first example, CHP ''Z'' would be required to obtain an HPID, as it meets the definition of health plan and controls its own business activities, actions, and policies.

CHP ''Z'' may determine that none of its SHPs needs to be identified in standard transactions, and therefore none of the SHPs needs its own HPID. Instead, CHP ''Z'' may direct SHPs Z–1, Z–2, Z–3, and Z–4 to use the CHPs' HPID in the standard transactions.

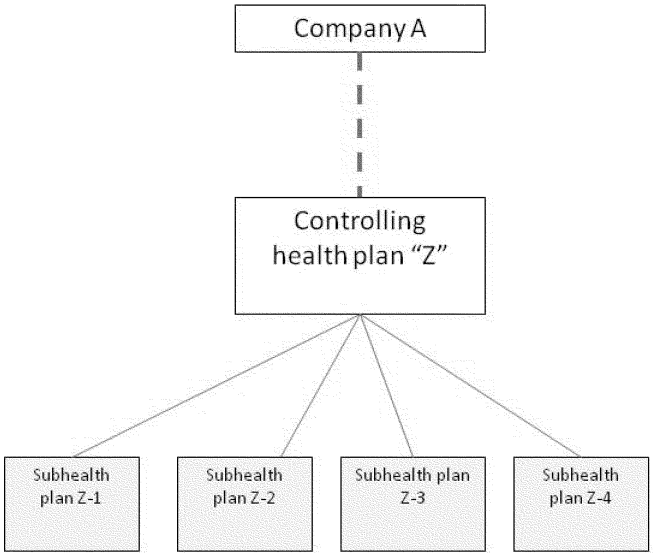
(3) Illustration A. Enumeration Option 3: CHP obtains HPID. Some, But Not All SHPs Obtain HPIDs

Again, CHP ''Z'' would be required to obtain an HPID, as it meets the definition of health plan and controls its own business activities, actions, and policies.

CHP ''Z'' may then examine its organizational structure to determine which of its SHPs need an HPID for use in a standard transaction. CHP ''Z'' may determine that SHPs Z–3 and Z–4 must be uniquely identified in the covered transaction because, for example, they do not share the same data processing centers as CHP ''Z'' and would each want to use their own HPID. SHPs Z–3 and Z–4 would use their own HPIDs in standard transactions. SHPs Z–3 and Z–4 could obtain their HPIDs in one of the following ways:

- CHP ''Z'' could direct SHPs Z–3 and Z–4 to obtain their own HPIDs.
- CHP ''Z'' could obtain HPIDs on behalf of SHPs Z–3 and Z–4. CHP ''Z'' may determine that based on its organizational structure SHPs Z–1 and Z–2 do not need separate HPIDs for use in standard transactions as they may share data processing systems with CHP Z, SHP Z–3, or SHP Z–4. CHP ''Z'' may direct SHP Z–1 and Z–2 to use CHP ''Z''s HPID, SHP Z–3's HPID, or SHP Z–4's HPID in the transactions. CHP ''Z'' may make this determination based on the relevant data processing systems.

Illustration B



(4) Illustration B. Enumeration Option 1: CHP and Each SHP Obtain HPIDs

Illustration B provides an example of a health plan being controlled by Company A, which is a holding company. Holding companies are examples of entities that control the business, activities, actions, or policies of other legal entities such as health plans, but typically do not meet the definition of a health plan as defined in 45 CFR 160.103. Assuming Company A does not meet the definition of a ''health plan'' under the relevant definition in 45 CFR 160.103, it would not be eligible to obtain an HPID.

CHP ''Z'' meets the definition of health plan as found in 45 CFR 160.103, is controlled by an entity that is not a health plan, and exercises sufficient control over the subhealth plans to direct their business activities, actions, or policies. Therefore, it meets the definition of ''controlling health plan'' as proposed in 45 CFR 162.103, and would be required to obtain an HPID for itself.

A similar analysis as discussed in Illustration A would need to be done to determine how subhealth plans Z–1, Z–2, Z–3, and Z–4 would be enumerated. CHP ''Z'' must examine its organizational structure to determine which of its SHPs need an HPID for use in standard transactions, and the same enumeration options for subhealth plans that existed for Illustration A would exist in this example.

b. Examples of Use of HPID in Standard Transactions

Within each transaction, a health plan may need to be identified in fields that do not specifically require the use of a health plan identifier. A health plan could need to be identified, for instance, in data fields that indicate the payer of the claim or the intended recipient of the transaction, or the information source for a particular request. To illustrate how the HPID could be used in standard transactions, we will look at a specific segment from one transaction standard. This example illustrates how covered entities would be required to identify a health plan in a standard transaction. This example is not meant to state who or what must be identified in the fields in the transaction, change what entities can be identified in specific loops or segments in the transaction standards, or affect the use of identifiers for non-health plans. It is important to note that the implementation of the HPID would not prohibit or affect the identification of other entities in these loops or segments if entities other than health plans need to be identified in those loops or segments.

For this example, we will look at a specific segment from one transaction standard—the ASC X12 Version 5010 health care eligibility benefit inquiry and response (also known as the 271). In this example, the segment is the NM1-Information Source Name in the 2100A loop—Information Source. The standard provides the following definition of information source: ''The information source is the entity that has the answer to the questions being asked in a 270 Eligibility or Benefit request transaction. The information source is typically the insurer or payer. In a managed care environment, the information source could possibly be a primary care physician or gateway health care provider. Regardless of the information source's actual role in the healthcare system, they are the entity who maintains the information regarding the patient's coverage.'' The information source is identified in loop 2100A. The NM1 segment, information source name, provides specific details about the information source through data elements. The NM1 segment is comprised of nine reference descriptors. These reference descriptors provide information about a specific data element. For instance, NM101—Entity ID Code—is the code identifying the organizational entity, a physical location, property or an individual. For NM101, there are specific codes that can be used to describe the information source. Table 3 represents the NM1 segment. The chart is meant to demonstrate how the identification of a health plan in the NM1 segment will change after use of the HPID is mandated. For this example, the information source is the health plan.

In Table 3, Column I, the reference descriptor provides the data element being described in the NM1 segment. Table 3, Column II provides the name of the reference descriptor in Table 3, Column I and describes what is being conveyed in that data element. Table 3, Column III lists the codes that the standard permits to be used to describe

the information source. Table 3, Column IV provides the definition of the corresponding code in Table 3, Column III. Table 3, Column V shows what could have been used to identify a health plan prior to the HPID implementation. Table 3, Column VI shows what will be used to identify a health plan after implementation of the HPID.

TABLE 3—EXAMPLE 1, ELIGIBILITY RESPONSE TRANSCTION, LOOP 2100A, SEGMENT NM1—INFORMATION SOURCE NAME (VERSION 5010)

I	II	III	IV	V	VI
Reference description	Name	Code	Definition	Content of the field before HPID compliance date	Content of the field after HPID compliance date
NM101	Entity identifier Code	2B	Third-Party Administrator	If a health plan is to be identified as the information source, then Entity Code Qualifier "PR" will be used.	If a health plan is to be identified as the information source, then Entity Code Qualifier "PR" will be used.
		36	Employer.		
		GP	Gateway Provider.		
		P5	Plan Sponsor.		
		PR	Payer.		
NM108	Identification Code Qualifier.	24	Employer's Identification Number (EIN).	If a health plan is to be identified as the information source, Identification Code Qualifier 24, 46, FI, NI, or PI can be used.	If a health plan is to be identified as the information source, only Identification Code Qualifier XV can be used.
		46	Electronic Transmitter Identification Number (ETIN).		
		FI	Federal Taxpayer's Identification Number.		
		NI	National Association of Insurance Commissioner's (NAIC) Identification.		
		PI	Payer Identification.		
		XV	Centers for Medicare & Medicaid Services Plan ID.		
		XX	Centers for Medicare & Medicaid Services Provider Identifier.		
NM109	Identification Code			Depending on the Identification Code Qualifier, this could be the EIN, ETIN, Tax Id, the NAIC, or any Proprietary Id.	HPID only (if a health plan is to be identified as the information source).

Currently, if the health plan is the information source and needs to be identified in the transactions, it may be identified using a number of different identifiers as shown in Table 3, Column V. If this proposal is finalized and the HPID is adopted, and if a health plan is identified as the information source, it must be identified using an HPID as shown in Table 3, Column VI.

As discussed earlier in this proposed rule, stakeholders at the NCVHS hearings expressed different viewpoints on the appropriate level of health plan enumeration. Some industry stakeholders encouraged health plan enumeration at a very high level (for example, at the level of the health plan's legal entity), while other stakeholders supported enumeration at the benefit package level. We analyzed and considered these viewpoints when we developed the HPID policy proposed herein.

We began by exploring the purpose of the HPID. While we considered multiple uses for the HPID, we determined that the primary purpose of the HPID is for use in standard transactions in order to identify health plans in the appropriate loops and segments and to provide a consistent standard identifier so a health plan no longer uses multiple identifiers in the HIPAA covered transactions. Therefore, we analyzed the transaction standards to determine the existing segments and loops where a health plan may need to be identified, what identifiers are currently used in those loops and segments to identify health plans, and what information that loop or segment is providing when a health plan is being identified. We also carefully considered the information that industry stakeholders reported was missing in covered transactions and suggested could be provided using a health plan identifier. We determined that much of the information testifiers wanted to obtain through the health plan identifier might already be available in other parts of the transaction standards and associated operating rules.

The CAQH CORE 154 eligibility content and operating rule, to be used with the ASC X12 Version 5010 Standard for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response

(270/271) (hereinafter referred to as the Version 5010 270/271 eligibility inquiry/response standard), was adopted through an interim final rule with comment period published in the July 8, 2011 **Federal Register** (76 FR 40458), with a compliance date of January 1, 2013. These operating rules require that more information be provided in the Version 5010 270/271 eligibility inquiry/response standard, including information about a patient's health plan name, coinsurance, copayment, and deductibles including in-network and out-of-network, as well as remaining deductible amounts. The loops, segments, and codes within the transaction standards are already available vehicles for providing this information today. Future versions of standards, as well as the adoption of operating rules to supplement the standards, can address many of the other issues raised by stakeholders and can continue to address issues or problems in the transactions as they arise. Therefore, we do not believe that the HPID needs to provide the level of detail that some testifiers suggested.

In addition, requiring health plans to enumerate to a more granular level may prove burdensome to the industry as benefit package information and offerings change frequently and would require constant updates by health plans. Health care providers may also need to update their software and systems frequently to ensure the accuracy of information. This could result in increased time spent by health plan and health care provider staff to ensure appropriate information is being used for eligibility determination and claim payments.

We developed the proposed HPID policy after considering stakeholder testimony, analyzing transaction standards' loops and segments where the health plan identifier will be used, and taking into account newer versions of the standards and the adoption of operating rules to complement the standards.

4. HPID Standard Format

a. Introduction

Per the NCVHS recommendations, which were based on stakeholder testimony from a wide range of potential HPID users, we propose to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the tenth digit. (See § 162.510). The Luhn check-digit is an algorithm used most often on credit cards as a check sum to validate that the card number issued is correct. See *http://www.merriampark.com/anatomycc.htm* for more information. We seek public and stakeholder comments on the feasibility and utility of this format for the HPID.

b. The International Organization for Standardization (ISO) Standard

The International Organization for Standardization (ISO) is the world's largest developer and publisher of international standards. National standards institutes from 160 nations comprise the ISO. The ISO has published more than 16,500 standards for numerous industries such as agriculture, electrical engineering, and other information technology industries. For more information on the ISO, refer to the Web site at *http://www.iso.org.* Based on stakeholder testimony, the NCVHS recommendations, and our review, we propose that the ISO 7812 standard format, ISO/IEC 7812–1:2006 and ISO/IEC 7812–2:2007, which consists of a 10-digit, all-numeric identifier with a Luhn check-digit as the tenth digit, be adopted as the standard for the HPID. This standard incorporates the same format that is used for the enumeration of health care providers via the National Provider Identifier (NPI), adopted in the NPI final rule, published in the January 23, 2004 **Federal Register** (69 FR 3434). Like the proposed standard for the HPID, the standard for the NPI is a 10-position all numeric identifier with a numeric check digit to assist in identifying erroneous or invalid NPIs. The HPID format would essentially be an intelligence-free identifier as the start digit of the number would provide the only piece of intelligence, signaling that the identifier had been provided to a health plan and not to an ''other entity'' or a health care provider. The OEID will have a different start digit than the HPID. The number of digits of the HPID would not exceed the number permitted for identifiers in the relevant data fields of the standard transactions. If additional capacity for HPIDs were needed in the future, the relevant data fields would permit additional numeric digits to be added at that time. Also, an all-numeric identifier: is more quickly and accurately keyed in data-entry applications; is more easily used in telephone keypad applications; does not require translation before application of the check digit algorithm and thus uses the full ability of the check digit algorithm to detect keying errors; will require less change for systems that currently use a numeric identifier; and is compatible with ISO identification card standards for a card issuer identifier, while Alphanumeric identifiers do not possess these important characteristics.

B. Adoption of the Other Entity Identifier (OEID)

In addition to proposing the adoption of an identifier for health plans, we are also proposing to adopt a data element in the form of an optional identifier for other entities for use in standard transactions, consistent with the recommendations of the NCVHS. Section 1104(c) of the Affordable Care Act provides in relevant part that the Secretary ''shall promulgate a final rule to establish a unique health plan identifier (as described in section 1173(b) of the Act (42 U.S.C. 1320d–2(b))) based on the input of the National Committee on Vital and Health Statistics.'' Section 1173(a)(1)(A) of the Act states in relevant part that ''[t]he Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—(A) the financial and administrative transactions described in paragraph (2)* * *, '' which contains a list of the transactions for which the Secretary has to adopt a standard.

The OEID would serve as an identifier for entities that are not health plans, health care providers, or ''individuals'',[3] yet they need to be identified in standard transactions. Under this proposed rule, these other entities would not be required to obtain an OEID, but they could obtain and use one if they needed to be identified in covered transactions. If they obtained an OEID, these entities would be expected to use it and disclose it upon request to entities that need to identify such entities for covered transactions.

We are proposing to make obtaining and using the OEID voluntary. Stakeholders expressed a strong interest in being able to obtain an identifier, and the NCVHS agreed and recommended that such an identifier would be beneficial to the industry. We believe that voluntary obtaining and using is appropriate at this time, although we recognize that the OEID may be more beneficial if obtaining and using an OEID were required. We could do this, for example, by requiring health plans that have business relationships with other entities that perform certain functions on their behalf to direct in a contract or other arrangement these other entities to obtain and use an OEID. Alternatively, covered entities could on

[3] Individual is defined at 45 CFR 160.103 as ''the person who is the subject of protected health information.''

their own initiative require their trading partners or business associates obtain OEIDs as part of their own agreed upon business arrangements. This rule does not propose to preclude such a business practice. We are interested in industry opinions about our proposal to make obtaining and using the OEID voluntary, and we also welcome comments about whether and how it should be made mandatory.

1. The Other Entity Identifier (OEID)

As discussed in section I. of this proposed rule, health plans often use the services of other entities to conduct certain financial and administrative transactions on their behalf. Rental networks, benefit managers, third party administrators, health care clearinghouses, repricers, and other third parties often perform functions similar to, or on behalf of, health plans. In many cases, these other entities are currently being identified in standard transactions in the same fields and using the same type of identifiers used by health plans. For example, when a covered health care provider conducts a transaction to determine eligibility for a health plan (referred to as an ''eligibility for a health plan transaction''), the health care provider may send an electronic request to obtain information about a patient's eligibility for health care services to an entity referred to as an ''information source.'' This ''information source'' provides information back to the health care provider about a specific patient's health care coverage that a particular health plan provides. The ''information source'' for the patient's eligibility information may be a health plan or one of these other entities that perform financial and administrative services on behalf of that health plan. Currently, in the transaction standard for the eligibility for a health plan transaction, health plans, and the other covered entities may use the same type of identifiers, such as a Payer Identifier (PAYERID) or an EIN, to identify themselves as the ''information source.''

In its September 30, 2010 letter to the Secretary, the NCVHS explained the integral role other entities play in health care administrative and financial electronic transactions. The NCVHS acknowledged that while these other entities may not meet the definition of ''health plan'' under HIPAA, they nevertheless need to be identified in the transactions to ensure successful, efficient communication. The reality is that these entities often need to be identified in the same fields in which a health plan would need to be identified because they perform very similar functions. These other entities are using many of the same identifiers health plans currently use in covered transactions. In addition, the NCVHS recommended that HHS consider allowing these entities to obtain HPIDs as they may be the actual recipients of eligibility queries or claims on behalf of the health insurance issuer or the entity ultimately responsible for payment. The NCVHS stressed the importance of enabling these entities to be enumerated, and recommended that HHS consider making these entities eligible to obtain an HPID where there is a clear use case for them to be enumerated. Based on the testimony NCVHS heard, information we have received, and for the reasons stated previously, we believe that a clear use case does exist for these other entities to be enumerated. Moreover, we anticipate that with the recent advances in health information exchange and the development of health information networks, the need to identify these other entities in financial and administrative electronic transactions will only increase.

Offering the OEID as an adopted data element to identify other entities that need to be identified in covered transactions should reduce costs and improve efficiency for covered entities. Because other entities are identified in the transaction standards in a similar manner as health plans, we believe that establishing a data element to serve as an identifier for these entities will increase efficiency by encouraging the use of a uniform identifier and promote compliant use of the HPID for health plans. Like the standard for HPID we are proposing to adopt, the OEID that we are proposing would follow ISO standard 7812, and be a 10-digit, all-numeric identifier with a Luhn check-digit as the tenth digit. Consequently, entities that have implemented the HPID and are seeking to implement the OEID would not need to significantly modify their information technology systems to accommodate the use of the OEID.

Therefore, we are proposing to establish the OEID for use in standard transactions to identify entities that are not eligible to obtain an HPID or NPI and are not individuals (as defined at 45 CFR 160.103). The OEID would be used to identify these other entities where these other entities need to be identified in the standard transactions, and for any other lawful purpose. These entities would be eligible, but not required, to obtain an OEID for themselves. An OEID would be obtained by the other entity from the Enumeration System identified in 45 CFR 162.508 as discussed in this proposed rule. Changes to its required data elements would need to be communicated to the Enumeration System within 30-days of the change. We solicit industry and stakeholder comments on our proposed enumeration of other entities and adoption of the OEID for use in the standard transactions.

C. Assignment of the HPID and OEID

1. The Enumeration System

We propose that in 45 CFR 162.508, the Enumeration System would assign unique HPIDs and OEIDs to eligible health plans and eligible other entities, respectively. The Enumeration System would be a comprehensive system for uniquely identifying and enumerating all eligible health plans and other entities. It would collect and maintain certain identifying and administrative information about CHPs, SHPs, and other entities. The Enumeration System would also disseminate information through a publicly available searchable database or through downloadable files. Entities may also obtain a CHP's or SHP's HPID or an entity's OEID by requesting the HPID from the health plan or the OEID from the other entity.

HPIDs and OEIDs would only be assigned by the Enumeration System through an online application process. A health plan or other entity, when applying online for an HPID or OEID, would be required to provide certain identifying and administrative information. We anticipate this information will be used to verify the identity and eligibility of health plans and other entities during the application process. We anticipate further that a help desk will be available to assist health plans and other entities with the online application process as necessary and to notify health plans or other entities about problems associated with their online applications.

The Enumeration System would also be able to deactivate or reactivate an HPID or OEID based on receipt of sufficient information. Examples of situations justifying deactivation of an HPID may include the fraudulent use of the HPID by the health plan itself or an other entity, the change of ownership of a health plan, or the restructuring of a health plan's data processing systems such that the SHP determines that its HPID would no longer be needed. Deactivation of an OEID may also occur in similar situations, for example the fraudulent use of an OEID by itself or an other entity, the change of ownership of the other entity, or if the other entity no longer exists.

Reactivation of an HPID or OEID could occur, for instance, if there were a change of ownership of a health plan or other entity, or for health plans if there were a restructuring of a health plan's data processing systems and the SHP determines that it again needs its HPID.

We solicit stakeholder comments on our proposals regarding the enumeration system and process.

D. Other Considerations

1. Pharmacy Transactions

During the July 2010 NCVHS hearings on the health plan identifier, industry stakeholders also expressed views on the use of the HPID in retail pharmacy transactions. Currently, the pharmacy industry utilizes two unique identifiers in retail pharmacy transactions, the Bank Identification Number/Issue Identification Number (BIN/IIN) and the Processor Control Number (PCN). These identifiers are programmed into the pharmacy's software and identify the route for processing the transaction from the pharmacy to the entity responsible for administering the claim, which could be the health plan or the pharmacy benefit manager. A pharmacy benefit manager is a third party administrator for prescription drug programs and is responsible for processing and paying claims on behalf of the health plan or drug plan sponsor.

The BIN/IIN is a 6-digit number, requested by the pharmacies from either the American National Standards Institute (ANSI) or the National Council for Prescription Drug Programs (NCPDP), for use by retail pharmacies to route prescription drug claims to the entity responsible for processing the transaction, usually the pharmacy benefit manager. The PCN is an identifier of up to 10 characters that is assigned by pharmacy benefit claim processors if there is a need to further define benefits and routing. For instance, the Medicare Part D prescription drug benefit plan Coordination of Benefits (COB) contractor has unique requirements for processing Medicare Part D claims. To accommodate those requirements, many administrators or processors have created PCNs to further differentiate the Medicare Part D prescription drug plan benefit COB business from their other (commercial or Medicaid) COB business. Both the BIN/IIN and PCN are embedded into pharmacies' software programs, and identify the entity for processing claims. The identifiers are tied to the entity that will be processing the transaction, or where the transaction is to be sent. These identifiers are included in information from pharmacy benefit managers and/or health plans that are distributed to pharmacies to provide details on who will be processing the transaction, where to route the transaction and what rules are expected to be applied during transaction processing. The use of the BIN/IIN and PCN allow pharmacy claims to be adjudicated and responded to by the pharmacy benefit manager or health plan within seconds. According to the NCPDP, the use of these two identifiers has been very effective in ensuring efficient, timely prescription claim processing. Both pharmacy and non-pharmacy stakeholders testified at the July 2010 NCVHS Subcommittee on Standards hearings that the HPID, BIN/IIN and PCN identifiers convey different information and serve different purposes. The BIN/IIN and PCN identifiers cannot provide the information needed about the health plan, nor can the information in the HPID provide the information inherent in the BIN/IIN and PCN identifiers.

A representative of the retail pharmacy industry testified that if the health plan identifier were required to replace the BIN/IIN and/or PCN, such a change would be extremely costly to the retail pharmacy industry. For example, combination medical and/or prescription drug plan identification cards would need to be re-issued with the HPID, with no direct patient or pharmacy benefit. The NCPDP also noted that an HPID-only requirement would require a substantive change to the NCPDP D.0. In Version D.0, the Plan ID field is either not used or its use is optional, meaning its use was not intentionally defined in the standard. However, the use of the BIN and PCN fields is mandatory.

In its September 30, 2010 recommendation letter to the Secretary, the NCVHS observed that based on the testimony presented at the July 2010 hearings, retail pharmacy transactions utilize the BIN/IIN and/or PCN identifier to facilitate their transaction processing and that changing to an other identifier would significantly affect existing data flows in the retail pharmacy industry that currently work effectively. As such, the pharmacy industry requested an exemption from the requirement to use only HPID in retail pharmacy transactions because of the current success with the BIN/IIN and PCN identifiers for routing purposes. The NCVHS recommended that use of the HPID in place of the existing BIN/IIN and PCN identifier in retail pharmacy business transactions not be required, but that the HPID be required on the HIPAA-named standard transactions for retail pharmacy. We are not proposing any changes to the NCPDP Version D.0 standard, and we do not believe that the HPID should be required in place of the existing BIN/IIN and PCN identifier in retail pharmacy transactions.

2. Definition of Covered Health Care Provider

We are proposing to move the definition of ''covered health care provider'' from 45 CFR 162.402 to 45 CFR 162.103 because the term ''covered health care provider'' has a broader application beyond just Subpart D.

E. Effective and Compliance Dates for the HPID

In section 1104(c)(1) of the Affordable Care Act, Congress specified that ''the Secretary shall establish a standard for a unique health plan identifier based on the input of the National Committee on Vital and Health Statistics.'' Congress further provided that the rule shall be ''effective'' not later than October 1, 2012. Therefore, we are planning for the effective date of this rule to be October 1, 2012. The effective date would mark the beginning of the implementation period for the HPID, which we expect would be the first day health plans may apply to obtain an HPID and the first day an entity may apply to obtain an OEID from the Enumeration System. We propose that the compliance date for all covered entities, except small health plans, to use the HPID in standard transactions be 2 years after the effective date of the final rule which, if the effective date is October 1, 2012 as we are planning, would be October 1, 2014. The compliance date for small health plans would be October 1, 2015. Small health plans would not be prohibited from complying earlier and using the HPID in their transactions at any time before October 1, 2015.

The Congress uses the terms ''effective'' and ''adoption'' in the Affordable Care Act as applied to both the rules that the Secretary must promulgate to adopt the various standards as well as to the standards themselves. In these provisions of the Affordable Care Act, Congress consistently uses the term ''effective date'' to mean the time when the relevant provision—either the rule or an adopted standard—must go into effect.

In line with our previous interpretations, we have interpreted the ''effective date'' of this rule to mean the date the Secretary adopts the HPID as the Unique Health Plan Identifier. In the NPI final rule, for instance, the effective date of the rule was the date the Secretary adopted a standard unique

health identifier for health care providers, and the compliance date marked the time by which an entity had to obtain and use an NPI in the standard transactions. We consequently interpret this section of the Act as specifying October 1, 2012 as the effective date of the final rule, when the policies take effect and the implementation period for the HPID begins.

