DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 162

[CMS–0040–F]

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Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD–10–CM and ICD–10–PCS) Medical Data Code Sets

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule adopts the standard for a national unique health plan identifier (HPID) and establishes requirements for the implementation of the HPID. In addition, it adopts a data element that will serve as an other entity identifier (OEID), or an identifier for entities that are not health plans, health care providers, or individuals, but that need to be identified in standard transactions. This final rule also specifies 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 a National Provider Identifier (NPI). Lastly, this final rule changes 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: *Effective date:* These regulations are effective on November 5, 2012.

Compliance dates: Health plans with the exception of small health plans must obtain an HPID by November 5, 2014. Small health plans must obtain an HPID by November 5, 2015. Covered entities must use HPIDs in the standard transactions on or after November 7, 2016. An organization covered health care provider must comply with the implementation specifications in § 162.410(b) by May 6, 2013.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary for This Final Rule

1. Purpose

a. Need for the Regulatory Action

This rule adopts a standard unique health plan identifier (HPID) and a data element that will serve as an other entity identifier (OEID). This rule also adopts an addition to the National Provider Identifier (NPI) requirements. Finally, this rule changes 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 health plans, and remittance advice that describes health care claim payments.

(2) NPI

In the January 23, 2004 **Federal Register** (69 FR 3434), 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 (''2004 NPI final rule''). The rule also established the implementation specifications for obtaining and using the NPI. 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 addition to the NPI requirements addresses this issue.

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

In the January 16, 2009 **Federal Register** (74 FR 3328), HHS published a final rule 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 (diagnoses), and 3 (procedures) including the Official ICD–9–CM Guidelines for Coding and Reporting. 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 ensue if they do not meet the date. Some providers' concerns about being able to meet the ICD–10 compliance date are based, in part, on difficulties they had meeting the 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 affect all other industry segments and result in returned claims and provider payment delays. We believe the change in the compliance date for ICD–10 gives covered health care providers and other covered entities more time to prepare and fully test their systems to ensure a smooth and coordinated transition by all covered entities.

b. Legal Authority for the Regulatory Action

(1) HPID

This final rule implements section 1104(c)(1) of the Affordable Care Act and section 1173(b) of the Social

Security Act (the Act) which require the adoption of a standard unique health plan identifier.

(2) NPI

This final rule imposes an additional requirement on