Understanding that Congress intended the effective date for the HPID final rule to be October 1, 2012, we note that this date marks the first day that a health plan will be able to apply to obtain an HPID. The 2-year implementation period for this new standard sets the date by which health plans (excluding small health plans) must obtain and covered entities (excluding small health plans) must use an HPID in the standard transactions as October 1, 2014. The compliance date for small health plans would be October 1, 2015.

We are soliciting comment on the effective and compliance dates for the HPID.

III. Proposed Addition to the National Provider Identifier Requirements

A. Background

As discussed in section I of this proposed rule, the final rule adopting the NPI as the standard unique health identifier for health care providers was published on January 23, 2004 (69 FR 3434) (''2004 NPI final rule''). While the 2004 NPI final rule requires covered health care providers to obtain NPIs for themselves and certain subparts and use them in standard transactions, it does not require a health care provider who is not a covered entity to obtain an NPI. Even if a noncovered health care provider chooses to obtain an NPI, the provider is not required to comply with certain NPI requirements, which means the provider does not have to disclose its NPI to entities who may need it for standard transactions. When a noncovered health care provider does not obtain an NPI or does not disclose it, certain problems arise for entities that need to identify that noncovered health care provider in standard transactions. We are proposing an addition to the requirements for the NPI regulations to address such problems.

The 2004 NPI final rule (69 FR 3445) recognized that, ''[s]ituations exist in which a standard transaction must identify a health care provider that is not a covered entity. * * * A noncovered health care provider may or may not have applied for and received an NPI. In the latter case, * * * an NPI would not be available for use in the standard transaction. We encourage every health care provider to apply for an NPI, and encourage all health care providers to disclose their NPIs to any entity that needs that health care provider's NPI for use in a standard transaction. Obtaining NPIs and disclosing them to entities so they can be used by those entities in standard transactions will greatly enhance the efficiency of health care transactions throughout the health care industry. * * * The absence of NPIs when required in * * * claims by the implementation specifications may delay preparation or processing of those claims, or both. Therefore, we strongly encourage health care providers that need to be identified in standard transactions to obtain NPIs and make them available to entities that need to use them in those transactions.''

The 2004 NPI final rule (69 FR 3445) provided the following example of a situation where a health care provider is not a covered entity but its NPI is needed for a standard transaction: ''A pharmacy claim that is a standard transaction must include the identifier (which, as of the compliance date, would be the NPI) of the prescriber. Therefore, the pharmacy needs to know the NPI of the prescriber in order to submit the pharmacy claim. The prescriber may be a physician or other practitioner who does not conduct standard transactions. The prescriber is encouraged to obtain an NPI so it can be furnished to the pharmacy for the pharmacy to use on the standard pharmacy claim.''

Within just a few months after implementation of the 2004 NPI final rule, this issue had been raised so frequently to HHS that, on September 23, 2008, it published a Frequently Asked Question to address questions about pharmacy claims rejected by payers for lack of an individual prescriber NPI (Answer ID 9419) (*https://questions.cms.hhs.gov/app/answers/detail/a_id/9419/~/does-the-national-provider-identifier-(npi)-final-rule-require-individual*).

Due to recurring issues, we believe this scenario described in the 2004 NPI final rule needs to be addressed. Pharmacies are encountering situations where the NPI of a prescribing health care provider needs to be included in the pharmacy claim, but the prescribing health care provider does not have an NPI or has not disclosed it. This situation has become particularly problematic in the Medicare Part D program, as we explain more fully later in this proposed rule.

By way of background, every prescriber has at least one identifier that may be submitted on a pharmacy claim. These identifiers include the NPI, Drug Enforcement Administration (DEA) number, uniform provider identification number (UPIN), or State license number. The Medicare Part D program is an optional prescription drug benefit for all Medicare beneficiaries. Medicare Part D contracts with private companies, called plan sponsors, to administer the benefit through Part D drug plans. In the Medicare Part D program, plan sponsors must submit a prescription drug event (PDE) record to Medicare Part D every time a beneficiary's prescription is filled under the program. Plan sponsors use information from the claim generated by the pharmacy to complete the PDE record, which contains summary information. These PDE records, which currently must contain a prescriber identifier are necessary to support accurate payments to plan sponsors by Medicare Part D.

The use of multiple and invalid prescriber identifiers in the Medicare Part D program has been identified as a concern. In a June 2010 report titled, ''Invalid Prescriber Identifiers on Medicare Part D Drug Claims'' (''June 2010 report''), the HHS Office of the Inspector General (OIG) reported the findings of its review of prescriber identifiers on 2007 Part D PDE records. The OIG reported finding 18.4 million PDE records that contained 527,749 invalid identifiers, including invalid NPIs, DEA registration numbers, and UPINs. Payments by Part D drug plans and enrollees for prescriptions associated with these PDE records totaled $1.2 billion. Prescriber identifiers are valuable Part D program safeguards. These identifiers are the only data on Part D drug claims to represent that licensed practitioners have written prescriptions for Medicare enrollees. Although invalid prescriber identifiers are not an automatic indication of erroneous or fraudulent prescriptions or pharmacy claims, the lack of valid prescriber identifiers on Part D drug claims hampers Medicare's program integrity efforts.

To address these concerns raised by the June 2010 report, in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' final rule (which was filed for public inspection onApril 2, 2012 (hereinafter referred to as April 2012 final rule). CMS requires Part D sponsors to include an active and valid prescriber National Provider Identifier (NPI) on prescription drug event records (PDEs) that they submit to CMS, which will assist the Federal government in fighting possible fraudulent activity in the Part D

program, because prescribers will be consistently and uniformly identified. This policy will not interfere with beneficiary access to needed medications because Part D sponsors must validate the NPI at point of sale, and if this is not possible, permit the prescription to be dispensed and obtain the valid NPI afterwards.''

Pharmacies that contract with Part D sponsors may be involved in obtaining a prescriber's NPI depending on the agreement between the pharmacies and Part D sponsors. Because Part D sponsors and pharmacies generally have no regulatory leverage or other recourse over prescribers who fail or refuse to disclose NPIs, they must resort to using provider information databases to determine if a prescriber has an NPI or contact the prescriber, if known. If a Part D sponsor or network pharmacy is unable to obtain a prescriber NPI for use on the claim and PDE, the reimbursement from Medicare Part D to the sponsor (or alternatively, from the sponsor to the pharmacy depending on the agreement between the parties), could be negatively affected. We seek to address both current and future problems described previously that are presented by prescribers who do not have NPIs or do not disclose them, by proposing an additional requirement for the NPI regulations.

B. Provisions for a Proposed Requirement To Obtain and Use NPIs

We are proposing an additional requirement for organization covered health care providers that have as a member, employ, or contract with, an individual health care provider who is not a covered entity and is a prescriber. Organization health care providers are health care providers that are not individuals. Our proposal would require an organization to require such a prescriber to: (1) obtain an NPI; and (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

Organization covered health care providers would be required to implement the requirement within 180 days after the effective date of the final rule, which would be reflected in 45 CFR 162.404(a)(2) with regulation text stating that an organization covered health care provider must comply with the implementation specifications in 45 CFR 162.410(b). We expect the final rule to be effective on October 1, 2012, in which case covered organization health care providers would have to meet the requirement by April 7, 2013.

The requirement would be reflected in the regulation text in 45 CFR 162.410(b) by adding the following new language. ''An organization covered health care provider that has as a member, employs, or contracts with an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to: (1) obtain an NPI from the National Plan and Provider Enumeration System (NPPES) and (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.''

This proposed requirement represents a narrow exception to the position we took in the 2004 NPI final rule. The 2004 NPI final rule (69 FR 3440), we stated ''[w]e do not consider individuals who are health care providers * * * and who are members or employees of an organization health care provider to be ''subparts'' of those organization health care providers, as described earlier in this section. Individuals who are health care providers are legal entities in their own right. The eligibility for an ''Entity type code 1'' NPI of an individual who is a health care provider and a member or an employee of an organization health care provider is not dependent on a decision by the organization health care provider as to whether or not an NPI should be obtained for, or by, that individual. The eligibility for an ''Entity type code 1'' NPI of a health care provider who is an individual is separate and apart from that individual's membership or employment by an organization health care provider.''

By virtue of this proposed rule, we are still not considering noncovered health care providers that are prescribers to be subparts of organization health care providers, nor are we proposing that they are not legal entities in their own right. Rather, our proposal would close a gap in the NPI rule by virtue of the relationships that covered organization health care providers have with noncovered individual health care providers.

The providers we seek to reach are prescribers who are not required to obtain and disclose an individual NPI under the current NPI regulations. To the best of our understanding, these prescribers are largely hospital-based providers who staff clinics and emergency departments, or otherwise provide on-site medical services, such as medical residents and interns, as well as prescribers in group practices, whose services are billed under a group or ''Entity type code 2'' NPI regardless of whether they have obtained an individual, or ''Entity type code 1,'' NPI. These prescribers are using the ''Entity type code 2'' to identify themselves on prescriptions, or an other or no identifier, which does not identify them as individuals. We believe this proposal describes the various relationships that organization health care providers have with such prescribers, and that the relationship is one in which organizations can exercise control over these prescribers and require them to do something.

For instance, a physician or dentist who prescribes may be a member of a group practice. As noted in the 2004 NPI final rule (69 FR 3439 and 3440), ''group health care providers are entities composed of one or more individuals (members), generally created to provide coverage of patients' needs in terms of office hours, professional backup and support, or range of services resulting in specific billing or payment arrangements.'' For purposes of this rule, we consider group health care providers to be organization health care providers.'' By virtue of the contractual or other relationship between a group and a member, a group can require the member to do certain things, such as work certain on-call hours. Likewise, a resident or nurse practitioner who performs medical services at a hospital can be required to do certain things, such as to abide by medical staff by-laws and hospital policies and procedures, as a hospital employee or contractor. This proposed rule does not specify how organization covered health care providers should impose the requirement to obtain an NPI and disclose it on prescribers. Organization covered health care providers may have a number of alternatives by which they may accomplish this, for example, through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures.

The requirement for a prescriber to disclose his or her NPI would apply for prescriptions written pursuant to the prescriber's relationship with the covered health care organization provider. For example, if a physician works for two group practices, A and B, group practice A would be required to require the physician to disclose his or her NPI for pharmacy claims that are for prescriptions written by the prescriber for a patient of group practice A, and group practice B would be required to do the same for pharmacy claims for

prescriptions written by the prescriber for a patient of that group practice.

We considered expanding our proposal to organization covered health care providers that grant clinical privileges to individual health care providers who are not covered entities and are prescribers, so that we would be certain to encompass hospital residents and interns under our proposal (to the extent they are not otherwise required to obtain Type 1 NPIs). However, it is our belief such prescribers will be encompassed under our proposal as drafted, as we further believe our proposal would encompass virtually all prescribers who are not currently required to obtain and disclose an individual NPI. Exceptions may include, by way of example, a self-employed physician who does not bill insurance plans and does not have a member, employee or contractual relationship with an organization covered health care provider (or has one with a noncovered organization health care provider), such as a psychiatrist or plastic surgeon who only accepts cash from patients. Even with respect to these prescribers, we hope this rule highlights the importance of voluntarily obtaining NPIs to facilitate their patients' access to prescribed items. We seek comment regarding the extent to which residents, interns, and any other prescribers would not be reached under our proposal and any alternative approach that would encompass them.

We believe this proposal furthers several goals and purposes identified in the Act. First, the statutory purpose of the Administrative Simplification provisions of HIPAA (see section 261 of the Act (42 U.S.C. 1320d note)) is,

> To improve the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information and to reduce the clerical burden on patients, health care providers, and health plans.

In accord with this statutory purpose, our proposal would improve the Medicare program by virtually ensuring the availability of an NPI as a prescriber identifier on pharmacy claims in the Part D program because virtually all prescribers would have to obtain an NPI and disclose it to entities that need it for use in standard transactions. That in turn would support program integrity efforts described in the April 2012 final rule noted previously which requires Part D sponsors to submit PDEs that contain only individual NPIs as prescriber identifiers, effective January 1, 2013. As noted in the April 2012 final rule, ''[w]hen multiple prescriber identifiers, not to mention dummy or invalid identifiers, are used, authorities must take an additional step in their data analysis before even achieving a refined data set to use for further analysis to identify possible fraud. For example, having to cross-reference multiple databases that update on different schedules to be certain of the precise prescribers involved when multiple identifiers were used, would necessitate several additional steps of data pre-analysis and also would introduce potential errors in correctly matching prescribers among databases.''

Invalid identifiers are generally those that do not appear as current in any prescriber identifier registry. Dummy or default identifiers have never appeared in any prescriber identifier registry but have been used successfully on pharmacy claims in place of valid prescriber identifiers (for instance, when the prescriber's NPI was not available), because they met the length and format requirements of a prescriber identifier. Default identifiers present additional challenges to authorities, since the actual prescription must be researched to identify the prescriber. Valid prescriber identifiers are essential to conducting claims analyses to identify aberrant claims prescribing patterns that may indicate fraudulent activity, such as drug diversion schemes or billing for prescription drugs not provided, which includes circumstances with active prescriber participation and those involving forged prescriptions. Improving the accuracy and dependability of the prescriber identifier on Part D claims and PDEs, improves the ability to identify fraud and, in turn, protects and improves the Medicare program.

This proposal would further improve the Medicare program by nearly eliminating the instances in which Part D sponsors' reimbursement (or possibly their network pharmacies' reimbursement, depending on the contractual relationship between the sponsors and the pharmacies) would be negatively impacted due to the actions of prescribers with whom they may have no business relationship. Part D sponsors would be expected to price any measurable expectation of financial risk, if any, due to nonreimbursement by CMS into their Part D bids, thus possibly increasing premiums and subsidies paid under the program. This proposal would make such action by Part D sponsors unnecessary by virtually ensuring the availability of prescriber NPIs.

This proposal also accords with the purpose of HIPAA as amended by the Affordable Care Act. Section 1104(a)(2) of the Affordable Care Act revised the statutory purpose of HIPAA Administrative Simplification by adding, at the end, that its purpose is to ''reduce the clerical burden on patients, health care providers, and health plans.'' To the extent pharmacies only have to accept one identifier—the NPI—rather than four possible identifiers from prescribers for the majority of their claims, the administrative burden on all parties involved in the processing and payment of these claims would be lessened. Pharmacies and payers would no longer have to cross-check provider identifier databases to determine if the prescriber had an NPI when an alternate identifier was used, or contact the prescriber. Moreover, pharmacies and prescribers would no longer have to respond to inquiries from payers regarding the existence of an NPI when an alternate prescriber identifier was used.

The proposal is also supported by section 1173(a)(3) of the Act, which requires the transaction standards adopted by the Secretary to accommodate the needs of different types of health care providers. Our proposal would accommodate the needs of pharmacies, a type of health care provider, by ensuring that a prescriber NPI is available to them when needed for their claims and reducing the instances in which they must cross-reference provider information databases or research a prescription. Similarly, section 1173(b)(1) of the Act states that,

> [t]he Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out [this requirement] for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

Our proposal takes into account the particular needs of pharmacies by addressing a problem they have under HIPAA.

While some prescribers will have to apply to obtain an NPI under this proposed requirement, the NPI is free of charge and requires only the completion of a three-page application form that seeks primarily identifying and location information. Thus, we believe the reduction in administrative burden that will be achieved by our proposal outweighs the minimal burden placed on prescribers who will have to obtain NPIs.

The 2004 NPI final rule, as noted previously, foretold the issues that could arise if noncovered health care providers did not obtain NPIs, and therefore encouraged them to do so. The preamble of the 2004 NPI final rule stated that disclosing NPIs to entities for use in standard transactions will greatly enhance the efficiency of health care transactions throughout the health care industry, and that the absence of NPIs when required in those claims by the implementation specifications may delay preparation or processing of those claims, or both. Health care providers responded by obtaining NPIs in large numbers even when not required to, and we believe the vast majority of prescribers already have NPIs. CMS data shows that approximately 90 percent of Medicare Part D claims as reported in PDEs currently submitted contain valid prescriber NPIs even though alternate prescriber IDs are permitted at this time. But, while the vast majority of Medicare Part D claims contain individual NPIs, 10 percent do not. This proposal would help ensure this last 10 percent is addressed. After discussions with representatives of the provider data industry, we estimate there are approximately 1.4 million active prescribers in the United States, of which approximately 160,000 do not have an NPI. It is these prescribers who would have to obtain an NPI if this rule is finalized as proposed.

C. Effective and Compliance Dates

We propose that the date by which an organization covered health care provider must comply is 180 days after the effective date of the final rule. In other words, if the final rule is effective on October 1, 2012, then by April 7, 2013, organization covered health care providers that have a prescriber as a member, employ, or contract with a prescriber who is not a covered entity, must require him or her to (1) obtain an NPI and; (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, to disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

IV. Proposed Change to the Compliance Date for ICD–10–CM and ICD–10–PCS

A. Background

As discussed in section I. of this proposed rule, the final rule adopting ICD–10–CM and ICD–10–PCS (collectively, ''ICD–10'') as HIPAA standard medical data code sets was published in the **Federal Register** on January 16, 2009 (74 FR 3328) (the ''ICD–10 final rule''). The ICD–10 final rule requires covered entities to use ICD–10 beginning October 1, 2013.

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 Version 5010 did not proceed as effectively as expected; (2) providers expressed concern that other statutory initiatives are stretching their resources; and (3) surveys and polls indicated a lack of readiness for the ICD–10 transition.

1. The Transition to Version 5010 and Its Effect on ICD–10 Readiness

Concurrent with the publication of the ICD–10 final rule, HHS published in the **Federal Register** the Modifications final rule which set January 1, 2012 as the compliance date for Version 5010 (74 FR 3296). As the industry approached the January 1, 2012 Version 5010 compliance date, a number of implementation problems emerged, some of which were unexpected. These included—

- Trading partners were not ready to test the Version 5010 standards due to vendor delays in delivering and installing Version 5010-compliant software to their provider clients;
- Version 5010 errata were issued to correct typographical mistakes and other maintenance issues that were discovered as the industry began its internal testing of the standards, which delayed vendor delivery of compliant products and external testing;
- Differences between address requirements in the ''provider billing address'' and ''pay to'' address fields adversely affected crossover claims processing;
- Inconsistent payer interpretation of standard requirements at the front ends of systems resulted in rejection of claims, as well as other technical and standard misinterpretation issues;
- Edits made in test mode that were later changed when claims went into production without adequate notice of the change to claim submitters; and
- Insufficient end to end testing with the full scope of edits and business rules in place to ensure a smooth transition to full production.

Given concerns that industry would not be compliant with the Version 5010 standards by the January 1, 2012 compliance date, we announced on November 17, 2011 that we would not initiate any enforcement action against any covered entity that was not in compliance with Version 5010 until March 31, 2012, to enable industry adequate time to complete its testing and software installation activities. On March 15, 2012, this date was extended an additional 3 months, until June 30, 2012.

The ICD–10 final rule set October 1, 2013 as the compliance date, citing industry testimony presented to NCVHS and many of the over 3,000 industry comments received on the ICD–10 proposed rule. The analysis in the ICD–10 final rule with regard to setting a compliance date emphasized the interdependency between implementation of ICD–10 and Version 5010, and the need to balance the benefits of ICD–10 with the need to ensure adequate time for preparation and testing before implementation. As noted in the ICD–10 final rule, ''[w]e cannot consider a compliance date for ICD–10 without considering the dependencies between implementing Version 5010 and ICD–10. We recognize that any delay in attaining compliance with Version 5010 would negatively impact ICD–10 implementation and compliance.'' (74 FR 3334) Based on NCVHS recommendations and industry feedback received on the proposed rule, we determined that ''24 months (2 years) is the minimum amount of time that the industry needs to achieve compliance with ICD–10 once Version 5010 has moved into external (Level 2) testing.'' (74 FR 3334) In the ICD–10 final rule, we concluded that the October 2013 date provided the industry adequate time to change and test systems given the 5010 compliance date of January 1, 2012.

As implementation of ICD–10 is predicated on the successful transition of industry to Version 5010, we are concerned that the delays encountered in Version 5010 have affected ICD–10 planning and transition timelines.

2. Providers have Expressed Concern That Other Statutory Initiatives Are Stretching Their Resources

Since publication of the ICD–10 and Modifications final rules, a number of other statutory initiatives were enacted, requiring health care provider compliance and reporting. Providers are concerned about their ability to expend limited resources to implement and participate in the following initiatives that all have similar compliance timeframes.

The EHR Incentive Program was established under the Health Information Technology for Economic and Clinical Health (HITECH) Act, a part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5). Medicare and Medicaid incentive payments are available to eligible professionals and hospitals for adopting electronic health record (EHR)

technology and demonstrating meaningful use of such technology. Eligible professionals and hospitals that fail to meaningfully use EHR technology could be subject to Medicare payment adjustments beginning in FY 2015. The Physician Quality Reporting System is a voluntary reporting program that provides incentives payments to eligible professionals and group practices that satisfactorily report data on quality measures for covered Physician Fee Schedule services furnished to Medicare Part B Fee-for-Service beneficiaries. The eRx Incentive Program is a reporting program that uses a combination of incentive payments and payment adjustments to encourage electronic prescribing by eligible professionals. Beginning in 2012 through 2014, eligible professionals who are not successful electronic prescribers are subject to a payment adjustment. Finally, section 1104 of the Affordable Care Act imposes additional HIPAA Administrative Simplification requirements on covered entities, shown in Chart 1.

CHART 1: HIPAA COMPLIANCE DATES FROM THE AFFORDABLE CARE ACT

Covered entity compliance date	HIPAA requirements from the Affordable Care Act
January 1, 2013	• Operating rules for eligibility for a health plan and health care claim status transactions.
December 31, 2013	• Health plan compliance certification requirements for health care electronic funds transfers (EFT) and remittance advice, eligibility for a health plan, and health care claim status transactions.
January 1, 2014	• Standards and operating rules for health care electronic funds transfers (EFT) and remittance advice transactions.
December 31, 2015	• Health plan compliance certification requirements for health care claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health care claims attachments, and referral certification and authorization transactions.
January 1, 2016	• Standard for health care claims attachments. • Operating rules for health care claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, referral certification and authorization transactions
Proposed October 1, 2014.	• Unique health plan identifier.

3. Current State of Industry Readiness for ICD–10

It is crucial that all segments of the health care industry transition to ICD–10 at the same time because the failure of any one industry segment to successfully implement ICD–10 has the potential to affect all other industry segments. Ultimately, such failure could result in returned claims and provider payment delays that disrupt provider operations and negatively impact patient access to care.

In early 2012, it became evident that sectors of the health care industry would not be prepared for the October 1, 2013 ICD–10 compliance date. Providers in particular voiced concerns about their ability to meet the ICD–10 compliance date as a result of a number of factors, including obstacles they experienced in transitioning to Version 5010 and the other initiatives that stretch their resources. A CMS survey conducted in November and December 2011 (hereinafter referred to as the CMS readiness survey) found that 26 percent of providers surveyed indicated that they are at risk for not meeting the October 1, 2013 compliance date.[4]

In February 2012, the Workgroup for Electronic Data Interchange (WEDI) conducted a survey on ICD–10 readiness, hereinafter referred to as the WEDI readiness survey.[5] WEDI received responses from more than 2,600 providers, health plans, and vendors showing that the industry is uncertain about its ability to meet ICD–10 compliance milestones. Data from the WEDI survey indicated that nearly 50 percent of the provider respondents did not know when they would complete their impact assessment.[6] In addition, the survey found that approximately 33 percent of providers did not expect to begin external testing in 2013, while approximately 50 percent of providers did not know when testing would occur.[7]

Other segments of the industry, such as health plans and software vendors, also reported that they would benefit from additional time for implementation. While the CMS ICD–10 Implementation Guide recommends that payers begin external testing in the fall of 2012, the WEDI readiness survey found that most health plans do not expect to begin external testing until 2013. In addition, about 50 percent of vendors are not yet halfway through development of ICD–10 products. Vendor delays in product development can result in provider and payer delays in implementing ICD–10.

Given the evidence that segments of the health care industry will likely not meet the October 1, 2013 compliance date, the reasons for that likelihood, and the likelihood that a compliance date delay would significantly improve the successful and concurrent implementation of ICD–10 across the health care industry, we are proposing to extend the compliance date for ICD–10.

B. One-Year Delay

We are proposing to extend the compliance date for ICD–10 for 1 year, from October 1, 2013 to October 1, 2014. This change would be reflected in the regulations at 45 CFR 162.1002. While we considered a number of alternatives for the delay, as discussed in the Impact Analysis of this proposed rule, we believe a 1-year delay would provide sufficient time for small providers and small hospitals to become ICD–10 compliant and would be the least financially burdensome to those who had planned to be compliant on October 1, 2013.

To determine the new compliance date for ICD–10, we balanced the need for additional time for small providers and small hospitals to become compliant with the financial burden of

[4] ''Version 5010 and ICD–10 Readiness Assessment: Conducted among Health Care Providers, payers, and Vendors for the Centers for Medicare & Medicaid Services (CMS),'' December, 2011, Prepared by CMS. Survey responses received from 404 health care providers, 101 payers, and 90 vendors.

[5] ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

[6] An impact assessment for ICD–10 is performed by a covered entity to determine business areas, policies, processes and systems, and trading partners that will be affected by the transition to ICD–10. An impact assessment is a tool to aid in planning for implementation.

[7] For providers, the CMS ICD–10 Implementation Guide recommends that they complete their impact assessments by Winter 2012 and begin external testing in the Fall of 2012. CMS provides implementation guides for providers, payers, and vendors to assist with the transition from ICD–9 to ICD–10 codes. It is a resource for covered entities providing detailed information for planning and executing the ICD–10 transition process. CMS recommends industry use the guide as a reference.

a delay on entities that have developed budgets and planned process and system changes around the October 1, 2013 compliance date. Entities that have started planning and working toward an October 1, 2013 implementation would incur costs by having to reassess and adjust implementation plans and maintain contracts to manage the transition beyond October 1, 2013. We concluded that a 1-year delay would strike a reasonable balance by providing sufficient time for small providers and small hospitals to become compliant and would minimize the financial burden on those entities that have been actively planning and working toward being compliant on October 1, 2013.

Data from two surveys helped us in our determination to propose 1 additional year for compliance. First, the CMS readiness survey revealed that 26 percent of providers reported that they are at risk for non-compliance on October 1, 2013, citing insufficient time as one risk factor.[8] Second, an informal survey conducted by Edifecs, a health care IT company, of 50 senior health care officials representing a wide range of organizations found that thirty-seven percent of respondents stated that a 1-year delay would be beneficial to them.[9]

While we considered a 2-year delay, we determined that the financial burden could be too significant for those entities that would otherwise be ready on October 1, 2013. As discussed further in the Impact Analysis of this proposed rule, we estimate it will cost health plans up to an additional 30 percent of their current ICD–10 implementation budgets for a 1-year delay and therefore, we assume that a 2-year delay would be at least double the cost of a 1-year delay; that is, a 2-year delay would cost at least $13 billion for all commercial and government health plans. In addition to financial concerns, industry has suggested that a 2-year delay may stop the implementation of ICD–10 completely. The Edifecs poll found that nearly 70 percent of respondents believe that a 2-year delay would be either ''potentially catastrophic or cause an unrecoverable failure,'' and that ''a delay of longer than a year will likely freeze budgets, slow down schedules, or stop work altogether.'' [10] Only 2 percent of Edifecs respondents said there would be a benefit to a 2-year delay.

Finally, in its March 2, 2012 letter to the Secretary on a possible delay of the ICD–10 compliance date, the NCVHS urged that any delay should be announced as soon as possible and should not be for more than 1 year. The NCVH made this recommendation in consideration of its belief that a delay would cause a significant financial burden ''that accrues with each month of delay.'' [11]

We believe that a 1-year delay would benefit all covered entities, even those who had are actively planning and striving for a 2013 implementation. A 1-year delay would enable the industry as a whole to test more robustly and implement simultaneously, which would foster a smoother and more coordinated transition to ensure the continued and uninterrupted flow of health care claims and payment. Therefore, we are proposing that covered entities must comply with ICD–10 on October 1, 2014.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment on a collection of information requirement submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency.
- The accuracy of the agency's estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

A. Information Collection Requirements (ICRs) Regarding HPID/OEID on Health Plan and Other Entities (§ 162.512 and § 162.514)

In order to apply for an HPID or OEID, there is an initial one-time requirement for information from health plans that seek to obtain an HPID and other entities that elect to obtain an OEID. In addition, health plans and other entities may need to provide updates to information.

With respect to the collection of information requirements for the HPID, it is important to bear in mind that: (1) Systems modifications necessary to implement the HPID/OEID may overlap with the other systems modifications needed to implement other Affordable Care Act standards; (2) some modifications may be made by contractors such as practice management vendors, in a single effort for a multitude of affected entities; and (3) identifier fields are already in place and HPID/OEID will, in many instances, simply replace the multiple identifiers currently in use.

Under this proposed rule, a CHP, as defined in 45 CFR 162.103, will have to obtain an HPID from a centralized electronic Enumeration System. A SHP, as defined in 45 CFR 162.103, would be eligible but not required to obtain an HPID. If a SHP obtains an HPID, it would apply either directly to the Enumeration System or its CHP would apply to the Enumeration System on its behalf. Other entities may apply to obtain an OEID from the Enumeration System. Health plans that obtain an HPID and other entities that obtain an OEID would have to communicate any changes to their information to the Enumeration System within 30 days of the change. A covered entity must use an HPID to identify a health plan in a standard transaction.

We estimate that there will be up to 15,000 entities that will be required to, or will elect to, obtain an HPID or OEID. We based this number on the following data in Chart 2.

CHART 2: NUMBER AND TYPE OF ENTITIES THAT MAY OBTAIN AN HPID OR OEID

Type of entity	Number of entities
Self insured group health plans	12,000*
Health insurance issuers, individuals and group health markets, HMOs, including companies offering Medicaid managed care	1,827**

[8] ''Version 5010 and ICD–10 Readiness Assessment: Conducted among Health Care Providers, payers, and Vendors for the Centers for Medicare & Medicaid Services (CMS),'' December, 2011, Prepared by CMS.

[9] ''Survey: Industry Reaction to Potential Delay of ICD–10—A Delay will be Costly, but Manageable * * * Unless it's more than a Year,'' February 27, 2012, conducted by Edifecs. The survey's participants included commercial payers (25%), Blue Cross Blue Shield plans (25%), healthcare providers (18%), government entities such as State Medicaids (9%), medical claim clearinghouses (6%), and other healthcare industry organizations (17%).

[10] Edifecs poll, 2012.

[11] Letter to Kathleen G. Sebelius, Secretary, U.S. Department of Health and Human Services, from the National Committee of Vital and Health Statistics (NCVHS), ''Possible Delay of Deadline for Implementation of ICD–10 Code Sets,'' March 2, 2012.

CHART 2: NUMBER AND TYPE OF ENTITIES THAT MAY OBTAIN AN HPID OR OEID—Continued

Type of entity	Number of entities
Medicare, Veterans Health Administration (VHA), Indian Health Service (IHS), TRICARE, and State Medicaid programs	60
Clearinghouses and Transaction Vendors	162***
Third Party Administrators	750 ****
Total	~15,000

*''Report to Congress: Annual Report on Self –Insured Group Health Plans,'' by Hilda L. Solis, Secretary of Labor, March 2011.

** ''Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, 2011 **Federal Register** (Vol. 76), July, 2011,'' referencing data from *www.healthcare.gov.*

*** Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf,* based on a study by Gartner.

**** Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rulemaking *http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf.*

Note that the number of health plans that will be required, or have the option, to obtain an HPID is considerably larger than the number of health plans for which we used in the calculations in section V. of this proposed rule. This is because self-insured health plans are required to obtain HPIDs if they meet the requirements of a Controlling health plan under this proposed rule. However, we assume that very few self-insured group health plans conduct standard transactions themselves; rather, they typically contract with TPAs or insurance issuers to administer the plans. Therefore, there will be significantly fewer health plans that use HPIDs in standard transactions than health plans that are required to obtain HPIDs, and only health plans that use the HPIDs in standard transactions will have direct costs and benefits.

To comply with these requirements, health plans and other entities will complete the appropriate application/update form online through the Enumeration System. This online form serves two purposes: applying for an identifier and updating information in the Enumeration System.

Most health plans and other entities will not have to furnish updates in a given year. However, lacking any available data on rate of change, we elected to base our assumptions on information in the Medicare program that approximately 12.6 percent of health care providers provide updates in a calendar year. We anticipate this figure would be on the high end for health plans and other entities. Applying this assumption, we can expect that 1,764 health plans will need to complete and submit the HPID application update form in a given year.

Applying for HPID or OEID is a one-time burden. In future years, this burden would apply only to new health plans and as an option for other entities as described in the section V of this proposed rule. From 2013 to 2018, industry trends indicate that the number of health plans will remain constant, or even decrease.[12] We assume that the number of new health plans will be small, and that the costs will be negligible. Therefore, our calculations reflect that there will be no statistically significant growth in the number of health plans or other entities and we calculate zero growth in new applications.

We estimate it will take 30 minutes to complete the application form and use an hourly labor rate of approximately $23/hour, the average wage reported for professional and business and services sector, based on data from the Department of Labor, Bureau of Labor Statistics, June 2011, ''Average hourly and weekly earnings of production and nonsupervisory employees (1) on private nonfarm payrolls.'' (*ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb11.txt*). This represents a unit cost of $11.50 per application for both HPID and OEID.

Because our initial estimate for the number of applications for OEID is small (162 Clearinghouses and Transaction Vendors + 750 TPAs = 912) and the costs negligible, we do not include separate calculations. We have elected instead to offer the unit cost figure as a baseline if commenters demonstrate that the universe of applications for OEID is likely to expand significantly.

To further reduce burden and plan for compliance with the Government Paperwork Elimination Act, we propose accepting electronic applications and updates over the internet. We explicitly solicit comment on how we might conduct this activity in the most efficient and effective manner, while ensuring the integrity, authenticity, privacy, and security of health plan and other entity information.

B. ICRs Regarding Implementation Specifications: Health Care Providers (§ 162.410)

We are proposing to put an additional requirement on covered organization health care providers that employ, have as members, or have contracts with individual health care providers who are not covered entities but who are prescribers. By 180 days after the effective date of the final rule, such organizations must require such health care providers: (1) To obtain, by application if necessary, an NPI from the National Plan and Provider Enumeration System (NPPES); (2) to the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose his or her NPI, upon request to any entity that needs the NPI to identify the prescriber in a standard transaction.

The burden associated with the addition to the requirements of § 162.410 as discussed in this proposed rule is the one-time application burden, and later update burden as necessary, on prescribers who do not already have an NPI, who have a relationship with a covered health care provider, and who must be identified in a standard transaction. We estimate that there are approximately 1.4 million prescribers in the United States, of which approximately 160,000 do not have an NPI. It is these prescribers who would have to obtain an NPI if this rule is finalized as proposed. Based on the estimations in the NPI final rule, we estimate that it will take 20 minutes to complete an application for an NPI and use an hourly labor rate of approximately $23/hour, the average wage reported for professional and business and services sector, based on data from the Department of Labor, Bureau of Labor Statistics, June 2011, ''Average hourly and weekly earnings of production and nonsupervisory employees (1) on private nonfarm payrolls.'' (*ftp://ftp.bls.gov/pub/suppl/empsit.ceseeb11.txt*). Additionally, we have calculated an increase of 3 percent for labor costs for each of the years 2013 through 2016 for an hour rate of approximately $24/hour for year 2013.

Table 4 shows the estimated annualized burden for the HPID and NPI PRA in hours.

[12] *See* Robinson, James C., ''Consolidation and the Transformation of Competition in Health Insurance,'' Health Affairs, 23, no.6 (2004):11–24; ''Private Health insurance: Research on Competition in the Insurance Industry,'' U.S. Government Accountability Office (GAO), July 31, 2009 (GAO–09–864R); American Medical Association, ''Competition in Health Insurance: A Comprehensive Study of US Markets,'' 2008 and 2009.

TABLE 4—ANNUAL INFORMATION COLLECTION BURDEN*

Regulation section	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden	Hourly labor cost of reporting ($)	Total labor cost	Total capital/ maintenance costs ($)	Total cost ($)
§ 162.410	0938–New	160,000	160,000	0.33	52,800	24	1,267,200	0	1,267,200
§ 160.512	0938–New	15,000	15,000	0.50	7,500	24	180,000	0	180,000
Total		175,000	175,000		60,300				1,447,200

*2013 dollars.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced previously, access our Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326. If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–0040–P Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*

VI. Regulatory Impact Analysis

A. Need for Regulatory Action

1. NPI for Non-Covered Health Care Providers

The compliance date for use of the NPI by health care providers was May 23, 2007. At this point, we believe there are 160,000 health care providers who do not already have an NPI. For these health care providers, obtaining an NPI is not a burdensome endeavor, as it is free of charge and takes approximately 20 minutes to file an application to obtain one. However, the availability of these additional prescriber NPIs will greatly assist entities who need them for use in standard transactions, including for the Medicare Part D program, as described previously. See section V.B. of this proposed specifically for a summary of the time costs associated with obtaining an NPI. We have included the costs associated with obtaining an NPI detailed in section V.B in the summary Tables 32 and 33 of the RIA. Because there are few health care providers who do not already have an NPI, we estimate that the addition to the NPI requirements will have little impact on health care providers and on the health industry at large. We solicit comment on this.

2. HPID

As noted in section I of this proposed rule, health plans and other payers are identified in a number of different ways in covered transactions by the health care industry. Health plan identifiers are currently used to facilitate routing of covered transactions or, in other words, ''to determine either where the standard electronic transactions are to be sent if the receiver is [a] health plan or from where they came from if the sender is a health plan.''[13] The primary function of the HPID proposed in this rule is to create a standard data element for covered entities to identify health plans in HIPAA covered transactions.

Different segments in each HIPAA standard transaction require an identifier to identify the payer or sender/recipient of a particular transaction. (See Table 1 for a list of HIPAA standard transactions, and Table 3 for an example of a segment that requires a payer identifier.) Currently, when a covered entity, for business reasons, inputs an identifier that identifies a health plan into a transaction segment, the identifier is proprietary or based on the NAIC code, EIN, or TIN of the health plan or other entity. Some health plans use multiple identifiers to identify themselves in transactions.

Standardization of the health plan identifier is expected to ameliorate some routing issues. It is expected to clarify, to some extent, the sender or recipient of standard transactions, when the sender or recipient is a health plan. For instance, a health plan that uses different identifiers to identify itself in covered transactions creates inefficiencies and potential confusion among its trading partners. Participating health care providers that are its trading partners, for instance, could be required to use different identifiers for different transactions, even to identify the same health plan. If the HPID is adopted, such a health plan would likely use one identifier, thereby making it easier for the covered health care provider to identify the health plan as the sender or recipient of the standard transaction.

By ameliorating routing issues, the HPID and OEID will add consistency to identifiers, which will provide for a higher level of automation, particularly for provider processing of the X12 271 (eligibility response) and X12 835 (remittance advice). In the case of the X12 835, the HPID and OEID will allow reconciliation of claims with the claim payments to be automated at a higher level.

However, according to testimony and industry studies, the most significant value of the HPID and what is being proposed as the OEID is that they will serve as foundations for other regulatory and industry initiatives. The implementation of HPID, in and of itself, may not provide significant monetary savings for covered entities, with the exception of providing time savings by immediately solving certain routing issues. Instead, financial benefits are expected to be realized mostly downstream, when the HPID is used in coordination with other regulatory and industrial administrative simplification initiatives. Testimony from the July 19, 2010 NCVHS hearing reinforced this idea.

As an analogy, the standardization of the width of railroad tracks does not, in and of itself, result in monetary savings. However, such standardization has ensured connectivity between diverse railroad systems that has resulted in time and cost savings in the movement of freight across the country. In a like manner, standardization of a single data element in health care transactions does not, in and of itself, produce substantial time or cost savings. However, the diverse identifiers currently used by multiple health plans are akin to the different track widths used by various railroad systems. Like the standardization of railroad track widths, the HPID serves as a foundation for more efficient and cost effective transmission of health care information.

[13] J. Daley, ''Testimony before the NCVHS Subcommittee on Standards on the National Health Plan Identifier on behalf of America's Health Insurance Plans and the Blue Cross and Blue Shield Association,'' July 19, 2010, *http://www.ncvhs.hhs.gov.*

In an industry white paper, one health care provider association echoed the foundational importance of the HPID and stated that a standard identifier for health plans is ''viewed by many as a crucial step toward one-stop, automated billing.'' In the same paper, that association stated that, in order to begin the movement toward automated billing, standard identifiers were needed for more entities with ''payer'' function than just ''health plans,'' including entities with primary financial responsibility for paying a particular claim, entities responsible for administering a claim, entities that have the direct contract with the health care provider, and secondary or tertiary payers for the claim.[14] The association went on to contend that fee schedules and plan and product types would need to be identified with this health plan identifier.

In this rule, we are not proposing that the HPID or the OEID contain intelligence that would include fee schedules or benefit plans or product types. However, we are proposing that entities other than health plans may get an OEID. We view the adoption of the HPID and the suggested option of an OEID as foundations for the ''one-stop, automated billing'' that this professional association advocated.

This impact analysis will take these foundational benefits of HPID and, for the sake of illustration, attribute some of the monetary savings from the downstream results to implementation and use of the HPID. It is important to view these estimates as an attempt to illustrate the foundational effect of the HPID rather than as a precise budgetary prediction.

3. Need for a Delay in Implementation of ICD–10, and General Impact of Implementation

The ICD–10 final rule requires covered entities to comply with ICD–10 on October 1, 2013. The provisions of this proposed rule would change the compliance date to October 1, 2014.

The process of transitioning from ICD–9 to ICD–10, if not carefully coordinated, poses significant risk to provider reimbursement. Should health care entities' infrastructure not be ready or thoroughly tested, providers may experience returned claims and delayed payment for the health care services they render to patients. There has been mounting evidence over the past several months that a significant percentage of providers believe they do not have sufficient resources or time to be ready to meet the October 1, 2013 ICD–10 compliance deadline.

Two distinct types of issues are implicated by a transition of this magnitude, and the costs associated with both might be avoided if the ICD–10 compliance date is delayed as proposed in this rule. First, there may be entities that have not readied their systems, personnel, or processes to achieve compliance by October 1, 2013. For example, vendor practice management and/or other software must be updated to process claims with ICD–10 codes, then installed and tested internally. Likewise, staff needs to be trained and systems and forms prepared for the new code set. In a CMS survey conducted in November and December 2011 (hereinafter referred to as the CMS readiness survey), 25% of providers surveyed indicated that they are at risk for not meeting the October 1, 2013 compliance date.[15] In February 2012, the Workgroup for Electronic Data Interchange (WEDI) conducted a survey on ICD–10 readiness (WEDI readiness survey) that indicated that nearly 50 percent of the 2,140 provider respondents did not know when they would complete their impact assessment.[16] An illustration of what could occur if elements of industry are not prepared for the transition to ICD–10 can be seen by the January 1, 2012 transition to Version 5010, where we have heard from several provider organizations reporting numerous practices have not been paid for long periods due to the Version 5010 transition.

Second, beyond ''readiness'' and ''compliance,'' there are issues that will arise if trading partners have not thoroughly tested ICD–10. ''Readiness'' is only a self-reported indicator of the potential success of an ICD–10 transition and can be unreliable; we know this from similar industry surveys done for Version 5010 that indicated high levels of readiness only to find multiple issues once claims were submitted in production mode. The other indicator of success is the quality and robustness of testing. Clearinghouses cannot assist in the ICD–10 transition as they are unable to correct coding issues without viewing the underlying documentation, which is not a typical clearinghouse role. In general, only a provider can change/modify a code, so it is incumbent upon providers to ensure a successful ICD–10 conversion. In many cases, providers' success will be predicated upon timely vendor delivery of ICD–10-compliant software, and coordination must be developed with payer systems and new fee schedules. Providers' practice management systems (PMS) must be programmed to process ICD–10 codes, and, with many providers transitioning to EHRs, there needs to be a well-tested interface between electronic health records and the PMS.

In an informal poll conducted by Edifecs (hereinafter referred to as the Edifecs poll), a health care IT company, with responses from 50 senior health care officials representing a wide range of organizations, 37 percent of respondents stated that a 1-year delay would be beneficial for them.[17] According to the Edifecs analysis, ''For those organizations that have the determination to keep moving forward as if the delay had never been announced, it may end up being a true gift on the testing front.''[18]

In the CMS readiness survey, 75 percent of providers surveyed cited the lack of time and/or staff as a barrier to implementing ICD–10 on time. The survey also indicated that given just 3 additional months, an additional 14 percent of providers would be able to achieve compliance by December 31, 2013. This indicates that a delay would be helpful in overcoming one of the major obstacles to compliance—lack of time—and that a delay of a year would enable providers to achieve not only ''readiness'' in terms of system interoperability, but also give the time for more thorough testing of ICD–10.

B. Introduction

We have examined the impacts of this notice of proposed rulemaking 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), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354) (as amended by the Small Business

[14] ''National Health Plan Identifier White Paper,'' prepared by the American Medical Association (AMA) Practice Management Center (PMC), September 22, 2009.

[15] ''Version 5010 and ID–10 Readiness Assessment: Conducted among Health Care Providers, payers, and Vendors for the Centers for Medicare & Medicaid Services (CMS),'' December, 2011, Prepared by CMS.

[16] ''Survey: ICD–10 Brief Progress,'' February 2012, conducted by the Workgroup for Electronic Data Interchange (WEDI).

[17] ''Survey: Industry Reaction to Potential Delay of ICD–10—A Delay will be Costly, but Manageable * * * Unless it's more than a Year,'' February 27, 2012, conducted by Edifecs. The survey's participants included commercial payers (25%), Blue Cross Blue Shield plans (25%), healthcare providers (18%), government entities such as State Medicaids (9%), medical claim clearinghouses (6%), and other healthcare industry organizations (17%).

[18] Ibid.

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 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13563 also directs agencies not only to engage the public and provide an opportunity to comment on all regulations, but also calls for greater communication across all agencies to eliminate redundancy, inconsistency, and overlapping, as well as outlines processes for improving regulation and regulatory review.

A Regulatory Impact Analysis must be prepared for major rules with economically significant effects ($100 million in 1995 dollars or more in any 1-year). Because of the impact on the health care industry of the proposed adoption, implementation, and use of the HPID and the proposed delay in the compliance date for ICD–10, this rule has been designated an ''economically'' significant regulatory action, under section 3(f)(1) of Executive Order 12866 as it will have an impact of over $100 million on the economy in any 1 year.

The impacts of implementing HPID and delaying the compliance date for transition to ICD–10 are quite different, and, because of their respective impacts, both provisions of the proposed rule would be considered economically significant. Accordingly, we have prepared two independent RIAs: One analysis of the impact of the proposed adoption and use of the HPID and one for the proposed delay of compliance date for transition to the ICD–10. These RIAs, to the best of our ability, present the costs and benefits of this notice of proposed rulemaking, and this proposed rule has been reviewed by the Office of Management and Budget. The RIA on the proposed delay of ICD–10 follows the RIA on the proposed implementation and use of the HPID.

We anticipate that the adoption of the HPID and the OEID and the additional requirement for organization covered health care providers to require certain non-covered individuals who are prescribers to obtain and use an NPI would result in benefits that outweigh the costs to providers and health plans. We anticipate that the delay of ICD–10 will have costs to health plans and clearinghouses, though it will be beneficial to a group of providers.

In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives for the HPID that are referenced in the section VI.D. of this proposed rule, HHS has concluded that the provisions in this rule are the most cost effective alternative for implementing HHS' statutory requirements concerning administrative simplification. We did not consider alternatives to the addition to the NPI requirements that is proposed in this rule, as the NPI is the standard identifier for health care providers under HIPAA and based on ongoing industry feedback, prescriber NPIs are not always available. Therefore, we believe a regulatory requirement closing the prescriber loophole in the NPI rule is necessary to ensure that the remaining prescribers without an NPI obtain one. We estimate that the proposed addition will have little financial impact on industry and is therefore cost effective in its own right.

Similarly, we have considered four alternatives for delaying ICD–10 compliance.

The Regulatory Flexibility Act (RFA), as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the Small Business Administration (SBA). Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, most physician practices, hospitals and other health care providers are small entities, either by nonprofit status or by having revenues less than $10 million for physician practices and less than $34.5 million for hospitals in any 1 year. We have determined that the proposed adoption of the HPID in this proposed rule will have an impact on a substantial number of small entities and that an initial regulatory flexibility analysis, an analysis on the impact of this proposed rule on small entities, is required. The regulatory flexibility analysis on the impact of the proposed adoption of HPID will come after the RIA. However, the initial regulatory flexibility analysis for HPID concludes that, although a significant number of small entities may be affected by this proposed rule, the economic impact on small entities will not be significant.

We have also determined that the proposed delay of the compliance date for ICD–10 will have an impact on a substantial number of small entities and this regulatory flexibility analysis will follow the RIA for the proposed delay of ICD–10. The initial regulatory flexibility analysis for the proposed delay of ICD–10 concludes that small entities will be positively impacted economically by the proposed compliance date delay and that there will be no significant burden.

In addition, section 1102(b) of the Act requires a regulatory impact analysis for ''any rule or regulation proposed under title XVIII, title XIX, or part B of [the Act] that may have a significant impact on the operations of a substantial number of small rural hospitals.'' This proposed rule, however, is being proposed under title XI, part C, ''Administrative Simplification,'' of the Act, and, therefore, does not apply. As to the addition to the NPI requirements, the method for compliance by covered organization health care providers, including small rural hospitals, is discretionary, and could vary. It could take the form of a verbal directive to prescribers whom they employ or contract with, to revising hospital policies and procedures as part of routine updating, or some other option. We believe there will not be a significant impact to the operations of a substantial number of small rural hospitals. We seek industry feedback on this assumption.

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 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This proposed rule contains mandates that would likely impose spending costs on State governments and the private sector, of more than $139 million. We will illustrate the costs of adoption of the HPID to the State governments, specifically the impact to State Medicaid programs, and to the private sector in our consideration of costs to health plans in the RIA. As to the addition to the NPI requirements, again, since the method for compliance by covered organization health care providers is discretionary and could vary, for example, from a verbal directive to prescribers whom they employ or contract with, to updating employment or contracting

agreements, we believe there is no mandate which imposes spending costs on State government or the private sector in any 1 year of $139 million or more.

We will illustrate the costs of the proposed delay of ICD–10 to State Medicaid programs and to the private sector in our consideration of costs to health plans in the RIA that addresses costs and benefits of the delay of compliance of ICD–10.

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 laws, or otherwise has Federalism implications. The proposed adoption of the HPID in this proposed rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications. The proposed delay of compliance with ICD–10 in this proposed rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications.

C. HPID: Assumptions Regarding the Use of Transaction Standards

1. Current and Projected Use of Three Transactions

A major assumption in our impact analysis of the HPID is that the health care industry will experience increased use of three electronic health care standard transactions over the next 10 to 15 years. The three transactions are the eligibility for a health plan transaction, the health care claim status transaction, and the health care electronic funds transfer (EFT) and remittance advice transaction. The reason we chose these three transactions in particular is because we assume these three transactions will see the greatest increase in use from 2013 to 2023. We base the assumption that these three transactions will increase in use on the following three premises:

First, the number of total health care claims is expected to increase considerably in the United States. Claims are expected to increase due to an aging population that will require an increasing number of health care services. For instance, aging baby boomers will double Medicare's enrollment between 2011 and 2031.[19] Also, the Affordable Care Act is expected to increase the number of insured adults by 30 to 33 million from 2016 on.[20] Moreover, the average American has increased the number of visits to a physician's practice: According to data from HHS, ''From 1997 through 2007, the annual number of ambulatory care visits increased by 25 percent, driven both by the aging of the population, as older persons have higher visit rates than younger persons in general, and by an increase in utilization by older persons.'' [21] All these indicators point to a substantial increase in patients and patient visits to providers. The expected increase in patients and patient visits will drive providers to seek more automated processes in order to check patients' eligibility through the eligibility for a health plan transaction, check claim status with the health care claim status transaction, and receive payments and remittance advice through the health care EFT and remittance advice transaction.

Second, it is anticipated that the use of electronic business transactions and electronic transmissions in general is expected to become more widespread for U.S. businesses and society at large. For example, in 2007, the typical organization made 26 percent of its payments to other business (B2B) electronically; by 2010, that percentage rose to 43 percent.[22] Overall, the number of noncash payments among consumers and businesses alike increased about 4.5 percent per year from 2003 to 2009.[23]

Third, statutory and regulatory initiatives at the State and Federal level will drive or attract health care entities to increased usage of health care electronic transactions. On the Federal level, initiatives include the adoption and implementation of standards for health care EFT and the implementation of a unique health plan identifier as proposed by this rule. Likewise, the increase will be due to the adoption of operating rules for the eligibility for a health plan transaction and for the health care EFTs, and remittance advice transaction. The operating rules for the eligibility for a health plan transaction will go into effect in 2013 and the operating rules for the health care EFTs transaction, will take effect in 2014.

While our impact analysis is based on the expected increase in usage of three HIPAA transactions, other HIPAA transactions may increase in use as well. However, we have not attempted to draw conclusions about other HIPAA transactions because (1) there are no regulatory attempts to streamline other transactions in the near term (with, for example, the adoption of operating rules); and (2) we have less of an understanding of the impact that implementation of the HPID will have on covered transactions other than these three.

Table 5 lists our assumptions on the increased use of these three HIPAA transactions between 2013 and 2023. We have calculated the 2013 estimates—for example, our baseline—based on a number of sources and calculations:

- We estimated the number of eligibility requests (electronic and non-electronic) by taking 90 percent [24] of the total the projected number of claims.[25] The percentage estimate of electronic eligibility requests as a proportion of total eligibility requests in 2013 is derived from an analysis of a number of different industry studies on electronic data interchange (EDI) usage.[26]
- Similarly, we estimated the number of claim status requests by taking 0.14 percent of the total projected number of claims.[27] The percentage estimate of electronic claim status requests as a proportion of total claim status request in 2013 is derived from an analysis of a number of different industry studies on EDI usage.[28]

[19] ''The 2011 Medicare Trustees Report: The Baby Boomer Tsunami,'' presentation by the American Enterprise Institute for Public Policy Research, May 2011: *http://www.aei.org/event/100407*

[20] *http://www.whitehouse.gov/healthreform/relief-for-americans-and-businesses*

[21] S.M. Schappert and E.A. Rechsteiner, ''Ambulatory Medical Care Utilization Estimates for 2007,'' Vital and Health Statistics, Series 13, Number 169, 2011.

[22] ''2010 AFP Electronic Payments: Report of Survey Results,'' November 2010, Association for Financial Professionals, underwritten by J.P. Morgan.

[23] ''The 2010 Federal Reserve Payments Study; Noncash Payment Trends in the United States 2006–2009,'' sponsored by the Federal Reserve System, April 5, 2011.

[24] The Oregon Survey found that, for every claim, .9 requests for eligibility were conducted. ''Oregon Provider and Payer Survey,'' 2010 (*http://www.oregon.gov/OHPPR/HEALTHREFORM/AdminSimplification/Docs/FinalReport_AdminSimp_6.3.10.pdf*).

[25] An average of high and low projected estimates of claims from Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8–19296.pdf.*

[26] ''Oregon Provider and Payer Survey,'' 2010 ''Overhauling the US Healthcare Payment System,'' conducted by McKinsey & Company, published in *The McKinsey Quarterly,* June 2007. (*http://www.mckinseyquarterly.com/Overhauling_the_US_health_care_payment_system_2012).*

The National Progress Report on Healthcare Efficiency, 2010, Produced by the U.S. Healthcare Efficiency Index.

[27] The Oregon Survey found that, for every claim, .14 were followed up by a claim status request. ''Oregon Provider and Payer Survey,'' 2010.

[28] ''Oregon Provider and Payer Survey,'' 2010 ''Overhauling the US Healthcare Payment System,''

Continued

• For remittance advice, we started with the projection for national health expenditures [29] and used Medicare data to arrive at the average dollar amount of a single payment.[30] Using that calculation, we were able to estimate the projected number of health care claim payments for 2013 considering the ratio of remittance advice per payment according to Medicare data.[31] The percentage estimate of electronic remittance advice as a proportion of total remittance advice was calculated using a weighted average of Medicare data (electronic remittance advice as a percentage of total remittance advice), VHA data,[32] and industry studies.[33]

We have projected the percentage use of EDI out to 2023 using a number of calculations:

• In the Eligibility and Claim Status Operating Rules IFC published in the July 8, 2011 **Federal Register** (76 FR 40458), we projected that electronic eligibility requests will increase by 15 percent year over year from 2013 through 2017 and by 8 percent year over year from 2018 through 2022 due to a number of factors. See the Eligibility and Claim Status Operating Rules IFC (76 FR 40481) for the assumptions behind that projection. Note that, despite the 15 percent increase, the number of claims (patient visits) will increase substantially over that same period, so the percentage of electronic eligibility requests as a proportion of all eligibility requests will increase at a much slower rate.

• In the Eligibility and Claim Status Operating Rules IFC, we projected that electronic claim status inquiries will increase by 20 percent year over year from 2013 through 2017 and by 10 percent year over year from 2018 through 2022 due to a number of factors. See the Eligibility and Claim Status Operating Rules IFC (76 FR 40481) for the assumptions behind that projection. Again, despite the year over year increases, the number of claims (patient visits) will increase substantially over that same period, so the percentage of electronic claim status requests as a proportion of all claim status requests will increase at a much slower rate.

• We have noted previously the reasons why we predict that electronic transactions, overall, will increase, including a substantial increase in the number of claims, more widespread use of electronic transactions by U.S. businesses and society at large, and State and Federal mandates requiring or promoting electronic transactions of health information. Due to these reasons, we estimate 20 percent increase of electronic remittance advice transactions year over year from 2013 through 2018, and a 12 percent increase year over year from 2019 through 2023. Again, despite the year over year increases, the number of total remittance advice transactions will increase substantially over that same period, so the percentage of electronic remittance advice as a proportion of all remittance advice will increase at a much slower rate.

We believe these estimates to be conservative: The increase in patients and patient visits in the next decade alone may drive a greater number of health care entities to adopt EDI. However, we recognize the uncertainties inherent in this projection, and we are specifically soliciting comments on these assumptions.

TABLE 5—PREDICTED PERCENTAGE IN EDI USAGE

Year	Eligibility for a health plan transaction: percentage of electronic transactions as a proportion of total eligibility inquiries and responses	Health care claim status transaction: percentage of electronic transactions as a proportion of total claim status transactions	Health care payment and remittance advice (electronic remittance advice) transaction: percentage of electronic transactions as a proportion of total remittance advice transactions (does not include percentage of electronic payments)
2013	14	12	26
2023	25	26	70

2. Projected Increased Use of Three Transactions Attributable to Implementation of HPID

When attempting to quantify anticipated savings, we recognize that some of increased use of three HIPAA transactions from 2013 to 2023 will be attributable to the implementation of administrative simplification initiatives, including the adoption of the EFT standard, operating rules for four transactions, and Version 5010 of the HIPAA transactions as implemented by the Modifications final rule. Therefore, we attribute some of the savings that are derived from an increased use in these transactions to these other initiatives.

For purposes of this impact analysis, we will assume a percentage of the increase in use of electronic transactions by health care providers and health plans as attributable to implementation of an HPID in order to illustrate that the HPID is foundational for overall administrative simplification (Table 6).

Our basic argument is echoed in the Transactions and Code Sets proposed rule, NPI proposed rule, and the Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards proposed rule (73 FR 49742), published in the **Federal Register** on August 22, 2008, (hereinafter referred to as the Modifications proposed rule): Administrative simplification initiatives drive covered entities to increase their usage of electronic transactions, and electronic transactions have substantial cost savings over manual transactions. The implementation of administrative simplification initiatives mandated by the Affordable Care Act is expected to streamline HIPAA electronic

conducted by McKinsey & Company, published in *The McKinsey Quarterly,* June 2007. (*http://www.mckinseyquarterly.com/Overhauling_the_US_health_care_payment_system_2012*).

[29] National Health Expenditure Projections 2009–2019 (CMS), *http://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp*).

[30] CMS Electronic Data Interchange (EDI) Performance Statistics (*http://www.cms.gov/EDIPerformanceStatistics/*) and CMS CROWD data.

[31] There are 6 percent more remittance advice sent than payments (some remittance advice adjusts to no payment). CMS Electronic Data Interchange (EDI) Performance Statistics (*http://www.cms.gov/EDIPerformanceStatistics/*) and CMS CROWD data.

[32] Financial Management Service, U.S. Department of Treasury, Payment Volume Charts Treasury-Disbursed Agencies (*www.fms.treas.gov/eft/reports.html*).

''Comments from VHA Health Care as Health Care Provider,'' testimony by Barbara Mayerick for NCVHS December 3, 2010 hearing.

''FY10 Geographic Distribution of VA Expenditures (GDX),'' Veterans Health Administration Chief Business Office.

[33] The National Progress Report on Healthcare Efficiency, 2010, Produced by the U.S. Healthcare Efficiency Index.

transactions, make them more consistent, and decrease the dependence on manual intervention in the transmission of health care and payment information. This, in turn, will drive more health care providers and health plans to utilize electronic transactions in their operations.

The anticipated cost savings of all administrative simplification regulations and initiatives, therefore, can be divided into two categories: Materials and time. First, the material cost savings that results from each transaction that moves from a non-electronic, manual transmission of information to an electronic transaction. These cost savings result from covered entities using less paper, postage, and equipment which are required for paper-based transactions. Second, the use of electronic transactions to conduct billing and insurance related tasks takes considerable less time than when the same transactions are done through phone, email or postal mail, or manually. Therefore, each move from non-electronic transaction to an electronic transaction results in staff-time savings and cost reductions.

The estimated cost and benefits of implementation and use of HPID need to be understood in the context of the HPID being foundational to other administrative simplification initiatives, both those initiated by industry and those regulated by State or Federal governments. If other initiatives do not follow, then the HPID will likely have little substantive impact. The ranges given of possible cost and benefit impacts are reflective of the uncertainty inherent in multifactorial environments such as the health care industry.

To illustrate the foundational aspects of the HPID, we estimated a range of overall increase of 1 to 2 percent per year, starting in 2015, in the use of both the eligibility for a health plan transaction and the claim status transaction ''attributable'' to implementation of the HPID over the next decade. In addition, we estimate a 1 to 3 percent increase in the use of electronic health care payment and remittance advice transaction attributable to implementation of the HPID because the routing of that transaction is especially important for the payment process. Given the overall increase in both EDI and health care transactions in general expected over the next decade, this annual increase attributable to HPID accounts for a small percentage of electronic transactions as a proportion of total transactions over those 10 years. For example, after an annual increase in remittance advice due to implementation of the HPID of 1 to 3 percent from 2013 through 2023, ultimately, only 1 to 2 percent of all electronic remittance advice transactions from 2013 through 2023 will be attributable to implementation of the HPID. We welcome comments about this approach from industry and other stakeholders.

TABLE 6—PREDICTED PERCENTAGE OF EDI USAGE FROM 2013 TO 2023 ATTRIBUTABLE TO IMPLEMENTATION OF HPID

Year	Eligibility for a health plan transaction: percentage of electronic transactions attributable to implementation of HPID as a proportion of eligibility inquiries and responses	Health care claim status transaction: percentage of electronic transactions attributable to implementation of HPID/OEID as a proportion of total claim status transactions	Health care payment and remittance advice (electronic remittance advice) transaction: percentage of electronic transactions attributable to implementation of HPID as a proportion of total remittance advice transactions (does not include percentage of health care claim payments EFT)
2023	1% to 2%	1% to 2%	1% to 2%

D. Alternatives Considered Regarding the HPID and NPI

In deciding to adopt the HPID as the format for the national unique health plan identifier, we considered a number of alternatives, on which we solicit public and stakeholder comments. As noted, we did not consider alternatives to the addition to the NPI requirements.

For the most part, the HPID alternatives were not chosen because they were inconsistent with the testimony given at the July 2010 NCVHS hearing on HPID and because they were not included in NCHVS' recommendations. As noted previously, section 1172(f) of the Act provides that ''the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)). * * *'' Section 1104(c) (1) of the Affordable Care Act directs the Secretary to promulgate a final rule to establish a unique health plan identifier ''based on input of the National Committee on Vital and Health Statistics.'' The NCVHS recommendations recommended what it thought was the most cost effective and efficient approach to standardizing the HPID, and, consequently, the Secretary has relied heavily on its recommendations for these proposals.

1. The NAIC Company Code

The NAIC Company Code is a 5-digit alphanumeric identifier that resides in a proprietary database maintained by the NAIC. The company code is assigned to insurers, including managed care organizations, to identify insurance companies on financial reports filed with the States. We decided against using the NAIC company code because it has embedded intelligence, multiple company codes have been assigned to the same insurer for the same line of business, and fewer than half of the entities with NAIC company codes are entities listed in the statute as health plans. In addition, a 5-digit number would only allow 100,000 entities to be enumerated. We also considered the NAIC Company Code to be a comparably expensive alternative.

2. The Federal Tax Identification Number

The EIN, also referred to as a Federal Tax Identification Number, was designed and is used to identify business entities for tax purposes. While the EIN is an appropriate and cost-effective standard for the unique employer identifier, we do not believe it would be appropriate for the standard for the unique health plan identifier for the following reasons. Using the EIN to identify employers and health plans under HIPAA could cause confusion among users of the numbers. Also, the current EIN scheme does not cover all health plans, for instance, an employer group health plan would not have its own EIN, so the EIN would need to be expanded to accommodate all health plans.

3. IRS Identifier

We also considered the IRS and DOL Identifier. An Employee Benefit Plan subject to ERISA may be required to file

an Annual Report/Report of Employee Benefit Program Plan (Form 5500 Series Reports). This includes Pension Benefit Plans, and Direct Filing Entities. The IRS and DOL have combined their filing requirements on Form 5500 Series Report to minimize the efforts of plan administrators and employers. The Form 5500 Series Reports are used by both the IRS and the DOL for audit purposes to ensure that the employee benefit plans are operated and managed in accordance with certain prescribed standards and to protect the rights and benefits of participants. These benefit plans use their 9-digit EIN with a 3-digit suffix that is assigned according to the type of plan they offer. The IRS provides very specific guidelines on the selection of the 3-digit suffix. The 3-digit suffix has required guidelines that would be too specific for the purposes of the HPID. In addition, this format would not be capable of incorporating a check digit without modification. Therefore, we did not consider the IRS identifier as a viable alternative for identifying health plans in a manner consistent with our statutory mandates and our program objectives.

E. Impacted Entities—HPID and NPI

All HIPAA covered entities may be affected by the standard proposed in this proposed rule although, as we estimate, only a segment of covered entities will have substantive cost or benefits associated with the adoption of the HPID. HIPAA 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.

Table 7 outlines the number of entities that may be affected by the HPID and OEID, along with the sources of those data.

TABLE 7—TYPES AND NUMBERS OF AFFECTED ENTITIES

Type	Number	Source
Health Care Providers—Offices of Physicians (includes offices of mental health specialists and substance use treatment practitioners).	234,222	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf* (based on AMA statistics).
Health Care Providers—Hospitals	5,764	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf*.
Health Care Providers—Nursing and residential Care Facilities not associated with a hospital.	66,464	2007 Economic Census Data—Health Care and Social Assistance (sector 62) using the number of establishments. ~NAICS code 623: Nursing Homes & Residential Care Facilities n = 76,395 × 87 percent (percent of nursing and residential care facilities not associated with a hospital) = 66,464.
Other Health Care Providers—Offices of dentists, chiropractors, optometrists, mental health practitioners, substance use treatment practitioners, speech and physical therapists, podiatrists, outpatient care centers, medical and diagnostic laboratories, home health care services, and other ambulatory health care services, resale of health care and social assistance merchandise (durable medical equipment).	384,192	2007 Economic Census Data—Health Care and Social Assistance (sector 62) using the number of establishments: ~NAICS code 621: All ambulatory health care services (excluding offices of physicians) = 313,339 (547,561 total − 234,222 offices of physicians). ~NAICS code 62-39600 (product code): Durable medical equipment = 70,853.
Health Plans—Commercial: Impacted commercial health plans considered in this RIA are health insurance issuers; that is, insurance companies, services, or organizations, including HMOs, that are required to be licensed to engage in the business of insurance in a State.	1,827	This number represents the most recent number as referenced in ''Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment,'' Proposed Rule, 2011 **Federal Register** (76 FR 41930), July 15, 2011,'' from *http://federalregister.gov/a/2011-17609.*
Health Plans—Government	60	Represents the 56 State Medicaid programs, Medicare, the Veteran's Administration (VHA), and Indian Health Service (IHS), TRICARE.
Health Plans—All	1,887	Insurance issuers (n = 1,827) + Medicaid agencies + Medicare, VHA, TRICARE, and IHS (n = 60) = 1,887 total health plans.
Third Party Administrators	750	Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rulemaking *http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf.*
Transaction Vendors and Clearinghouses	162	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf,* based on a study by Gartner.

F. Scope and Methodology of the Impact Analysis for the HPID and NPI

This impact analysis estimates the costs and benefits that will be realized through the implementation and use of the HPID. We do not analyze the costs and benefits of the addition to the NPI requirements, apart from the costs associated with applying for an NPI that are already addressed in section V.B. of this proposed rule concerning the collection of information requirements. Aside from the time necessary to apply, we do not anticipate any financial impact as a result of the addition to the NPI requirements. We ask for comments on this approach.

In this RIA, we do not analyze the impact of implementation and use of the OEID. The OEID, as proposed herein, would be a data element that could be voluntarily used by entities other than health plans. These other entities may include, for example, health care clearinghouses, transaction vendors, and third party administrators that provide administration or management for self-insured health plans. The range of total entities that may apply for and use an OEID is zero to approximately 900 entities (750 Third party administrators + 169 transaction

vendors). Therefore, using the methodology we use in this RIA, the cost for implementation of the OEID for other entities ranges from no cost to approximately $500 million, depending on choices made by those entities. Because of the uncertainty inherent in this range of cost, based on the number of entities that may apply for the OEID we will not attempt to quantify the impact of applying for or using an OEID beyond this limited analysis. Nor will we include this range of costs in our summary of this RIA. However, we can assume that implementing and using OEID would be accompanied by a proportional range of costs and benefits akin to the cost and benefits estimated for health plans in this RIA. We welcome comments on the number and kind of entities that may apply for and use an OEID. We estimate the cost of the Enumeration System to be $1.5 million. The Federal Government will bear the costs associated with the Enumeration System that will enumerate health plans and other entities and maintain their information. These include the costs of enumerating health plans and other entities, the cost of maintaining health plan and other entity information in the Enumeration System, and the costs of disseminating HPID and OEID data to the health care industry and others, as appropriate. HHS will develop the Enumeration System, and conduct the updating and data dissemination activities. We will apply this cost to our summary of costs and the accounting statement, but will not provide any further analysis of this cost within the narrative of the RIA.

The costs to health plans of applying for an HPID and updating and maintaining the information in the Enumeration System are detailed in section III of this proposed rule. We will reflect these costs in the summary of the costs to health plans in this RIA.

While we assume that adoption of the health plan identifier standards will affect a broad range of health care providers, as illustrated in Table 7, we will only be examining the costs and benefits of implementation and use of the HPID on two types of health care providers: Hospitals and physician practices. We will not analyze the impact to nursing and residential care facilities, dentists, or suppliers of durable medical equipment.

There are two reasons for narrowing the scope of this analysis to only two categories of health care providers: we have very little data on the usage of EDI among dentists, suppliers of durable medical equipment, 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.[34] We assume that the greatest benefits will be gained by hospitals and physician practices as they conduct the majority of standard transactions. We welcome comment from industry and the public as to our assumptions.

We have not included an analysis of the impact on pharmacies because the HPID will not be used extensively in electronic transactions by the pharmacy industry. This industry will instead be using the BIN/IIN and PCN as described previously in this proposed rule. Therefore, we assume no impact on pharmacies.

With respect to health care providers, only health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a HIPAA transaction standard are considered covered entities.

We assume that the HPID may be used to identify health plans in non-electronic transactions as well, but, as this standard is only required for use in HIPAA standard transactions, we have not tried to measure the impact on non-electronic transactions. The costs and benefits included in this analysis do not include infrastructure or software costs for health care providers who are equipping their practices for the transmittal of electronic transactions for the first time. The costs in this impact analysis include only those that are necessary to implement the standard for the national unique health plan identifier.

We include health care clearinghouses and transaction vendors as affected entities in Table 7. Transaction vendors are entities that process claims or payments for other entities, which may include health plans. Transaction vendors may not meet the HIPAA definition of health care clearinghouse, but as used in this context, health care clearinghouses would constitute a subset of transaction vendors. Payment vendors would be a type of transaction vendor—a transaction vendor that ''associates'' or ''reassociates'' health care claim payments with the payments' remittance advice for either a health plan or provider. For our purposes here, transaction vendors do not include developers or retailers of computer software, or entities that are involved in installing, programming or maintaining computer software. Health care clearinghouses and transaction vendors may be impacted because their systems would have to accommodate the adoption of the new standards such as the HPID to identify health plans in standard transactions. However, we did not calculate costs and benefits to health care clearinghouses and transaction vendors in this cost analysis because 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 or providers.

We use the total number of health insurance issuers as the number of commercial health plans that will be affected by this proposed rule, and will use this number in our impact analysis. A health insurance issuer is an insurance company, insurance service, or insurance organization, including an HMO, that is required to be licensed to engage in the business of insurance in a State, and that is subject to State law that regulates insurance. Although this number is specific to the individual and small group markets, we assume that many health insurance issuers in the large group market are included in this number because they are likely to market to individuals and small groups as well. While the category or ''health insurance issuers'' represents a larger number of health plans than those included in the NAICs codes for ''Direct Health and Medical Insurance Carriers'' (897 firms), we believe the category of health insurance issuers is a more accurate representation of companies conducting HIPAA transactions. Companies that provide Medicaid managed care plans are included in the category of commercial health plans.

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 obtain the HPID, we assume that, with a few exceptions, such plans do not send or receive HIPAA electronic transactions because most are not involved in the day-to-day activities of a health plan and outsource those services to third party administrators or transaction vendors. Because they do not meet the definition of ''health plans,'' TPAs and transactions vendors are not required to obtain or use an HPID, though they may elect to obtain and use an OEID. The costs and benefits associated with the HPID are applicable only to entities that are directly involved in sending or receiving

[34] ''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.

standard transactions, though we recognize that some of the cost and benefits will trickle down to employers and their employees.

We have no data concerning how many health plans are actually identified in standard transactions, as opposed to ''other entities'' that are identified in their stead. Therefore, we have no assurance of how many health plans may be affected by this proposed rule. We base our cost estimates on the highest number of entities that would likely be affected. The number of health plans is used as a factor in our calculation of costs, but not in our calculation for savings. We are therefore taking a conservative approach to the costs to health plans which we believe is warranted given the uncertainties in our estimates. We solicit industry and stakeholder comments on our assumptions.

G. Costs Associated with HPID and NPI

Due to a lack of baseline data, we use the cost estimate calculations provided in the impact analysis for the Modifications proposed rule and the clarifications of that impact analysis contained in the Modifications final rule.

We chose the costs in the Modifications proposed and final rules as our baseline for costs for a number of reasons:

- The cost categories in the Modifications rules are similar to the cost categories anticipated by implementation of the HPID: one-time or short-term costs such as software conversion, and cost of automation, training, implementation, and implementation guides.
- There are no analogous national standard identifiers from which to derive costs and benefits.

In our discussion of the HPID, we considered the NPI as a potential analogous identifier; however, the cost/benefit analysis for the NPI, included in the ''National Standard Health Care Provider Identifier,'' proposed rule,'' published in the May 7, 1998 **Federal Register** (63 FR 25320) does not analyze the cost/benefits of implementation of the NPI itself. Instead, the analysis reiterates the cost/benefits of the Transactions and Code Sets final rule (65 FR 50312). The Transactions and Code Sets final rule analyzes the costs/benefits of sending and receiving all HIPAA transactions. The Modifications final rule is another reiteration of the original cost/benefit analysis of the Transactions and Code Sets final rule, but the data has been adjusted to 2009, and so we will use it because it is more recent but adjust the costs to 2012 dollars. In the impact analysis for the Modifications final rule, the estimated costs to implement the update to the standards were 25 percent less (minimum) to 50 percent (maximum) of the costs estimated in the Transactions and Code Sets final rule.

To determine the anticipated costs for health care providers and health plans, we used 25 percent of the cost estimates for the Modifications final rule. We used this percentage because we determined that implementation of HPID will not be as significant as the impact of Version 5010 adopted in the Modifications final rule for the following reasons: First, the implementation of the Modifications final rule is much broader and more complex than the implementation of a unique health plan identifier. The Modifications rule broadly amends or alters every HIPAA transaction standard. This rule proposes a standard that will need to be included in every HIPAA transaction; however, it is only one data field, compared to a multitude of data fields that were affected by the adoption of the transaction standards outlined in the Modifications final rule.

Second, we believe covered entities are more prepared for the implementation of the HPID than they may have been for the Modifications final rule. Because the standards for transactions and codes sets, security and privacy, employer identifier, and health care provider identifier have already been adopted, we assume that covered entities have already made significant system investments. In addition, a data field already exists for the health plan identifier in the HIPAA standard transactions.

To support our estimate that the HPID will cost 25 percent of the costs of the Modifications final rule, we make a number of assumptions. We assume many of the implementation costs covered entities will experience will be short term or one-time costs for system implementation and transition costs. System implementation costs include software and software development, testing, training, and other conversion costs. Conversion will require training for staff and will require changes to documentation, procedures, records, and software. Some covered health care entities may choose to use the services of software system vendors, billing companies, transaction vendors, and/or health care clearinghouses to facilitate the transition to the HPID.

''Transition'' costs, which we assume will occur in the second and third years of implementation, are defined as the post-implementation costs for monitoring, maintaining, and adjusting the upgraded systems and related processes with trading partners until all parties reach a ''steady state'' with regard to utilizing the HPID. While there will be initial costs to implement the HPID, we believe a standard HPID will simplify standard transactions and improve their efficiency and effectiveness. In addition, the lack of embedded intelligence within the HPID will result in lower implementation and maintenance costs for covered entities.

1. Costs of HPID to Health Plans

Health plans will bear most of the cost of implementing the HPID. We estimate the cost to health plans to implement and use an HPID will be 25 percent of the costs that the impact analysis in the Modifications final rule calculated in order for industry to implement Version 5010 of the standard transactions. As noted previously, implementation of the HPID will be analogous to—yet significantly less than—implementation of Version 5010 because the same systems will be affected, and, in both cases, there are both implementation and transition costs. Beyond these general similarities, we assume that implementation of HPID will be much less expensive for the reasons stated previously.

The estimate that HPID implementation and transition will be 25 percent of the cost of Version 5010 is a conservative estimate, we believe, and it is probable that the costs will be much less. However, by estimating HPID implementation at 25 percent of the cost of Version 5010, we are able to reflect the uncertainty in our calculations because our calculations maintain the range of minimum and maximum costs from the Modifications final rule.

In addition, the cost estimates from the Modifications final rule have been adjusted down because we estimate there will be fewer health plans impacted by this rule than are impacted by the Modifications final rule. For costs associated with applying for and obtaining an HPID, see section V.A. of this proposed rule. We welcome comments and data from the industry and other stakeholders on this assumption.

To comply with this proposed rule, a health plan that is not a small health plan must start using the HPID in the standard transactions on or after October 1, 2014 (small health plans must start using the HPID in the standard transactions on or after October 1, 2015). As we note in the RFA, section V.J.1.d of this proposed rule, there are, perhaps, 100 health plans that can be defined as small health plans. While we expect these

costs will accrue between the time the final rule is published and the date the HPID is fully implemented, for purposes of simplification we have placed all system implementation costs—including those for small health plans—in 2014. Transition costs will occur in 2015 and 2016.

TABLE 8— HPID COST FOR COMMERCIAL AND GOVERNMENT HEALTH PLANS*

	Cost category	Minimum cost estimate per modifications rule (in millions)	Maximum cost estimate per modifications rule (in millions)	Applied percentage	Minimum estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
Commercial Health Plans **	System Implementation	$1935.0	$3870.5	25	$483.76	$967.63
	Transition (Year 2 and 3)	341.5	683.0	25	85.37	170.76
Government Health Plans (Medicare, Medicaid, VHS, TRICARE, IHS).	System Implementation	281.0	537.8	25	70.25	134.45
	Transition (Year 2 and 3)	49.6	94.9	25	12.40	23.73
All Health Plans	Enrollment and Updates***				0.18	0.18
	System Implementation				554.19	1102.26
	Transition (Year 2 and 3)				97.77	194.48
	Total				651.95	1296.74

* Based on 2012 dollars.
** Minimum and maximum cost estimates per Modifications Rule for commercial health plans is adjusted to account for a lesser number of health plans considered than is estimated in the Modifications Rule.
*** See section V.A of this proposed rule; Collection of Information Requirements, for calculations on enrollment to HPID enumeration system.

2. Costs of HPID for Physician Practices and Hospitals

Covered physician practices and hospitals will be required to use the HPID in standard transactions. Health care providers that do not conduct covered transactions (for example, by submitting a paper claim that the health plan subsequently transmits electronically to a secondary payer) could also use the HPID, but would not be required to do so. Implementation costs for covered physician practices and hospitals depend on whether they generate claims directly or use a health care clearinghouse or transaction vendor.

If covered physician practices and hospitals submit claims directly, they would incur implementation costs in converting their systems to accommodate the HPID. Some covered health care providers may choose to use the services of software system vendors, billing companies, transaction vendors, and/or health care clearinghouses to facilitate the transition to the HPID. These health care providers would incur costs in the form of potential fee increases from billing agents or health care clearinghouses. For example, if a health care provider pays a fee to a billing agent or health care clearinghouse to process its health care transactions, the billing agent or health care clearinghouse might increase the cost to perform this service for the health care provider.

Table 9 illustrates the costs to covered hospitals and physician practices. Again, the costs are 25 percent of the costs estimated in the Modifications proposed and final rules. We invite comments on our assumptions and method for estimating the implementation costs.

TABLE 9—HPID COSTS TO COVERED HOSPITALS AND PHYSICIAN PRACTICES *

I	II	III	IV	V	VI	VII
	Cost category	Minimum cost estimate per modifications rule (in millions)	Maximum cost estimate per modifications rule (in millions)	Applied percentage	Minimum estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
Hospitals	System Implementation	1042.5	$2085.9	25%	$260.63	$521.48
	Transition (Year 2 and 3)	184.0	368.1	25%	45.99	92.03
Physician Practices	System Implementation	486.8	973.6	25%	121.70	243.40
	Transition (Year 2 and 3)	85.9	171.8	25%	21.48	42.95
All Providers (Total)	System Implementation	1529.3	3059.5	25%	382.33	764.88
	Transition (Year 2 and 3)	269.9	539.9	25%	67.47	134.98
	Total				449.80	899.86

* Based on 2012 dollars.

H. Savings Associated With HPID and NPI

1. Savings to Health Plans

We have identified two areas in which health plans will experience savings due to the adoption of HPID: A reduction in the number of pended claims and an increased use of electronic health care transactions.

2. Pended Claims

Pended claims are claims that necessitate a manual review by the health plan. Pended claims are more expensive than ''clean'' claims, which do not require a manual review or

additional information in order to be processed. We are projecting a 5 to 10 percent annual reduction of pended claims as attributable to implementation of the HPID. We have calculated the savings that would come from this estimated projection from: data about claims receipts from the trade association America's Health Insurance Plans (AHIP),[35] information about eligibility transactions from the Oregon Provider and Payer Survey,[36] and data from the Modifications proposed and final rules.

One of the main goals of the use of the HPID is to have a consistent identifier for each health plan for use in standard transactions. This lack of a single identifier has resulted in the need for manual intervention to resolve eligibility questions and billing and payment issues when there are inconsistent approaches for identifying health plans. Covered health care providers would no longer have to keep track of and use multiple identifiers for a single health plan. After the initial outlay for changes to their systems, health care providers would be able to consistently identify the health plan to which they must submit claims.

According to AHIP, 14 percent of all claims were pended by health plans.[37] Assuming 6 billion claims will be submitted in 2014, as is projected in the Modifications proposed rule, this calculates to about 850 million pended claims (Table 10, Column 2).

We will assume that pended claims will decrease by a minimum of 5 percent to a maximum of 10 percent annually attributable to use of the HPID (Table 10, Columns 4 and 6). This estimate is based on an AHIP survey entitled, ''An Updated Survey of Health Care Claim Receipt and Processing Times.'' The survey concluded that 35 percent of all claims are pended because they are duplicate claims (or assumed to be duplicate claims), 12 percent are pended because of the lack of necessary information, 5 percent because of coordination of benefits (COB), and 1percent because of invalid codes.[38] The HPID may help alleviate these particular pended claims issues by enabling the automation of the COB process[39] and providing for more accurate routing of claims to the correct payer. This conclusion presumes that providing an HPID will lead to a measurable reduction of duplicate claims and/or claims pended because of a lack of necessary information. There is a large measure of uncertainty in this assumption and, as noted, the HPID would be foundational for subsequent activities such as the automation of the COB process. By itself, though, the HPID does not automate any processes. To reflect the uncertainty, we apply a range of percentages to the assumption.

According to AHIP, it costs a health plan $0.85 to reply electronically to a ''clean'' claim submission and $2.05 to reply to claims that ''necessitate manual or other review cost.'' Therefore, a health plan could save $1.20 per claim by automating a claim otherwise needing manual review (Table 10, Column 3). In order to calculate the savings from a 5 to 10 percent decrease in pended claims due to implementation of the HPID, we multiply the projected number of pended claims (Table 10, Column 2) times 5 percent for the low estimate and 10 percent for the high estimate. We then multiplied the high and low range of numbers of pended claims that will be avoided due to use of HPID times the $1.20 per claim that can be saved.

In considering how to project this cost avoidance, we decided that the 5 to 10 percent savings should continue each year over the 10 years following implementation of the standard, resulting in a savings of approximately $700 million to $1.4 billion. As stated previously, we consider the HPID standards in this notice of proposed rulemaking to be foundational standards that will be built upon by future operating rules and regulations over the next decade.

We welcome input and data from industry and other stakeholders with regard to these assumptions.

TABLE 10—ANNUAL SAVINGS TO HEALTH PLANS DUE TO DECREASE IN PENDED CLAIMS

(In millions) *

Year	Number of pended claims annually (in millions) **	Cost to review a pended claim ***	LOW number of pended claims (5%) that will be avoided attributable to HPID (in millions)	LOW total annual savings through reduction in pended claims (in millions)	HIGH number of pended claims (10%) that will be avoided attributable to HPID (in millions)	HIGH total annual savings through reduction in pended claims (in millions)
(Col. 1)	(Col. 2)	(Col. 3)	(Col. 4)	(Col. 5)	(Col. 6)	(Col. 7)
2014	848.4	$1.35	.0	.0	0	.00
2015	882.0	1.35	44.1	$59.5	88.2	$119.1
2016	917.0	1.35	45.9	61.9	91.7	123.8
2017	952.0	1.35	47.6	64.3	95.2	128.5
2018	994.0	1.35	49.7	67.1	99.4	134.2
2019	1036.0	1.35	51.8	69.9	103.6	139.9
2020	1077.4	1.35	53.9	72.7	107.7	145.5
2021	1120.5	1.35	56.0	75.6	112.1	151.3
2022	1165.4	1.35	58.3	78.7	116.5	157.3
2023	1212.0	1.35	60.6	81.8	121.2	163.6
2024	1260.5	1.35	63.0	85.1	126.0	170.2

[35] ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006,'' America's Health Insurance Plans (AHIP) Center for Policy and Research.

[36] A comprehensive survey of 55 percent of Oregon's hospitals and 225 of the State's ambulatory clinics. *http://www.oregon.gov/OHPPR/HEALTHREFORM/AdminSimplification/Docs/FinalReport_AdminSimp_6.3.10.pdf.*

[37] AHIP, 2006.

[38] ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006,'' America's Health Insurance Plans (AHIP) Center for Policy and Research.

[39] ''National Health Plan Identifier White Paper,'' prepared by the American Medical Association (AMA) Practice Management Center (PMC), September 22, 2009.

TABLE 10—ANNUAL SAVINGS TO HEALTH PLANS DUE TO DECREASE IN PENDED CLAIMS—Continued

(In millions) *

Year	Number of pended claims annually (in millions) **	Cost to review a pended claim ***	LOW number of pended claims (5%) that will be avoided attributable to HPID (in millions)	LOW total annual savings through reduction in pended claims (in millions)	HIGH number of pended claims (10%) that will be avoided attributable to HPID (in millions)	HIGH total annual savings through reduction in pended claims (in millions)
(Col. 1)	(Col. 2)	(Col. 3)	(Col. 4)	(Col. 5)	(Col. 6)	(Col. 7)
Total	.....	.....	.....	716.6	.....	1433.3

* Based on 2012 dollars.
** Based on 14% of total number of annual claims as projected in Modifications proposed rule.
*** AHIP, 2006, adjusted to 2012 dollars.

3. Increase in Electronic Transmittal of Three Standard Transactions

The implementation of all administrative simplification initiatives mandated by the Affordable Care Act are expected to streamline HIPAA electronic transactions, make them more consistent, and decrease the dependence on manual intervention in the transmission of health care and payment information. This, in turn, will drive more health care providers and health plans to utilize electronic transactions in their operations. Each transaction that moves from a non-electronic, manual transmission of information to an electronic transaction, brings with it material and time cost savings by virtue of reducing or eliminating the paper, postage, and equipment and additional staff time required to conduct paper-based transactions.

Table 11 lists our estimates of the savings for health plans when they move from a non-electronic transaction to an electronic transaction on a per transaction basis. For a more detailed description of how we arrived at the savings associated with the eligibility for a health plan transaction and the health care claim status transactions, see the RIA in the ''Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions,'' published in the July 8, 2011 **Federal Register** (76 FR 40471).

The estimated savings associated with the health care payment and remittance advice transaction is taken from Medicare data. Medicare found that the average estimated cost avoidance in terms of printing and mailing charges was $4.24 per electronic remittance advice transaction when it was sent electronically as opposed to through the mail in paper form.

TABLE 11—BASELINE COST SAVINGS PER TRANSACTION FOR COMMERCIAL AND GOVERNMENTAL HEALTH PLANS (DIFFERENCE BETWEEN NON-ELECTRONIC TRANSACTION AND ELECTRONIC TRANSACTION) IN THREE TRANSACTIONS *

Transaction	Savings per transaction for commercial and government health plans
Eligibility for a health plan	$3.15
Health care claim status	3.78
Health care electronic funds transfer (EFT) and remittance advice (Remittance Advice only)	4.24

* Based on 2012 dollars.

We expect that the use of the HPID will result in greater efficiency and savings across all HIPAA transactions in addition to the three transactions we specifically analyze here. However, we expect that the impact will be considerably less in other transactions because operating rules for these transactions will likely take effect a number of years after the implementation of the HPID.

We estimate an annual increase of 1 (LOW) to 2 (HIGH) percent in the use of the eligibility for a health plan transaction and the health care claim status transaction attributable to the implementation of the HPID over the next 10 years as illustrated in Table 12. We estimate an annual increase of 2 (LOW) to 3 (HIGH) percent in the use of the electronic remittance advice transaction resulting from the adoption of the HPID. These are not annual increases in percentage points, but rather percent increases in the use of electronic transactions from the year before. The impact of the HPID on the electronic health care payment and remittance advice transaction is more than the impact on the other two transactions because NCVHS testimony supported the notion that the greatest impact of a standardized health plan identifier would be on the payment process.[40]

Based on these assumptions, we estimate that the savings to health plans because of increased usage in three transactions will be at least $500,000 within 10 years of HPID implementation. Health plan savings are summarized in Table 13.

[40] Tammy Banks, Director, Practice Management Center and Payment Advocacy, ''Testimony By The American Medical Association,'' National Committee on Vital and Health Statistics Subcommittee on Standards, July 19, 2010.

TABLE 12—ANNUAL COST SAVINGS FOR HEALTH PLAN FROM INCREASE DUE TO HPID IN VOLUME OF THREE ELECTRONIC TRANSACTIONS *

[In millions]

I	II	III	IV	V	VI	VII
	Savings from increase in eligibility for a health plan transaction attributable to HPID		Savings from increase in health care claim status transaction attributable to HPID		Savings from increase in health care payment and remittance advice transaction attributable to HPID (remittance advice only)	
Year	LOW annual cost savings attributable to HPID	HIGH annual cost savings attributable to HPID	LOW annual cost savings attributable to HPID	HIGH annual cost savings attributable to HPID	LOW annual cost savings attributable to HPID	HIGH annual cost savings attributable to HPID
2014	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
2015	31.4	54.6	5.1	8.5	6.4	16.0
2016	36.1	62.8	6.1	10.2	7.7	19.2
2017	41.5	72.2	7.4	12.3	9.2	23.0
2018	44.8	83.0	8.1	14.7	11.0	27.6
2019	48.4	89.7	8.9	16.2	12.4	33.1
2020	52.3	96.8	9.8	17.8	13.8	37.1
2021	56.5	104.6	10.8	19.6	15.5	41.5
2022	61.0	113.0	11.9	21.6	17.4	46.5

Cumulative Annual Cost Savings:
LOW: $534 million.
HIGH: $1,042 million.

* Based on 2012 dollars.

TABLE 13—TOTAL SAVINGS FOR COMMERCIAL AND GOVERNMENTAL HEALTH PLANS *

[In millions]

I	II	III	IV	V	VI
Savings from decrease in pended claims		Savings from increase usage of EDI in three transactions		Total savings for health plans	
LOW	HIGH	LOW	HIGH	LOW	HIGH
$717	$1,433	$534	$1,042	$1,250	$2,475

* Based on 2012 dollars.

4. Savings to Health Care Providers

We have quantified two areas of savings for health care providers. First, time and money will be saved at an administrative-level because of a decrease in claims issues that require manual intervention. Medical practices will experience these administrative savings by virtue of decreased time spent interacting with health plans. Second, material savings will be derived because of an increase in the number of transactions that are conducted electronically, as we explained in our discussion of the potential impact of this rule on health plans.

a. Time Savings for Health Care Providers

One of the main goals of the use of the HPID is to have a consistent identifier for each health plan for use in standard transactions. This lack of a single identifier has resulted in the need for manual intervention to resolve eligibility questions and billing and payment issues when there are inconsistent approaches for identifying health plans. Covered health care providers would no longer have to keep track of and use multiple identifiers for a single controlling health plan. After the initial outlay for changes to their systems, health care providers would be able to simplify their billing systems and processes and reduce administrative expenses.

The HPID would also assist and simplify coordination of benefits. Health plans that have sole or shared fiduciary responsibilities for payment would be more readily identified, and the movement of information among these entities would be enhanced. According to a 2009 study published in Health Affairs, approximately 60 hours per physician per week are spent on average interacting with health plans when the time spent by the single physician, the staff, and the physician practice's administration are totaled.[41] Of the time spent interacting with health plans, 88 percent was spent on authorizations and claims/billing issues.

We believe the implementation of an HPID will eliminate some of the manual intervention that is required when there are questions or errors identifying the entity responsible for eligibility of a patient or the payment of a claim. We estimate that the implementation and use of an HPID by health plans would save a physician's practice a number of phone calls and emails otherwise required to investigate or verify the identifier needed for the health plan. Of the 60 hours reported previously, our estimate would be that 15 minutes to 30 minutes per week—or .4 to .8 percent of the total time spent interacting with

[41] Lawrence P. Casalino, S. Nicholson, D.N. Gans, T. Hammons, D. Morra, T. Karrison and W. Levinson, ''What does it cost physician practices to interact with health insurance plans?'' Health Affairs, 28(4)(2009):w533–w543.

health plans—could be eliminated if the HPID were implemented. We welcome input on our assumption.

Table 14 illustrates the savings if a physician's office spends 15 to 30 minutes a week interacting with health plans. Table 14, Column I shows the number of hours spent per week per physician interacting with health plans, according to the 2009 Health Affairs study. This number represents the sum total of hours spent by the physician, the physician's staff, and senior administrative staff, accountants, and lawyers that support the physician.

Table 14, Column II is the low to high estimate of 15 to 30 minutes (or .4 to .8 percent of the total time spent interacting with health plans) that we estimate would be saved with the implementation of the HPID.

Table 14, Column III is the annual cost for a physician's office of interacting with a health plan, based on time spent and hourly wages of various employees of a physician's office, according to the 2009 Health Affairs study. The wages are adjusted 3 percent annually to account for cost of living increases.

Table 14, Column IV is the estimate of savings generated by decreasing the time spent interacting with health plans by 15 minutes a week (LOW). It is the low estimate of the percentage reduction in time (Table 14, Column II) times the annual cost per physicians of interacting with health plans (Table 14, Column III). Table 14, Column V is the high estimate of savings generated by decreasing the time spent interacting with health plans by 30 minutes a week (HIGH estimate). It is the high estimate of the percentage reduction in time (Table 14, Column II) times the annual cost per physicians of interacting with health plans (Table 14, Column III).

Table 14, Column VII is the low and high estimated savings for all physician offices if their interaction with health plans is reduced by 15 to 30 minutes a week. Table 14, Column VII is the cost avoidance per year per physician (Table 14, Column IV and V) times the number of physicians (Table 14, Column VI). The number of physicians was calculated by taking the average of the projected supply of physicians in physician practices and the projected demand for physicians in physician practices as calculated in ''Physician Shortages to Worsen Without Increases in Residency Training,'' a summary of an analysis by the Association of American Medical Colleges.[42]

Based on our calculations, we anticipate that the time physicians in physician practices will spend per week interacting with health plans will decrease. Due to a lack of baseline data regarding other providers and physicians working in hospitals, our calculations do not reflect a similar anticipated decrease in time for other providers and physicians working in hospitals. We assume, though, that hospitals, because they typically consolidate their billing functions, will have analogous savings to physicians in physician practices, albeit less on a ''per physician'' basis.

TABLE 14—PHYSICIAN SAVINGS THROUGH DECREASE IN TIME INTERACTING WITH HEALTH PLANS *

Year	I	II	III	IV	V	VI	VII
	Hours spent per week per physician interacting with health plans	LOW to HIGH percent of time interacting with health plans (Col I) saved per week per physician attributable to HPID (15 to 30 minutes)	Total annual cost per single physician to interact with health insurance plans	LOW reduction in cost per year per physician attributable to HPID	HIGH Reduction in cost per year per physician attributable to HPID	Number of physicians	LOW to HIGH total savings per year attributable to HPID (in millions)
2014	60	0.4 to 0.8%	$74,605	$0	$0	340,146	$.00
2015	60	0.4 to 0.8%	76,843	320	640	345,173	111 to 221.0
2016	60	0.4 to 0.8%	79,148	330	660	348,638	115 to 230.0
2017	60	0.4 to 0.8%	81,523	340	679	352,103	120 to 239.2
2018	60	0.4 to 0.8%	83,969	350	700	355,568	124 to 248.8
2019	60	0.4 to 0.8%	86,488	360	721	359,033	129 to 258.8
2020	60	0.4 to 0.8%	89,082	371	742	362,498	135 to 269.1
2021	60	0.4 to 0.8%	91,755	382	765	366,561	140 to 280.3
2022	60	0.4 to 0.8%	94,507	394	788	370,625	146 to 291.9
2023	60	0.4 to 0.8%	97,343	406	811	374,688	152 to 303.9
2024	60	0.4 to 0.8%	100,263	418	836	378,752	158 to 316.5
Total							1,330 to 2,659

* In 2012 dollars.

b. Increase in Three Transactions

The second area of savings for providers is the per transaction savings of moving from non-electronic to electronic transactions. We used the same assumptions on the number and rate of increase of three electronic transactions methodology as illustrated for health plans in Table 12. However, the savings per transaction for health care providers differ from the savings that health plans will realize, as reflected in Table 15. For a more detailed description of how we arrived at the savings associated with the eligibility for a health plan transaction and the health care claim status transaction, see the RIA in the ''Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions,'' published in the July 8, 2011 **Federal Register** (76 FR 40471). The estimated savings associated with the health care payment and remittance advice transaction were taken from the ''National Progress Report on Healthcare Efficiency: 2010'' at *www.ushealthcareindex.com.*

[42] Summary of ''The Complexities of Physician Supply and Demand: Projections Through 2025, Center for Workforce Studies, AAMC,'' 2008, by the Association of American Medical Colleges, and ''The Impact of Health Care Reform on the Future Supply and Demand for Physicians Updated Projections Through 2025,'' June 2010, AAMC.

TABLE 15—COST SAVINGS PER TRANSACTION (DIFFERENCE BETWEEN NON-ELECTRONIC TRANSACTION AND ELECTRONIC TRANSACTION) IN THREE TRANSACTIONS *

Transaction	Savings per transaction for providers
Eligibility for a health plan	$2.02
Health care claim status	2.42
Health care payment and remittance advice (Remittance Advice)	1.55

* In 2012 dollars.

Table 16 reflects the same assumption that use of the HPID will lead to increased use of three electronic transactions. We estimate an annual increase of 1 (LOW) to 2 (HIGH) percent in the use of the eligibility for a health plan transaction and the health care claim status transaction attributable to implementation of the HPID over the next 10 years as illustrated in Table 15. We estimate an annual increase of 1 (LOW) to 3 (HIGH) percent in the use of the electronic health care payment and remittance advice transaction (in the health care electronic funds transfers (EFT) remittance advice transaction). The savings in each column are a product of the number increase in each transaction, with high and low ranges, multiplied by the cost savings of each move to an electronic transaction detailed in Table 15.

TABLE 16—ANNUAL COST SAVINGS FOR PROVIDERS FROM INCREASE DUE TO HPID IN VOLUME OF THREE ELECTRONIC TRANSACTIONS *

I	II	III	IV	V	VI	VII
	Savings from increase in eligibility for a health plan transaction attributable to HPID		Savings from increase in health care claim status transaction attributable to HPID		Savings from increase in health care payment and remittance advice transaction attributable to HPID/OEID (remittance advice only)	
Year	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)	LOW annual cost savings attributable to HPID (in millions)	HIGH annual cost savings attributable to HPID (in millions)
2014	$0.0	$0.0	$0.0	$0	$0.0	$0
2015	20.13	35.01	3.28	5.46	2.34	5.84
2016	23.15	40.26	3.93	6.56	2.80	7.01
2017	26.62	46.30	4.72	7.87	3.36	8.41
2018	28.75	53.24	5.19	9.44	4.04	10.09
2019	31.05	57.50	5.71	10.39	4.52	12.11
2020	33.53	62.10	6.28	11.42	5.06	13.56
2021	36.22	67.07	6.91	12.57	5.67	15.19
2022	39.11	72.43	7.60	13.82	6.35	17.01

Cumulative Annual Cost Savings.
LOW: $316 million.
HIGH: $601 million.

* Based on 2012 dollars.

To summarize health care provider savings, providers can expect savings from two indirect consequences of the implementation of a health plan identifier, as demonstrated in Table 17: the cost avoidance of a decrease in administrative time spent by physician practices interacting with health plans, and a cost savings for physician practices and hospitals for every transaction that moves from a manual transaction to an electronic transaction.

TABLE 17—TOTAL HEALTH CARE PROVIDER HPID SAVINGS *

I	II	III	IV	V	VI
Savings from decrease in pended claims (in millions)		Savings from increase usage of EDI in three transactions (in millions)		Total savings for providers (in millions)	
LOW	HIGH	LOW	HIGH	LOW	HIGH
$1,330	$2,659	$316	$601	$1,646	$3,260

* Based on 2012 dollars.

c. Savings to Transaction and Software Vendors and Health Care Clearinghouses

None of the studies considered for this analysis was able to quantify the costs and savings, or the return on investment of adopting the HPID for software vendors and health care clearinghouses. As noted previously, we expect that some indirect costs will be borne by health care providers in the form of increased fees from transaction vendors and health care clearinghouses such as upgraded software costs and an increase in volume of claims transactions.

We anticipate that the savings, as well as the costs, to software vendors of upgrading health care provider software will be passed along to their provider clients. We therefore assume that the return on investment for software vendors in implementing the operating rules reflected in our estimates as those for health care providers.

Additionally, since health care clearinghouses work on behalf of health plans and act as intermediaries between health care providers and health plans in regard to electronic transactions, we believe that the savings, as well as the costs, to health care clearinghouses will be the same savings and costs as those expected by health plans.

I. Summary for the HPID and NPI

TABLE 18—HPID SUMMARY TABLE FOR HEALTH CARE INDUSTRY

	I	II	III	IV	V	VI
	Savings (in millions)		Costs (in millions)		Range of return on investment (in millions)	
	LOW	HIGH	LOW	HIGH	LOW (low savings/high costs)	HIGH (high savings/low costs)
Commercial and Governmental Health Plans	$1,250	$2,475	$652	$1,297	−$47	$1,823
Health Care Providers	1,646	3,260	450	900	746	2,810
Total	2,896	5,735	1,102	2,197	700	4,633

J. Regulatory Flexibility Analysis the HPID and NPI

The Regulatory Flexibility Act (RFA) of 1980 (Pub. L. 96–354) requires agencies to describe and analyze the impact of the proposed 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: Offices of Physicians are defined as small entities if they have revenues of $10 million or less; most other health care providers (dentists, chiropractors, optometrists, mental health specialists) are small entities if they have revenues of $7 million or less; hospitals are small entities if they have revenues of $34.5 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).

For 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. In the following discussion, we have attempted to estimate the number of small entities and provide a general discussion of the effects of this proposed rule, and where we had difficulty or were unable to find information, we solicit industry comment.

1. Number of Small Entities and Scope of Analysis

a. Individual ''Prescribers''

As detailed in section IV.B. of this proposed rule, the addition to the requirements for the NPI will impose a time cost to prescribers in terms of applying for an NPI. These individual prescribers are members of an organization, or are employed, subcontracted, or given clinical privileges by an organization. We assume the majority of these prescribers cannot be defined as small entities, because they are individuals, not legal businesses. A small number of prescribers are sole proprietors [43] and may be considered small business entities under the RFA. However, the only cost to prescribers is the cost to obtain an NPI and therefore does not represent a substantive impact. Therefore, we will not be including the impact to individual prescribers in this analysis. We request industry feedback on this assumption.

b. Health Care Providers: Physician Practices and Hospitals

As with our RIA for the HPID, in the category of health care providers, we analyzed physician practices and hospitals only in terms of how they will be impacted by implementation and use of the HPID. (There will be no analysis of the impact to physician practices or hospitals with regard to the addition to the NPI requirements for the reasons described previously.) We did not analyze the impact to nursing and residential care facilities, dentists, or suppliers of durable medical equipment.

We narrowed our analysis to physician practices and hospitals for two reasons: (1) We have very little data on the usage of EDI among dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities. The lack of data for these types of health care providers have been noted in other studies on administrative simplification;[44] and (2) we assume that the greatest costs will be borne by hospitals and physician practices as they conduct the majority of standard transactions. While we believe that some small health care provider entities outside of these two categories may be impacted, albeit in much fewer numbers, we believe the analysis gathered here would be indicative of the costs that we would expect all small health care provider entities to experience. We welcome comment from industry and the public as to our assumptions.

Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For physician practices, we assumed that the costs to implement the HPID would be accounted for at the level of firms rather than at the individual establishments.

[43] For purposes of this RFA, a sole proprietor may be contracted by other business entities.

[44] ''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.

According to the U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, there are approximately 220,100 physician practices. The U.S. Census Bureau data indicates that two percent of physician practices have revenues of $10 million or more, therefore approximately 4,400 physician practices are *not* small entities.

Nevertheless, we have decided to consider all physician practices small entities. Our basis for this is the fact that Census Bureau data is calculated from report forms that are sent to only a sample of small employers (less than 10 employees). Therefore, we can assume that the estimates from the Census Bureau are low. The estimated number of physician practices in the Modifications proposed rule (234,222 physician practices) includes physician practices with one to two physicians and is within 6 percent of the total number of physician practices estimated by the Census Bureau. Therefore, we will assume that all physician practices, as calculated by the Census Bureau (220,100), are small entities, and accept a small margin of error.

The 2007 Census Bureau reports that there are approximately 6,500 hospitals. The data indicates that 85 percent of hospitals have sales/receipts/revenues of $10 million or more. While we can assume that, of those 85 percent, some have revenues over $34.5 million; we do not have specific numbers that detail this assumption. Therefore, as with physician practices, we will make calculations on the assumption that all hospitals are small entities.

c. Health Care Clearinghouses and Transaction Vendors

We did not calculate costs and benefits to health care clearinghouses and transaction vendors in this RFA because we assume that any associated costs and benefits will be passed on to the health plans or health care providers, and will be included in the costs and benefits we apply to health plans and health care providers.

d. Health Plans

The health insurance industry was examined in depth in the RIA prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few, if any, ''insurance firms,'' including HMOs that fell below the size thresholds for ''small'' business established by the SBA Health. We assume that the ''insurance firms'' are synonymous, for the most part, with health plans that conduct standard transactions with other covered entities and are, therefore, the entities that will have costs implementing the use of HPIDs. In fact, then, and even more so now, the market for health insurance is dominated by a relative handful of firms with substantial market shares. There are, however, a number of health maintenance organizations (HMOs) that are small entities by virtue of their nonprofit status even though few if any of them are small by SBA size standards. There are approximately 100 such HMOs. These HMOs and those Blue Cross and Blue Shield plans that are non-profit organizations, like the other firms affected by this proposed rule, will be required to obtain and use HPID in standard transactions. Accordingly, this proposed rule will affect a ''substantial number'' of small entities. We estimate, however, that the costs of this proposed rule on health plans do not remotely approach the amounts necessary to be a ''significant economic impact'' on firms with revenues of tens of millions of dollars. Therefore, we do not include health plans in our RFA, but have analyzed the costs and benefits to health plans in our RIA.

We welcome industry and stakeholder input on our assumption in this regard.

2. Cost for Small Entities

In Table 19, we take the information from the impact analysis and break out the costs for both physician practices and hospitals, using the maximum cost of implementation in any one year. As we are treating all health care hospitals and physician practices as small entities for the purpose of this RFA, we allocated 100 percent of the implementation costs reported in the impact analysis for physician practices and hospitals. We used the maximum estimated costs from the RIA. Table 19 shows the impact of the implementation costs of HPID as a percent of the health care provider revenues.

TABLE 19—ANALYSIS OF THE BURDEN OF IMPLEMENTATION OF HPID ON SMALL COVERED ENTITIES*

I	II	III	IV	V
Entities	Total number of small entities	Revenues or receipts (in millions)	Maximum cost of health care EFT standard annual (in millions)	Implementation cost revenue receipts (percent)
Physician practices	220,100	$359,853	$272	0.00076
Hospitals	6,500	729,870	583	0.00080

* In 2012 dollars.

Table 19, Column II shows the number of entities as discussed in this section. Table 19, Column III shows revenues that were reported for 2009 in the Survey of Annual Services (*http://www.census.gov/services/sas_data.html*). Table 19, Column IV shows the costs to health care providers for implementation of the HPID, as described in the RIA. The estimated high range of costs was used. Table 19, Column V shows the percent of the small entity share of implementation costs as a percent of the small entity revenues.

K. Conclusion for the HPID and NPI

We use a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. The anticipated economic effect of this rule on small entities would not exceed or even come close to meeting this threshold. Based on the foregoing analysis, we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general 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 small entities affected by this proposed rule.

L. Alternatives Considered for the ICD–10

Faced with growing evidence that a group of providers would not be ready for the transition to ICD–10, and the possibility that payment for millions of health care claims would be delayed, we considered a number of options before proposing a 1-year delay in the compliance date in this proposed rule.

1. Option 1: Maintain October 1, 2013 Deadline

Segments of the health care industry have expressed strong support for staying the course regarding the 2013 date. Many health plans, large hospitals, physician practices, and IT vendors have already made large investments upgrading systems, hiring personnel for the transition, and making other preparations for implementation. There is a financial and psychological momentum toward implementing ICD–10 that may be disrupted by a delay. According to the Edifecs poll, ''a potential delay of the ICD–10 compliance deadline could have far reaching—and highly negative—impact to the health care industry's effort to implement the mandate.'' [45]

A major health informatics association, citing the large investments that providers, health plans, academic programs, and others have made in creating new jobs, upgrading systems, deploying new EHR systems, and other efforts has urged no delay in the ICD–10 2013 compliance date.[46] Likewise, due to the long lead time required for textbook development and publication, authors and educational institutions have already changed their textbooks and coding curricula to ICD–10. One university coding program has expressed concern that its 30 coding students would have to revert to learning ICD–9 codes and take additional classes to gain proficiency with ICD–9, at a cost of $2,036 per student, so that upon graduation they will be employable in an ICD–9 environment should the compliance date for ICD–10 be delayed. Other institutions, such as medical schools that include coding as part of their curricula, technical and vocational schools, community colleges and other entities that offer coding training, would experience similar challenges with a delayed ICD–10 compliance date.

Hospitals also report extensive ICD–10 financial investments in information technology systems re-programming, business process changes, and staff training premised upon the October 1, 2013 compliance date. While a major hospital association has advocated retaining the October 1, 2013 compliance date, it still welcomed a review of the date as a delay could benefit smaller hospitals with fewer resources to invest in ICD–10 implementation.[47]

Nevertheless, it is clear that a significant number of health care entities will not be prepared to meet the October 1, 2013 ICD–10 compliance date. Reasons for this vary—entities may not have altered their systems, thoroughly analyzed their processes, changed their forms, prepared for training their personnel, or begun testing their internal systems. Regardless of the reason entities will not be able to achieve compliance, given the substantial effect that delayed claim payments would have on health care delivery industry-wide, a delayed compliance date appears to be warranted.

As demonstrated in the impact analysis in this proposed rule, we anticipate that a substantial number of small providers (medical practices of between 1 to 5 physicians), would not be ready to use ICD–10–CM codes by the October 1, 2013 compliance date. If 25 percent of physician claims were to continue to be submitted using ICD–9 codes after an October 1, 2013 compliance date, millions of claims would likely be returned and physicians might experience devastating cash flow problems. Lack of reimbursement could force practices to shut down, making medical services inaccessible to patients and/or forcing physicians to ask patients to pay up front, out-of-pocket, for medical services, which, aside from being barred by the terms of some insurance programs, would be extraordinarily burdensome to patients.

Although we believe that a majority of the health care industry supports maintaining the October 1, 2013 ICD–10 compliance date and is justly concerned that the ill-preparedness of a minority of the industry might adversely affect its efforts to achieve timely compliance, as we stated in the January 2009 final rule, successful ICD–10 compliance is dependent on all industry segments being ready for ICD–10 at the same time. More importantly, we believe that concern for patient well-being and physicians' continued rendering of health care services must be a prime consideration. We have determined that maintaining the October 1, 2013 ICD–10 compliance date could disrupt significant numbers of physicians' reimbursements, which in turn could jeopardize patient care.

2. Option 2: Maintain the October 2013 Compliance Date for ICD–10–PCS (Procedure Coding) and Delay the Compliance Date for ICD–10–CM Diagnosis Codes Only

We also considered a split implementation alternative: Maintaining the compliance date for ICD–10–PCS, which is used for inpatient hospital procedure coding only, at October 1, 2013, while delaying the compliance date for ICD–10–CM, the diagnosis codes used by physicians, to some later date, for example October 1, 2015. The rationale for this option was that hospitals, with their greater access to resources, would be in a better position to move forward with ICD–10–PCS, which would result in at least partial compliance with the October 1, 2013 date. This option would also afford small providers additional time to become compliant with the ICD–10–CM diagnosis codes.

However, after analysis, we discerned that this option held the potential for penalizing hospitals in that they would effectively have to implement ICD–10 twice: Once in 2013 for ICD–10–PCS and then again in 2015 for ICD–10–CM, increasing their implementation costs. This option also held great potential for confusion among providers and payers.

3. Option 3: Forgo ICD–10 and Wait for ICD–11

The option of foregoing a transition from ICD–9 to ICD–10, and instead waiting for ICD–11, was another alternative that was considered. This option was eliminated from consideration because the World Health Organization, which creates the basic version of the medical code set from which all countries create their own specialized versions, is not expected to release the basic ICD–11 medical code set until 2015 at the earliest.

From the time of that release, subject matter experts state that the transition from ICD–9 directly to ICD–11 would be more difficult for industry and it would take anywhere from 5 to 7 years for the United States to develop its own ICD–11–CM and ICD–11–PCS versions.[48]

[45] Edifecs poll, 2012.

[46] Letter to Kathleen G. Sebelius, Secretary, U.S. Department of Health and Human Services, from American Health Information Management Association (AHIMA), February 23, 2012.

[47] ''CMS Hints at Delay in ICD–10 Implementation Deadline,'' HCPRO Web site, February 14, 2012, *http://www.hcpro.com/HOM-276578-6962/CMS-hints-at-delay-in-ICD10-implementation-deadline.html*

[48] Rhonda Butler, ''Why we can't skip ICD–10 and go straight to ICD–11,'' Healthcare Finance News, March 29, 2012;

Carl Natale, ''Why we're not ready to plan ICD–11 implementation,'' ICD10Watch, February 20,

Continued

4. Option 4: Mandate a Uniform Delay in Compliance Date for ICD–10

The fourth option considered was a uniform delay in the compliance date for both ICD–10–CM and ICD–10–PCS. The advantage to contemplating an across-the-board delay was that it would yield a single compliance date among all industry segments. Contemplating such an option gave rise to a secondary question—what length of delay would be appropriate?

Using the existing October 1, 2013 compliance date as a starting point, we looked at the potential impact of delaying compliance to October 1, 2015. While offering, in effect, an additional 3-year implementation timeline (from 2012 through 2015), a delay to 2015 would have damaging effects on industry and on the transition to ICD–10 in general. The Edifecs poll found that nearly 70 percent of respondents felt that a two-year delay would be either ''potentially catastrophic or cause an unrecoverable failure,'' and that ''a delay of longer than a year will likely freeze budgets, slow down schedules, or stop work altogether.'' [49] A mere 2 percent of Edifecs respondents said there would be a benefit to a 2-year delay. Entities' difficulties would likely include having to modify their preparation now (likely through actions like staff layoffs or terminating contracts), only to have to hire other staff or enter into new or revised contracts later.

Based upon the methodology and baseline estimates from the RIA that follows, we estimate it will cost health plans up to an additional 30 percent of their current ICD–10 implementation budgets for a 1-year delay. We can assume, therefore, that a 2-year delay would be at least double the cost; that is, a 2-year delay would cost at least $13 billion for all commercial and government health plans.

An informal survey of State Medicaid programs also indicated that an October 1, 2015 compliance date may be problematic for some States that are undergoing IT-intensive Medicaid Management Information System (MMIS) transitions that same year.

Extending the ICD–10 compliance date to October 1, 2015 would likely result in having to lift the current code set freeze, as the industry could not wait an additional 2 years for maintenance updates to the medical data code sets. A code set freeze is a suspension of updates to code sets, in this case, ICD–9. Updates to code sets are usually necessary on an annual basis in order to encompass new diagnosis and procedure codes that capture new technologies or diseases. The ICD–9–CM Coordination and Maintenance Committee implemented a partial code set freeze of the ICD–9–CM and ICD–10 codes prior to the October 1, 2013 ICD–10 compliance deadline. On October 1, 2012, there will be only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108–173. On October 1, 2013, there will be only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by that same provision, while no updates will be made to the then-obsolete ICD–9–CM. On October 1, 2014, regular updates to ICD–10 will begin. For more information on the code set freeze, see *http://www.cms.gov/ICD9ProviderDiagnosticCodes/Downloads/Partial_Code_Freeze.pdf.*

Lifting the code set freeze would result in the release of potentially thousands of changes to the ICD–10–CM and ICD–10–PCS code sets, all of which would have to be re-programmed into systems in order to be ready for an October 1, 2015 compliance date, at considerable industry cost. The Medicare fee-for-service health plan estimated that the cost for re-programming just one of its systems due to a code set freeze lift would result in, at minimum, $1 million in additional expense. If each of the nation's approximately 1,887 health plans incurred a similar cost, it would translate into a minimum additional expense of nearly $2 billion.

A 2-year delay in the ICD–10 compliance date may also signal a lack of HHS' ICD–10 commitment, potentially engendering industry fear that there could be another delay in, or complete abandonment of, ICD–10 implementation, with subsequent heavy financial losses attributable to ICD–10 investments already made. Industry representatives also expressed concern about the loss of momentum in progress toward ICD–10 compliance that would result from a 2-year compliance extension.[50]

5. Conclusion

We believe a 1-year delay in compliance with ICD–10–CM and ICD–10–PCS achieves a balance between the needs of those who have already taken the initiative to plan for on-time compliance with ICD–10 and the need for small providers and small hospitals to have additional time to become ICD–10 compliant. While not without additional costs, a 1-year delay to October 1, 2014 represents what we consider to be a reasonable compromise. Short of maintaining the 2013 date, delaying ICD–10–CM and ICD–10–PCS by 1-year does the least to disrupt existing implementation efforts, while affording the small provider community an additional year to become compliant. A 1-year delay does not significantly penalize those that have made significant investments to become prepared to implement ICD–10 and better maintains momentum than would a 2-year delay.

Any ICD–10 delay decision must be accompanied by increased industry and Departmental efforts, including further outreach and education, and joint pilot testing, to ensure that small providers and hospitals achieve compliance. Additionally, a 1-year delay means that the current code freeze—which was not contemplated in either the ICD–10 proposed or final rules—could be maintained, avoiding costly systems reprogramming. Finally, as opposed to the likely significant impact of a possible 2-year delay, a 1-year delay allows the industry to maintain momentum already achieved in readying for the current October 1, 2013 compliance date.

We invite industry and stakeholder comment on all of our ICD–10 compliance date alternatives and assumptions.

M. Impacted Entities—ICD–10

All covered entities may be affected by a delay in the compliance date of ICD–10 as proposed in this rule. 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.

Table 7 outlines the number of covered entities that may be affected by a delay in ICD–10, along with the sources of those data. These are the same entities that will be affected by HPID.

While covered entities are required to transition to ICD–10, many other entities not required to abide by HIPAA (such as workers' compensation

2012, *http://www.icd10watch.com/,* ''ICD–10 Frequently Asked Questions,'' American Health Information Management Association (AHIMA), *http://www.ahima.org/ICD10/faqsall.aspx#36.*

[49] Edifecs poll, 2012.

[50] Edifecs poll, 2012: And February 28, 2012 Letter In Regards to ICD–10, Implementation Date Delay to Denise M. Buenning, Director, Administrative Simplification Group, Office of E–Health Standards and Services (OESS), from Maria Buonos, Business Development Manager, Wolters Kluwar Law & Business.

programs and automobile and personal liability insurers) currently use ICD–9 for a variety of purposes. Because their operational and business needs often intersect with covered entities, for practical and business purposes these other entities may voluntarily transition to ICD–10 alongside HIPAA covered entities. ICD codes are used in nearly every sector of the medical and health industry.

N. Scope and Methodology of the Impact Analysis for ICD–10

This impact analysis estimates the costs and benefits of a proposed delay in required compliance with ICD–10. We are analyzing only the impact of a delay, not the impact of ICD–10 implementation that we addressed in the August 2008 ICD–10 proposed rule (73 FR 49476) and the January 2009 ICD–10 final rule (74 FR 3328).

Despite the broad utilization of ICD codes that extends beyond covered entities, with one exception our analysis is restricted only to those entities as only they fall under the auspices of this rule. With respect to health care providers, only health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a HIPAA transaction standard are considered covered entities. The one area where we provide additional analysis is the cost to educational institutions to educate students being trained in ICD–10 coding because such training costs have been of particular concern to industry and have been included in the August 2008 and January 2009 ICD–10 proposed and final rules' cost analyses.

Moreover, while we assume that a delay in the implementation of ICD–10 will affect a broad range of health care providers, as illustrated in Table 7, we only examine the costs and benefits of a delay on two types of health care providers: Hospitals and physician practices. We do not analyze the impact on other industry sectors, including, but not limited to, nursing and residential care facilities, dentists, durable medical equipment (DME) suppliers, or pharmacies for various reasons. Consistent with our previous impact analysis in the 2008 ICD–10 proposed rule, we continue to have very little data on the use of 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.[51] We assume that the greatest benefits will be gained by hospitals and physician practices as they conduct the majority of standard transactions, although it cannot be assumed that the costs will necessarily be borne by physician practices and hospitals only. We have not included an analysis of the impact on pharmacies because pharmacies typically do not use ICD codes in their routine course of business so we assume there is no impact on pharmacies. We welcome comment regarding our assumptions.

We include health care clearinghouses and transaction vendors as affected entities in Table 7. Transaction vendors are entities that process claims or payments for other entities such as health plans. Transaction vendors may not meet the HIPAA definition of health care clearinghouse, but, as used in this context, health care clearinghouses would constitute a subset of transaction vendors. Payment vendors would be a type of transaction vendor—a transaction vendor that ''associates'' or ''reassociates'' 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. Health care clearinghouses and transaction vendors will be impacted because they will need to transition their systems to accept ICD–10 codes. However, we did not calculate costs and benefits to health care clearinghouses and transaction vendors in this cost analysis because, as in our previous impact analysis in the August 2008 ICD–10 proposed 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 or 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 implement ICD–10, we assume that, with a few exceptions, such plans do not send or receive HIPAA electronic transactions because most are not involved in the day-to-day activities of a health plan and outsource those services to TPAs or transaction vendors.

However, we do include 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 be required to make the transition in order to continue to conduct electronic transactions on the part of self-insured plans. However, 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 since they 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 will be including TPAs, and we include all TPAs in the category of ''small health plans'' in the RFA.

Software vendors will incur considerable responsibility and cost with respect to ICD–10 implementation, but we do not analyze the cost of delay to software vendors as they ultimately pass their costs to their clients.

O. Cost Avoidance of a 1-Year Delay in the ICD–10 for the Health Care Industry

Our analysis of industry benefit is based on cost avoidance. That is, we anticipate that there will be greater costs associated with the current compliance date for ICD–10 of October 1, 2013 than if the compliance date were to be delayed 1 year, as proposed in this rule. Therefore, our analysis will demonstrate the costs associated with the current compliance date of October 2013, and apply those as savings or benefits attributable to a delayed compliance date.

The assumption behind these savings is that a specific number of physicians and hospitals will not be prepared to use ICD–10 by the compliance date of October 1, 2013. This lack of readiness would engender a number of costly consequences.

Estimates on the benefit of a 1-year delay are subject to considerable variation. A delay in the ICD–10 compliance date increases the opportunity for a successful, timely transition and provides an opportunity to reduce disruptions in health care delivery and payment. A basic assumption in this projection of a benefit is that entities will take the 1-year delay to become compliant and to conduct robust testing as discussed previously. This is possible, but by no means inevitable, even if a vigorous public/private campaign is undertaken to promote and assist with compliance and testing.

[51] ''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.

In order to make these projections on cost avoidance, we must first estimate the number of physicians and hospitals that we expect will not be capable of successfully making the transition to ICD–10 on October 1, 2013 such that that their claims would be rejected or returned by health plans. We base our assumptions on CMS' recent assessment survey. The survey was an assessment of health care providers, payers, and vendors to determine their awareness of and preparation for the transitions to ICD–10 and Version 5010. The research was conducted November 1 through December 5, 2011. Table 20 illustrates the number of survey participants from the specific health care entity:

TABLE 20—CATEGORIES OF PARTICIPANTS OF CMS READINESS SURVEY

Providers Including hospital and pharmacy chain administrators and health care practice managers	*Payers* Including directors or higher at health insurance companies, managed care organizations, and pharmacy benefits managers	*Vendors* Including managers at health IT system developers, billing services and clearing houses, outlined as follows:
192 = Provider practices with 10 or fewer physicians.	45 = Private payers	33 = Software vendors
45 = Provider practices with 11 or more physicians.	43 = Public payers (for example, Medicaid, TRICARE).	2 = Clearinghouse
50 = Small hospitals with 99 or fewer beds	13 = Other insurer (for example, property and casualty).	22 = Third party biller
117 = Large hospitals with 100 or more beds		33 = Third party administrator
Total: 404 providers	101 payers	90 Vendors

The questions in the survey were aimed at assessing the entities' self-reported readiness. We believe the question of compliance by October 1, 2013 is a good baseline from which to draw estimates, specifically with regard to providers, approximately a quarter of whom stated that they will not be compliant by the October 1, 2013 compliance date. In general, the survey found no significant differences in the responses based on the size or type of provider, payer or vendor.[52] Table 21 illustrates the self-reported assessments of readiness for ICD–10 among providers and the other sectors. Refer to Table 20 for descriptions of the sectors.

TABLE 21—SUMMARY OF CMS READINESS SURVEY RESPONSES

	Will be compliant by October 1, 2013 (percent)	Additional percentage will be compliant by December 31, 2013 (percent)	Do not know when they will be compliant (percent)	Do not plan on being compliant (percent)
Providers	74	14	11	1
Payers	72	17	4	8
Vendors	78	8	13	1

This RIA will base the benefits of the proposed delay of the compliance date of ICD–10 on cost avoidance, as opposed to an actual financial savings or cost savings. That is, we are proposing that, by delaying the compliance date by 1 year, a number of costly, predicted consequences will be avoided. Therefore, we use the survey results from providers as our baseline for estimating the issues that may arise if the compliance date remains October 1, 2013. The providers must first code and initiate transactions with ICD–10. Ultimately, the costs of noncompliance—returned unpaid claims—will be borne by the providers.

Based on the CMS readiness survey, we will use the percentage of providers who believed they would not be compliant by October 1, 2013 (26 percent) as our high estimate and the percentage of providers who believed they would not be compliant by December 31, 2013 (12 percent) as our low estimate. We use 12 percent as the low estimate because that percentage seems to indicate that only 12 percent of providers believe they will miss the compliance date by more than 3 months. It is reasonable to assume that, with some tools and careful planning, some to all of the 14 percent of providers that believe they are within 3 months of making the October 1, 2013 could be assisted in meeting the compliance date. Therefore, we estimate that 12 to 26 percent of providers will not have achieved ''readiness'' by the October 1, 2013 compliance date.

We recognize that the providers that were surveyed in the CMS readiness survey do not represent all the various categories of providers, and did not include, for example: dentists, chiropractors, optometrists, mental health practitioners, substance use treatment practitioners, speech and physical therapists, podiatrists, home health care services, other ambulatory health care services, resale of health care and social assistance merchandise (durable medical equipment), and nursing and residential care facilities not associated with a hospital. However, as the survey did not find significant differences[53] between the categories of providers surveyed, we will assume that the providers in the categories that were not surveyed would have similar experience with October 2013 readiness for ICD–10. Further, physician practices and hospitals submit the bulk of total

[52] Differences among provider subgroup categories are reported in the CMS Readiness Survey; however, for many questions and response options, the base sizes of respondents are too small to be eligibilityfor significance testing.

[53] Differences among provider subgroup categories are reported in the CMS Readiness Survey; however, for many questions and response options, the base sizes of respondents are too small to be eligibility for significance testing.

health care claims. Therefore, we have based our estimates of the cost of not delaying the compliance date of ICD–10 on the projection that 12 to 26 percent of providers will not be ready or will not have appropriately tested for implementation of ICD–10 by October 1, 2013.

We also recognize that the survey does not represent a statistically valid sample of providers, but we have no other recent data with which to base our readiness estimates. We welcome industry input and comment on our assumptions with regard to the readiness of covered entities.

The total savings attributable to the 1-year compliance date delay is based on the premise that providers who are not ready for ICD–10 will submit claims to payers that will be automatically returned beginning on the October 1, 2013 compliance date. Providers will then have to manually crosswalk ICD–9 to ICD–10 codes and ostensibly submit paper claims. (Alternately, providers who have not readied their systems or processes may proactively submit paper claims using ICD–10 on October 1, 2013. We assume that the cost to these providers to manually crosswalk will entail similar costs to what would be required to resubmit returned claims, as the manual task will be similar in nature.) We calculate the cost avoidance of a 1-year delay in the compliance date of ICD–10 based on two probable scenarios: Returned claims will: (1) Cause expensive manual intervention on the part of both providers and health plans in order for the ''not ready'' providers to be paid; and (2) financially impact providers by potentially requiring them to take out loans or apply for lines of credit to be able to continue to provide health care in the face of delayed payments. We apply calculations to each of these scenarios in the analysis that follows. Although the cost to manually process returned claims will ostensibly occur from, roughly, October 1, 2013 through March, 2014, for simplicity sake our calculations reflect a cost avoidance that is calculated for 1 year only—the year 2014.

A halt to the payment process for 12 to 26 percent of all providers has a greater effect than requiring manual intervention and requiring business loans or lines of credit. In some cases, a payment delay may pose a serious threat to the continued operation of some providers. For example, many health care safety net clinics operate with no more than 30 to 60 days of cash on hand, so any prolonged delay would threaten such entities' viability.

We also anticipate that health care services for a great number of patients will be adversely affected or interrupted because providers will need to spend more time to obtain health care claim payments leaving less time to render health care services.

1. Cost Avoidance: Manual Processing of Returned Claims

Using the estimate of 12 to 26 percent of providers who will not be ICD–10 compliant on October 1, 2013, we have calculated that 58 to 126 million claims per month will be returned as unprocessable across the industry. We have estimated the cost of returned claims for health plans and for physician practices and hospitals that would follow the implementation of ICD–10 in Table 22, assuming that providers could not electronically transmit claims with ICD–10 codes for 6 months past an October 1, 2013 compliance date. From this calculation, based on the following assumptions, we estimate the cost to the health care industry to manually process returned claims for 6 months after an October 1, 2013 compliance date to be approximately $2 to $5 billion. This is based on the following assumptions:

- The total number of health care claims in 2013 is projected to be 5.8 billion. This is an average of the low and high range estimates of total claims as calculated in the Modifications proposed rule.
- We use the percentage of providers that project they would not be compliant on October 1, 2013 to calculate the percentage of claims that will be returned (12 to 26 percent). This is a rough equivalency. However, the survey assessed both large and small physician offices and hospitals and found no significant difference in their readiness. As stated previously, we have projected the readiness of physician practices and hospitals, as estimated by the CMS readiness survey, as the readiness of all other providers (dentists, etc.). We believe the range of the estimate accounts for the great number of variables and unknowns inherent in this kind of calculation.
- We use the cost of pended claims to calculate the cost to health plans of returned claims. Returned claims are claims that will be automatically returned by health plans because their systems will not be able to accept the ICD–9 codes that the non-compliant providers will submit. Returned claims, in and of themselves, have no cost to health plans. Pended claims are claims that require manual intervention by the health plan to be processed for payment. While we assume that 12 to 26 percent of all claims will be returned, we assume that these claims will be followed up by providers with calls or contacts with the health plans. Ultimately, it is probable that health plans will have to manually intervene with the claims submitted in ICD–9, and therefore the cost of these returned claims will be similar to the cost of pended claims for health plans. The cost to health plans for manually processing a pended claim is $2.30 per claim.[54]
- According to the Medical Group Management Association (MGMA), the staff time required to manually process a returned claim is 15 minutes,[55] at a cost of approximately $4.14 for labor, a factor derived from the Bureau of Labor Statistics.[56] This includes staff time spent to correct the error and resubmit claims that are returned.

We are basing our estimates on the cost to manually process health care claims, both to the provider and to the health plan. However, it should be clear that these claims, so long as they are otherwise properly payable, would ultimately be paid. The impact to providers is not that they will lose money from claims altogether. Rather, it will take costly staff time for the providers to resubmit properly coded claims in order to receive payment, and it will take costly staff time for the health plan to manually process and pay the claims. We welcome comments on this analysis and these assumptions.

[54] ''An Updated Survey of Health Care Claims Receipt and Processing Times,'' May 2006, American Health Insurance Plans (AHIP) Center for Policy and Research. Cost in 2006 was $2.05 per claim. We have adjusted the cost to 2012 dollars.

[55] ''Project Swipe IT Savings Model,'' 2009, citing a LEARN Research median figure.

[56] For billing and posting clerks in physician offices, Department of Labor, 2010 dollars.

TABLE 22—COST AVOIDANCE IN 2014 FOR HEALTH PLANS AND PROVIDERS ATTRIBUTABLE TO A DELAY IN THE COMPLIANCE DATE OF ICD–10 *

LOW to HIGH number of claims returned per month	LOW to HIGH cost of processing returned claims manually for health plans over 6 months	LOW to HIGH cost of returned claims for providers over 6 months	LOW to HIGH total over 6 months
58 to 126 million	$800 to 1,700 million	$1.5 to 3 billion	$2.2 to 4.7 billion

* Calculated in 2012 dollars.

2. Cost Avoidance: Interest on Loans and Lines of Credit

The time between when a provider originally submits the claim and when the provider finally gets paid will be considerably longer than if the claim were an electronically submitted ''clean'' claim; that is., a claim for which no additional information or intervention is needed. During this time, providers, specifically small physician practices, will need to have cash on hand in order to ''keep the doors open'' by paying salaries, staying current with contract and lease obligations, purchasing equipment and medicines, and maintaining the physical plant. In some cases, in order to continue as a health care provider, this will require a business loan or a line of credit with interest.

In Table 23, we estimate the costs in terms of interest if 12 to 26 percent of physician practices were required to take out a loan in order to continue to provide health care services. We use the following assumptions in the calculation:

- Using data from the National Health Expenditures Projections 2010 to 2020, we calculate the average expenditure per physician practice.[57]
- We assume that 12 to 26 percent of physician practices (or 28,107 to 60, 898 providers who would not be ready for the ICD–10 transition) times the average expenditure per physician practice over half a year would be equal to the monetary amount in payments that would be delayed.
- As per the most recent estimate by the Federal Reserve,[58] we use 7.6 percent as the average interest rate on a small business loan from $100,000 to $1 million.

Based on these assumptions, we estimate the cost avoidance for physician practices to be between $1.4 to $3 billion if interest on loans to cover delayed payments were to accumulate over 6 months. Although these avoidable costs will ostensibly occur at the end of 2013 through 2014, for simplicity sake we have calculated the cost avoidance as occurring in 2014.

For this calculation, we make no distinction between large or small physician practices, though we assume that the 12 to 26 percent of providers that may not be ready for the October 1, 2013 compliance date are mostly small physician practices. Because we make no distinction between the size of physician practices, however, our cost avoidance may be high because we are basing our calculation on an average dollar amount per physician practice that will be delayed. It is likely that the average expenditure per physician practice is much higher than the actual expenditure per small physician practices. While there is a high level of uncertainty in terms of all of our assumptions, we think it illustrative to make the calculation in order to demonstrate the affect that a delay in payments will have on small physician practices. In this RIA, we only account for interest on loans taken out by the 12 to 26 percent of providers that do not anticipate being compliant with ICD–10 to cover delayed payments. We did not account for any possible interest accrued by payers that retain claim payments in our calculations, because we do not have sufficient information on the financing vehicles used by payers to pay claims. We welcome comments on our assumptions and calculations.

TABLE 23—COST AVOIDANCE IN 2014 FOR PHYSICIAN PRACTICES BASED ON INTEREST ON BORROWED FUNDS

Percent of providers that will not be ready for October 1, 2013 compliance date	Expenditure over six months per physician practice in millions = (annual expenditure on physician practices) divided by (# of physician practices) divided by 2	LOW to HIGH amount of delayed payments over a six month period in millions (% not ready * number of physician practices) * (expenditure per practice)	Avg Annual interest rate on small business loans (Federal Reserve, 2011)	LOW to HIGH Cost to providers in interest in millions
12% to 26%	$1.3	$36,450 to $78,975	0.076	$1,385 to $3,000

* In 2012 dollars

P. Costs for ICD–10

The cost of a 1-year delay falls on the health care entities that are already far along on their preparation for ICD–10. In summarizing its February 2012 poll, Edifecs noted that:

''Many entities have brought ICD–10 subject matter experts on board with defined term contracts. A 1-year delay means entities will have to choose between two unpleasant scenarios: Either extend the contract or terminate the contract* * * Most entities will likely choose [to extend the contract] and retain the expertise they already have.

[57] The Center for Medicare & Medicaid Services (CMS), ''National Health Expenditure Data,'' *https://www.cms.gov/NationalHealthExpendData/.*

[58] ''Small Business Rate Report,'' Friday, March 16, 2012, *http://www.businessweek.com/smallbiz/resources/rate_report/lenders.htm.*

Many are also concerned about the added costs of maintaining technology resources, such as test regions, for an extended time period. Unfortunately, this means most organizations will incur a much greater cost to implement ICD–10 than originally anticipated.'' [59]

1. Costs of a 1-Year Delay of Implementation of ICD–10 for Health Plans

a. Cost for 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. We assume that system costs for health plans to transition to ICD–10 have already been budgeted and funds already spent. A delay of a year for ICD–10 compliance primarily 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 originally budgeted. In fact, one of the main issues for entities that argue against a delay is the concern that their companies would divert funds currently dedicated to the transition to ICD–10 to other priorities.

We use the following assumptions in calculating the costs for health plans of a 1-year delay in the ICD–10 compliance date.

• We assume that continued training, testing, and retention of personnel and contracts will cost plans an additional 10 to 30 percent of what health plans have already budgeted on the ICD–10 transition to date. We have based this range approximately on the Edifecs poll. The Edifecs poll found that, ''Forty-nine percent estimated that every year of delay would increase their required budget between 11 and 25 percent, while another 37 percent estimated the increase would be somewhere between 26 and 50 percent.'' [60] We summarize this by approximating that nearly 86 percent of respondents of the Edifecs poll would agree that the cost of a 1-year delay is at least in the range of 10 to 30 percent of currently budgeted implementation costs.[61]

• We analyzed the costs that were estimated in studies by the HayGroup, Inc. (2006), [62] the Robert E. Nolan Company (2003) [63] the RAND Corporation (2004),[64] and AHIP (2010).[65] The estimates from the various studies on the costs to health plans are summarized in Table 24. These studies were authored before ICD–10 implementation began. Since these studies, we have actual health plan costs dedicated to the transition to ICD–10. However, we used some of the calculations that those studies employed in order to project the experience of a few health plans to the larger universe of all health plans.

TABLE 24—ESTIMATED COST TO HEALTH PLANS FOR IMPLEMENTING ICD–10 ACCORDING TO STUDIES

Study	Estimated Total Cost to Health Plans (in millions)	
	LOW	HIGH
Nolan (2003)	$432	$913
RAND (2004)	150	363
Haygroup (2006)	384	868
ICD-10 Proposed Rule (2008) *	110	274
AHIP (2010) **	2,000	3,000

* Estimate under ICD–10 Proposed Rule does not include training costs.

** AHIP study provided costs for specific sized health plans. We have projected those costs onto all the health plans.

• As a baseline, we use the analysis of ICD–10 costs conducted by the HayGroup, Inc. on behalf of AHIP in 2006. The HayGroup study analyzed the other ICD–10 cost studies that had been published up to that point and summarized their shared conclusions, including studies conducted by the Robert E. Nolan Company (2003) [66] and RAND Corporation (2004).[67] The HayGroup estimated implementation of ICD–10 would cost national health insurers between $324 to $748 million, plus about 20 percent more in training costs. (The HayGroup estimate was approximately the average of the Nolan and Rand estimates.) The HayGroup had a high estimate for national health plans of $25 million for implementation (plus an implied $5 million for training). Recently, however, national health plans have announced that their budgets for ICD–10 add up to nearly $100 million.[68]

In other words, the HayGroup high estimate appeared to be off by a factor of four in its projections. As illustrated in Table 25, we use $100 million as the high cost of implementing ICD–10 for national health plans, and $50 million as the low cost. This cost includes both system implementation and training. From that baseline, we have attributed costs for multi-regional, large, mid-sized, and small health plans, proportionate to the costs that are reflected in the HayGroup estimate.

• We calculate 10 to 30 percent of the total costs of health plans' ICD–10 system implementation and training as the range of costs for a 1-year delay.

• For simplicity sake, we have calculated all costs as if they occurred in the calendar year 2014.

Health plans made and continue to make a large investment in preparing for ICD–10 based on the expectation that there would be a return on investment from the transition to a more robust code set. A 1-year delay in the compliance date of ICD–10 will also postpone the expected time when health plans can expect to see a return on these investments (ROI). This delay in ROI will likely have negative impacts on health plans in terms of their business plans, budgeting, and investor relations. Because of the uncertainties in predicting impacts of this sort, we have not attempted to quantify any impact resulting from a delay in ROI for health plans. We welcome industry comment or guidance on impacts of this category.

[59] Edifecs poll, 2012.

[60] *Ibid.*

[61] The Edifecs poll found that ''Forty-nine percent estimated that every year of delay would increase their required budget between 11 and 25 percent, while another 37 percent estimated the increase would be somewhere between 26 and 50 percent.''

[62] ''Examining the Cost of Implementing ICD–10,'' October 12, 2006, White Paper Prepared by Thomas F. Wildsmith, HayGroup, Inc. on behalf of American's Health Insurance Plans.

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

[64] Libicki, Martin and Brahmakulam, Irene, ''The Costs and Benefits of Moving to the ICD–10 Code Sets,'' March 2004, RAND Corporation, Prepared for the Department of Health and Human Services.

[65] ''Health Plans' Estimated Costs of Implementing ICD–10 Diagnosis Coding,'' September, 2010, America's Health Insurance Plans, Center for Policy & Research.

[66] Nolan, 2003.

[67] Libicki, 2004.

[68] Joseph Zubretsky, Aetna Chief Financial Officer and Senior Executive Vice President. Aetna Fourth Quarter 2011 Earnings Call Webcast (transcript), Feb. 1, 2012. Wayne S. Deveydt, WellPoint Chief Financial Officer and Executive Vice President. WellPoint Fourth Quarter 2011 Results Conference Call (transcript), Jan. 25, 2012.

TABLE 25—COST IN 2014 OF A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

Health insurer categories	Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9
	Number of health plans	LOW total cost per health plan (in millions)	HIGH total cost per health plan (in millions)	LOW total implementation/training for all health plans in category (Col. 1 * Col 2)	HIGH total implementation/training for all health plans in category (Col. 1 * Col. 3)	LOW percent of total cost for one year delay	HIGH percent of total cost for one year delay	LOW estimate of one-year delay (in millions)	HIGH estimate of one-year delay (in millions)
National	6	$50.40	100.80	$302.40	$604.80	10	30	$30.24	$181
Multi Regional	6	24.00	40.32	144.00	241.92	10	30	14.40	73
Large	75	14.40	24.19	1080.00	1814.40	10	30	108.00	544
Mid-Sized	325	3.60	6.05	1170.00	1965.60	10	30	117.00	589
TPAs and Small Health Plans	2166	1.20	2.02	2599.20	4366.66	10	30	259.92	1310
Total								530	2,698

* Calculated in 2012 Dollars.

b. Cost of a One-Year Delay for CMS Health Plans

The Medicare program reports that it is prepared to be ICD–10 compliant on October 1, 2013. CMS components affected by an ICD–10 transition delay estimate that there will be additional costs for extending contracts for systems programming and testing work and extended staff training and associated development costs. It is estimated that a 1-year delay in ICD–10 compliance would be reflected by additional work at an estimated total cost of $5 to $10 million in addition to funding already requested for the coming fiscal years.

c. Cost of a One-Year Delay in the Compliance Date of ICD–10 for State Medicaid Agencies

State Medicaid Agencies (SMAs) were queried informally during routine status update calls in February 2012 regarding potential mitigation strategies for ICD–10 implementation. Thirty-nine SMAs responded, representing all regions of the country from predominantly rural to densely populated States. We have extrapolated from these responses as best we could to present a quantitative assessment of costs and benefits.

The responses were clearly split between 46 percent predicting more benefits than detriments to a delay in the compliance date of ICD–10 and 37 percent indicated that any delay would prove more detrimental than beneficial to their transition to ICD–10. Another 10 percent specifically indicated a delay of 1 year would be preferred even though a 1 year delay was not a specific option they were asked to consider. Of the 46 percent of States that indicated benefits to delay, many cited opportunities to improve testing and risk mitigation strategies. Another important benefit seen was the ability to spread out implementation costs over one or more additional fiscal years. A few indicated they would slow or even stop their existing efforts.

Of the 37 percent of States reporting indicated any delay would be detrimental, most indicated additional costs associated with maintaining or sustaining ICD–10-related contracts and staff resources and potential risks for significant losses of momentum and funding. The 10 percent of SMAs opposed to a delay longer than 1 year expressed concerns that longer delays would put funding and the priority status of ICD–10 projects at risk.

One predominantly rural SMA estimated that a 1-year delay could potentially result in a cost increase of over $4 million to their overall project. This increase would be due, primarily, to costs associated with maintaining contracts and the project staffs.

Two SMAs specifically reported significant numbers of providers in the States that were lagging in preparation and planning. Additionally, they indicated the complications with the Version 5010 transition is resulting in less time and fewer resources available for ICD–10. Many of the resources that would have been working on ICD–10 remediation were still committed to the Version 5010/D.0 implementation for both SMAs and many providers.

We note that the types of concerns elicited by SMAs were very similar to those expressed in the Edifecs poll. The further along a SMA was in its implementation, the more likely it was to view a delay as being costly or burdensome and to characterize delays longer than a year as placing their conversion efforts at great risk for losses of funding and key resources. At the same time, many felt they could make good use of a 1 year delay to delay to improve the quality of their testing and risk mitigation strategies.

Those most supportive of delay were those SMAs with less mature projects and with few committed resources.

In Table 26, we calculate the cost to SMAs of a 1-year delay in the compliance date of ICD–10. We use the following assumptions:

- Based on the informal poll of SMAs, we assume that 37 percent or 20 SMAs would be ready for the October 1, 2013 compliance date. Therefore, the assumption is that 21 SMAs would be affected negatively by a delay.
- We assume that $4 million is the low estimate for a cost increase, as exemplified by the rural State that provided that estimate, while $7 million is the high estimate for a cost increase, as reported by an SMA. The high estimate is derived from a SMA that anecdotally described its costs per year of delay. For simplicity sake, we have calculated all costs as occurring in calendar year 2014.

TABLE 26—COST IN 2014 TO STATE MEDICAID AGENCIES OF A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

Number of State Medicaid that would be negatively affected	LOW cost of a one-year delay per state agency in millions	HIGH cost of a one-year delay per state agency in millions	LOW cost of a one-year delay for Medicaid agencies in millions	HIGH cost of a one-year delay for Medicaid agencies in millions
21	$4	$7	$83	$145

* In 2012 dollars.

2. Cost of a 1-Year Delay for Providers

We expect that many, if not most, hospitals and large provider organizations have already spent funds in preparation for the ICD–10 transition. As with health plans, any delay in compliance date will add costs because large providers must maintain the personnel and renegotiate contracts necessary to lengthen preparations an extra year. Likewise, large providers must maintain technological resources for an extra year.

Although the expectation is that providers will conduct more robust and extensive testing than what may have been originally planned, to the extent possible we have not included any testing costs in our analysis of provider costs attributable to a 1-year delay. While continued maintenance of test regions and resources dedicated to testing will be costly with a 1-year delay, it is assumed that continued and more robust testing will make it more likely that there will be a decrease in costly post-production issues such as returned claims. Increased testing costs will theoretically translate to decreased post-production error costs, and, therefore, because there is significant potential for an offset of expense to savings, no costs or benefits will be attributed to an extra year of testing. Because the October 1, 2013 compliance date is more than a year out, it is likely that few small physician practices have invested a modest amount of money and resources into the implementation of and training for ICD–10, although they may have begun planning and budgeting for the transition and may have contracts in place with vendors to purchase tools to manage the transition. While we recognize that there will be costs, we assume that these costs are negligible and that the extra time to prepare for the transition, as will be possible with a 1 year compliance date delay, will be more beneficial than costly for small providers. Therefore, we will not include small providers (under 50 physicians) in the cost analysis for providers.

There is an expectation that a 1-year delay will give small providers more time to analyze their processes, change their forms, develop their super bills, negotiate with their vendors, and, most importantly, test before production. In fact, giving small providers more time to prepare is the main justification for the 1-year delay. As with large providers, however, we will not attach any costs to these planning and testing activities since they have already been considered as costs for implementation of ICD–10 in the January 2009 ICD–10 final rule.

We use the following assumptions in calculating the costs for large providers of a 1-year delay, illustrated in Table 27:

- We use the Edifecs poll as a guide in establishing a range of costs for a delay of 1 year in implementing ICD–10 for providers. (A group of provider representatives participated in the survey.) We will use the ''HIGH'' and ''LOW'' estimate that the Edifecs poll suggests itself in its narrative: A 1 year delay will cost 10 to 30 percent of the costs that providers have spent or have budgeted for ICD–10 transition.
- We will use costs estimated by an October 2003 study by the Robert E. Nolan company commissioned by the Blue Cross and Blue Shield Association.[69] We employed this study, along with a March 2004 RAND study, in the IDC–10 proposed rule. We considered, as well, an October, 2008 analysis on the impact of ICD–10 on physician practices and clinical laboratories by Nachimson Advisors, LLC.[70] The Nachimson study, however, approached cost by examining three very specific provider environments (for instance, practices with 10 physicians) and included costs that would occur after the transition to ICD–10, such as increased documentation and claim inquiries.

In general, the Nachimson study's costs were less than the Nolan study estimates, but because it is difficult to extrapolate the Nachimson study's conclusions to a meaningful cost estimate of a 1 year delay for all large providers, we have not used that study in this RIA. We have adjusted the Nolan study cost estimates to 2012 dollars.

- The number of physician practices and their categorization by size is derived from the Modifications proposed rule.
- The costs to physician practices and hospitals would probably be incurred during the year of the proposed delay in compliance date, from October 1, 2013 to October 1, 2014. For simplicity sake, we have calculated all costs to physician practices and hospitals as occurring over one calendar year, 2014.

TABLE 27—COST TO HOSPITALS AND LARGE PHYSICIAN PRACTICES IN 2014 FOR ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 [1] [2] [3]

	Hospitals: 400 or more beds	Hospitals: 100–400 beds	Hospitals: fewer than 100 beds	Large physician practices (over 100 physicians)	Mid sized physician groups (50–100 physicians)	Total cost of ICD–10 implementation (in millions)	LOW cost for 1-Yr delay (10% of current implementation costs) (in millions)	HIGH cost of 1-Yr delay (30% of current implementation costs) (in millions)
Number of entities	521	2486	2757	393	590			
LOW Cost Per Entity (in millions)	$1.85	$0.62	$0.12	$2.46	$0.5			
HIGH Cost Per Entity (in millions)	$6.16	$1.85	$0.31	$7.39	$1.48			
Total LOW (in millions)	$963	$1,531	$339	$968	$291	$4,093	$409	$1,227
Total HIGH (in millions)	$3209	$4,594	$850	$2,905	$872.17	12,429	1,243	3,728

[1] Numbers are rounded, so totals may not reflect sum of numbers shown.
[2] Adjusted to 2012 dollars.
[3] High and low ranges from Nolan 2003, adjusted to 2012 dollars.

[69] Nolan, 2003.

[70] ''The Impact of Implementing ICD–10 on Physician Practices and Clinical Laboratories: A Report to the ICD–10 Coalition,'' October 8, 2008, Nachimson Advisors, LLC.

Similar to health plans, we assume that hospitals and large physician practices have made, and continue to make, a large investment in preparing for ICD–10 based on the expectation that there would be a return on investment from the transition to a more robust code set. A 1 year delay in the compliance date of ICD–10 will also postpone the expected time when these entities can expect to see a return on these investments. This delay in ROI will likely have negative impacts on these large providers in terms of their business plans, budgeting, and investor relations. Because of the uncertainties in predicting impacts of this sort, we have not attempted to quantify any impact resulting from a delay in ROI. We welcome industry comment or guidance on impacts of this category.

3. Cost of Delay to Students

In the ICD–10 proposed rule, we presented an estimate of training costs to implementation of ICD–10. These training costs were calculated based on an estimated number of coders working in hospitals and ambulatory clinics and multiplying that number by a specific cost to train these coders.

A delay in the implementation of ICD–10 will not substantially impact training costs because we assume that the training costs are already a part of any entity's budget and a change in compliance date will not change the amount of training that is necessary. However, one consequence of a 1 year delay to ICD–10 will be the impact to students who are now studying to become coders.

Using the experience of one university's bachelor's-level health information management program, students take the ICD coding course in the spring of their junior year. Students enrolling in Spring 2012 courses will graduate in May 2013. Anticipating the October 1, 2013 compliance date, the university started offering ICD–10 courses this spring in place of ICD–9 with the understanding that it will be preparing students for employment after graduating in 2013. If ICD–10 is delayed a year, as proposed in this rule, the 30 students in the program will have to take ICD 9 courses in addition to their ICD–10 courses in order to obtain the ICD 9 competencies to get jobs. The extra course will cost each of the 30 students approximately $2,000 (in-state tuition) or a total of $61,000.

Taking the university experience, we have projected these costs on to students in college and university coding curriculum nationwide. We have illustrated our estimates in Table 28 and calculated all costs as occurring in 2014.

Although the impact on students is small when compared to the cost for health plans, this impact illustrates some of the practical consequences of delay that will affect lives beyond the health care financial impacts.

TABLE 28—COST TO STUDENTS OF A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

Cost of coding courses for 30 students	Number of institutions that provide coding courses	Cost to students/institutions to retrain in ICD–9 (in millions)
$6,000	68	$4.15

* In 2012 dollars.

Q. Summary for ICD–10

We summarize the low and high estimates of a 1-year delay in the compliance date for ICD–10 in Table 29. The total costs and cost avoidance of a proposed delay in the compliance date will likely be incurred over a 12 month period; however, due to the range in impacted entities, including educational institutions, those 12 months may span different dates and different budget periods. Further complicating the question of the timeframe in which the costs occur is the question of whether the cost should be calculated during the time it is incurred or in the budget period in which it is attributed. For instance, an educational institution may base its budget on a school year, September to August, while health plans and TPAs may base their budgets on calendar years or on varying fiscal years. Given the diversity of 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, 2013 to October 1, 2014 proposed delay in compliance date. For simplicity sake, we calculate all cost avoidance and costs of a delay in the compliance date for ICD–10 as occurring in the calendar year 2014.

In Table 30, the net cost avoidance is illustrated with a—

- Low net estimate that reflects the low estimate of cost avoidance less the high estimate of costs;
- High net estimate that reflects the high estimate of cost avoidance less the low estimate of costs; and
- Medium net cost avoidance that reflects the average cost avoidance less the average cost.

TABLE 29—SUMMARY OF COST AVOIDANCE AND COSTS IN 2014 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *

	LOW (in millions)	HIGH (in millions)	MEAN (average) (in millions)
Cost Avoidance for Providers (manual submission of claims)	$1,385	$3,001	$2,193
Cost Avoidance for Providers (cost of loan interest)	1,446	3,134	2,290
Cost Avoidance for Health Plans (manual submission of claims)	804	1,742	1,273
TOTAL COST AVOIDANCE FROM A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10	3,635	7,877	5,756
Cost to Commercial Health plans	530	2,698	1,614
Cost to Medicare	5	10	8
Cost to State Medicaid Agencies	83	145	114
Cost to Large Providers	409	3,728	2,069
Cost to Students	4	4	4
TOTAL COST OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10	$1,031	$6,586	$3,808

* Calculated in 2012 dollars.

TABLE 30—COST AVOIDANCE LESS COST (NET) OF A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In millions] *

Low Net Estimate (Low Cost Avoidance with High Costs) ..	−$2,950
High Net Estimate (High Cost Avoidance with Low Costs) ..	6,846
Mean Net Cost Avoidance (average)	1,948

* Calculated in 2012 dollars.

R. Regulatory Flexibility Analysis: Impact on Small Entities 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 proposed 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: Offices of Physicians are defined as small entities if they have revenues of $10 million or less; most other health care providers (dentists, chiropractors, optometrists, mental health specialists) are small entities if they have revenues of $7 million or less; hospitals are small entities if they have revenues of $34.5 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).

For 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. In the following discussion, we have attempted to estimate the number of small entities and provide a general discussion of the effects of this proposed rule, and where we had difficulty or were unable to find information, we solicit industry comment.

1. Number of Small Entities and Scope of Analysis

a. Health Care Providers: Physician Practices and Hospitals

As with the RIA on the delayed compliance date of ICD–10, in the category of health care providers, we analyzed physician practices and hospitals only in terms of how they will be impacted by a delay of 1 year in the compliance date of ICD–10. We did not analyze the impact to nursing and residential care facilities, dentists, or suppliers of durable medical equipment, nor did analyze the impact of implementation of ICD–10, as that analysis is provided in the RIA included in the ICD–10 proposed rule.

We narrowed our analysis to physician practices and hospitals for two reasons: (1) We have very little data on the usage of EDI among dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities. The lack of data for these types of health care providers have been noted in other studies on administrative simplification; [71] and (2) we assume that the greatest costs will be borne by hospitals and physician practices as they conduct the majority of standard transactions. While we believe that some small health care provider entities outside of these two categories may be impacted, albeit in much fewer numbers, we believe the analysis gathered here would be indicative of the costs that we would expect all small health care provider entities to experience. We welcome comment from industry and the public as to our assumptions.

Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For physician practices, we assumed that the costs of a delay of the compliance date for ICD–10 would be accounted for at the level of firms rather than at the individual establishments.

According to the U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, there are approximately 220,100 physician practices.. The U.S. Census Bureau data indicates that two percent of physician practices have revenues of $10 million or more, therefore approximately 4,400 physician practices are not small entities.

Nevertheless, we have decided to consider all physician practices small entities. Our basis for this is the fact that Census Bureau data is calculated from report forms that are sent to only a sample of small employers (less than 10 employees). Therefore, we can assume that the estimates from the Census Bureau are low. The estimated number of physician practices in the Modifications proposed rule (234,222 physician practices) includes physician practices with one to two physicians and is within 6 percent of the total number of physician practices estimated by the Census Bureau. Therefore, we will assume that all physician practices, as calculated by the Census Bureau (220,100), are small entities, and accept a small margin of error.

The 2007 Census Bureau reports that there are approximately 6,500 hospitals. The data indicates that 85 percent of hospitals have sales/receipts/revenues of $10 million or more. While we can assume that, of those 85 percent, some have revenues over $34.5 million; we do not have specific numbers that detail this assumption. Therefore, as with physician practices, we will make calculations on the assumption that all hospitals are small entities.

b. Health Care Clearinghouses and Transaction Vendors

We did not calculate costs and benefits to health care clearinghouses and transaction vendors in this Regulatory Flexibility Analysis because we assume that any associated costs and benefits will be passed on to the health plans or health care providers, and will be included in the costs and benefits we apply to health plans and health care providers.

c. Health Plans

The health insurance industry was examined in depth in the Regulatory Impact Analysis prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few if any ''insurance firms,'' including HMOs that fell below the size thresholds for ''small'' business established by the SBA Health. We assume that the ''insurance firms'' are synonymous, for the most part, with health plans who conduct standard transactions with other covered entities and are, therefore, the entities that will have costs associated with a delay of the compliance date for ICD–10. In fact, then, and even more so now, the market for health insurance is dominated by a relative handful of firms with substantial market shares.

There are, however, a number of health maintenance organizations (HMOs) that are small entities by virtue of their nonprofit status even though few if any of them are small by SBA size standards. There are approximately 100 such HMOs. These HMOs and those Blue Cross and Blue Shield plans that are non-profit organizations, like the other firms affected by this proposed rule, will be required to delay their implementation of ICD–10. Accordingly, this proposed rule will affect a ''substantial number'' of small entities,

[71] ''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.

and we include the impact of a delay in the compliance date of ICD–10 for the 100 HMOs and Blue Cross and Blue Shield plans in this RFA.

We welcome industry and stakeholder input on our assumption in this regard.

2. Cost for Providers

We have applied the same methodology and assumptions as we applied in the RIA to arrive at estimates to impacts to small entities. For providers, as we stated previously in the RIA, there is a distinction between the costs and benefits for large providers, hospitals and large physician practices, and smaller physician practices. In general, our assumption is that the delay in the compliance date of ICD–10 will be more costly for large providers because many of them have already made substantial investments. The cost of implementing ICD–10, for all entities that have already invested funds and resources to that endeavor, will increase by a factor of 10 to 30 percent of the current cost.

On the other hand, the justification for a delay in the compliance date of ICD–10 rests on the assumption that the delay will give many small providers more time to prepare for the transition. Therefore, our assumption is that there will be little to no cost for most small providers and that the cost avoidance of a delay will be high.

Table 31 illustrates the estimated costs and benefits for providers according to their size. All costs and benefits are calculated as occurring in 2014. It is important to note that these are very general estimates, and reflect our assumption for these provider groups at large. Due to the high variability in provider settings and systems, these estimates are not meant to reflect costs for specific providers. We welcome comments on our assumptions.

TABLE 31—COSTS AND BENEFITS IN 2014 OF A DELAY IN THE COMPLIANCE DATE OF ICD–10 FOR PROVIDERS

[Small Entities]*

	Physician practices with less than 50 physicians	Physician practices with 50 to 100 physicians	Physician practices with more than 100 physicians	Hospitals with less than 100 beds	Hospitals with 100 to 400 beds	Hospitals with more than 400 beds	Totals
Number of Entities	233,239	590	393	2,757	2,486	521	239,986
LOW Costs (in millions)	$.00	$29.07	$97	$34	$153	$96	$409
HIGH Costs (in millions)	$.00	$261.65	$871	$255	$1,378	$963	$3,728
LOW Cost Avoidance (in millions)	$1,446	$.00	$.00	$.00	$.00	.00	$1,446
HIGH Cost Avoidance (in millions)	$3,134	$.00	$.00	$.00	$.00	.00	$3,134

*Both cost and cost avoidance occur in 2014. In 2012 dollars.

3. Cost to Nonprofit Health Plans

As noted, there are a number of health maintenance organizations (HMOs) that are small entities by virtue of their nonprofit status even though few if any of them are small by SBA size standards. There are approximately one hundred such HMOs and 38 Blue Cross and Blue Shield plans that are non-profit organizations. We have applied the same methodology and assumptions as we applied in the RIA to arrive at estimates to impacts to these non-profit health plans. We have estimated that all of the Blue Cross and Blue Shield plans are large health plans, and all of the HMOs are small health plans.

Table 31 illustrates the costs and benefits for nonprofit health plans. We calculated the costs per health plan from the low and high range estimates used in the RIA for large health plans (for Blue Cross and Blue Shield plans), and small health plans (for non-profit HMOs). We calculated the cost avoidance by assuming that large health plans would return 10 percent of the total health care claims—and small health plans would return 5 percent of the total health care claims—if the compliance date of ICD–10 continued to be October 1, 2013. This assumption is based on the fact that 25 national and regional health insurers account for nearly two-thirds of the total market, and that this proportion accounts can be applied to total claims; for example that smaller health insurers process one-third of the claims. All costs and cost avoidance are calculated as occurring in 2014.

TABLE 32—COSTS AND COST AVOIDANCE IN 2014 FOR NON–PROFIT HEALTH PLANS FOR A 1–YEAR DELAY OF THE COMPLIANCE DATE FOR ICD–10*

	Number of non profit health plans	LOW COST per health plan in millions	HIGH COST per health plan in millions	LOW COST AVOIDANCE in millions	HIGH COST AVOIDANCE in millions
Blue Cross Blue Shield	38	$1.44	$7.26	$88.26	$122.21
HMO	100	.12	.60	4.02	5.57
Total	.00	1.56	7.86	92.28	127.77

*Both cost and cost avoidance occur in 2014. In 2012 dollars.

Tables 31 and 32 both illustrate that a 1-year delay in the compliance date of ICD–10 will be more beneficial to small and nonprofit entities than it will be burdensome. Nevertheless, we are specifically requesting comments on our analysis.

S. Summary and Accounting Statement for HPID, NPI and ICD–10

Table 33 summarizes the impacts of this proposed rule, including the costs and benefits of implementation of the

HPID and the costs and cost avoidance of a one-year delay in the compliance date of ICD–10. The costs and benefits of implementation of the HPID are calculated over a ten year period, while the cost avoidance and costs of the delay of the compliance date of ICD–10 will all occur in 2014.

TABLE 33—SUMMARY OF COSTS AND SAVINGS/COST AVOIDANCE, OF IMPLEMENTATION OF HPID, NPI AND A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10*

	LOW	HIGH	MEAN
Total Savings/Cost Avoidance	$6,532	$13,612	$10,072
Total Costs	2,133	8,784	5,459

*Costs and savings of HPID are calculated over 11 years, 2014 through 2024. Costs and cost avoidance of a delay in the compliance date of ICD–10 are calculated over 1 year, 2014.

In Table 34, the LOW estimate Net Savings/Cost Avoidance is calculated using the LOW Savings/Cost Avoidance minus the HIGH estimated Costs; that is, the worst case scenario in terms of low benefits and high costs. The HIGH estimate Net Savings/Cost Avoidance is estimated using the HIGH Savings/Cost Avoidance minus the LOW estimated Costs; that is the best case scenario in terms of high benefits and low costs. The MEAN Net Savings/Cost Avoidance is the average of the best case scenario and the worst case scenario.

TABLE 34—SUMMARY OF NET COST AVOIDANCE/SAVINGS OF IMPLEMENTATION OF HPID, NPI AND A ONE-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

	LOW cost avoidance/ savings less HIGH Costs (in millions)	HIGH cost avoidance/ savings less LOW costs (in millions)	MEAN (in millions)
Net Savings/Cost Avoidance	−$2,252	$11,478	$4,613

As required by OMB Circular A–4,[72] Tables 35, 36 and 37 are accounting statements showing the classification of the expenditures associated with the provisions of this proposed rule. Table 35 provides our best estimate of the costs and benefits associated with the implementation and use of the HPID. Table 36 provides our best estimates of the costs and benefits associated with a 1-year delay in the compliance date of ICD–10 proposed herein. Table 37 provides a combined estimate of the costs and benefits associated with implementation and use of HPID and a 1-year delay in the compliance date of ICD–10.

TABLE 35—ACCOUNTING STATEMENT FOR HPID IMPLEMENTATION: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2013 TO FY 2023

[In millions of dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$376	$252	$532	RIA.
3% Discount	367	258	527	RIA.
Qualitative (un-quantified) benefits.	HPID: Environmental (electronic over paper), patient benefits (more staff time), benefits from a decrease in time interacting with health plans for hospitals, dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities, and providers other than physician practices.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$203	$135	$270	RIA and Collection of Information.
3% Discount	172	115	229	RIA and Collection of Information.

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

TABLE 35—ACCOUNTING STATEMENT FOR HPID IMPLEMENTATION: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2013 TO FY 2023—Continued

[In millions of dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
Qualitative (unquantified) costs.	HPID: Cost for system changes for dentists, suppliers of durable medical equipment, nursing homes, residential care facilities, and providers other than physician practices and hospitals.	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.	

TABLE 36—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR ONE-YEAR DELAY OF ICD–10 COMPLIANCE DATE FROM FY 2013 TO FY 2023

[In millions of dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$717	$453	$982	RIA.
3% Discount	604	381	827	RIA.
Qualitative (un-quantified) benefits.	Avoidance of returned health care claims.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$475	$128	$821	RIA and Collection of Information.
3% Discount	400	108	691	RIA and Collection of Information.
Qualitative (unquantified) costs.	Downstream costs of a delayed return on investment for covered entities..	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.	

TABLE 37—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR HPID IMPLEMENTATION AND ONE-YEAR DELAY OF ICD–10 COMPLIANCE DATE, FROM FY 2013 TO FY 2023

[In millions of dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$1,069	$705	$1,479	RIA.
3% Discount	$960	$640	$1,338	RIA.

TABLE 37—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR HPID IMPLEMENTATION AND ONE-YEAR DELAY OF ICD–10 COMPLIANCE DATE, FROM FY 2013 TO FY 2023—Continued

[In millions of dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
Qualitative (unquantified) benefits.	HPID: Environmental (electronic over paper), patient benefits (more staff time), benefits from a decrease in time interacting with health plans for hospitals, dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities, and providers other than physician practices. Delay in Compliance Date for ICD–10: Avoidance of returned health care claims.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$677	$264	$1,091	RIA and Collection of Information.
3% Discount	$572	$223	$920	RIA and Collection of Information.
Qualitative (unquantified) costs.	HPID: Cost for system changes for dentists, suppliers of durable medical equipment, nursing homes, residential care facilities, and providers other than physician practices and hospitals.			
	DELAY IN COMPLIANCE DATE OF ICD–10: Downstream costs of a delayed return on investment for covered entities.	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	

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 part 162 to read 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. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), and secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917.

Subpart A—General Provisions

2. Section 162.103 is amended by adding the definitions of ''Controlling health plan (CHP),'' ''Covered health care provider,'' and ''Subhealth plan (SHP)'' in alphabetical order to read as follows:

§ 162.103 Definitions.

* * * * *

Controlling health plan (CHP) means a health plan that—

(1) Controls its own business activities, actions, or policies; or

(2)(i) Is controlled by an entity that is not a health plan; and

(ii) If it has a subhealth plan(s) (as defined in this section), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of ''covered entity'' at § 160.103.

* * * * *

Subhealth plan (SHP) means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

Subpart D—Standard Unique Health Identifier for Health Care Providers

§ 162.402 [Removed and Reserved]

3. Section 162.402 is removed and reserved.

4. Section 162.404 is amended as follows:

A. Redesignating paragraph (a) as paragraph (a)(1).

B. Adding a paragraph (a)(2).

The addition reads as follows:

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) * * *

(2) An organization covered health care provider must comply with the implementation specifications in § 162.410(b) by [Date 180 days after the effective date of the final rule].

* * * * *

5. Section 162.410 is amended as follows:

A. Redesignating paragraph (b) as paragraph (c).

B. Adding a new paragraph (b).

The addition reads as follows:

§ 162.410 Implementation specifications: Health care providers.

* * * * *

(b) An organization covered health care provider that has as a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to—

(1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES); and

(2) To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

* * * * *

6. Subpart E is added to part 162 to read as follows:

Subpart E—Standard Unique Health Identifier for Health Plans

Sec.

Subpart E—Standard Unique Health Identifier for Health Plans

§ 162.502 [Reserved]

§ 162.504 Compliance dates for the implementation of the standard unique health plan identifier.

(a) *Covered health care providers.* A covered health care provider must comply with the implementation specifications in § 162.510 no later than October 1, 2014.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.510 and § 162.512 no later than one of the following dates:

(1) A health plan that is not a small health plan—October 1, 2014.

(2) A health plan that is a small health plan—October 1, 2015.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the implementation specifications in § 162.510 no later than October 1, 2014.

§ 162.506 Standard unique health plan identifier.

(a) *Standard.* The standard unique health plan identifier is the Health Plan Identifier (HPID) that is assigned by the Enumeration System identified in § 162.508.

(b) *Required and permitted uses for the HPID.* (1) The HPID must be used as specified in § 162.510 and § 162.512.

(2) The HPID may be used for any other lawful purpose.

§ 162.508 Enumeration System.

The Enumeration System shall do all of the following:

(a) Assign a single, unique—

(1) HPID to a health plan, provided that the Secretary has sufficient information to permit the assignment to be made; or

(2) OEID to an entity eligible to receive one under § 162.514(a), provided that the Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health plan that applies for or has been assigned an HPID and each entity that applies for or has been assigned an OEID, and perform tasks necessary to update that information.

(c) If appropriate, deactivate an HPID upon receipt of sufficient information concerning circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated HPID or OEID upon receipt of sufficient information justifying reactivation.

(e) Not assign a deactivated HPID to any other health plan or OEID to any other entity.

(f) Disseminate Enumeration System information upon approved requests.

§ 162.510 Implementation specifications: Covered entities.

(a) A covered entity must use an HPID to identify a health plan where a covered entity identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

(b) If a covered entity uses one or more business associates to conduct standard transactions on its behalf, it must require its business associate(s) to use an HPID to identify a health plan where the business associate(s) identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

§ 162.512 Implementation specifications: Health plans.

(a) A controlling health plan must do all of the following:

(1) Obtain an HPID from the Enumeration System for itself.

(2) Disclose its HPID, when requested, to any entity that needs the HPID to identify the health plan in a standard transaction.

(3) Communicate to the Enumeration System any changes in its required data elements in the Enumeration System within 30 days of the change.

(b) A controlling health plan may do the following:

(1) Obtain an HPID from the Enumeration System for a subhealth plan of the controlling health plan.

(2) Direct a subhealth plan of the controlling health plan to obtain an HPID from the Enumeration System.

(c) A subhealth plan may obtain an HPID from the Enumeration System.

(d) A subhealth plan that is assigned an HPID from the Enumeration System must comply with the requirements that apply to a controlling health plan in paragraphs (a)(2) through (a)(3) of this section.

§ 162.514 Other entity identifier.

(a) An entity may obtain an Other Entity Identifier (OEID) to identify itself if the entity meets all of the following:

(1) Needs to be identified in a transaction for which the Secretary has adopted a standard under this part;

(2) Is not eligible to obtain an HPID;

(3) Is not eligible to obtain an NPI; and

(4) Is not an individual.

(b) An OEID must be obtained from the Enumeration System identified in § 162.508.

(c) *Uses for the OEID.* (1) An other entity may use the OEID it obtained from the Enumeration System to identify itself or have itself identified on all covered transactions in which it needs to be identified.

(2) The OEID may be used for any other lawful purpose.

Subpart J—Code Sets

7. Section 162.1002 is amended by revising paragraph (b) introductory text and paragraph (c) introductory text to read as follows:

§ 162.1002 Medical data code sets.

* * * * *

(b) For the period on and after October 16, 2003 through September 30, 2014:

* * * * *

(c) For the period on and after October 1, 2014:

* * * * *

Dated: February 2, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 5, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–8718 Filed 4–9–12; 11:15 am]

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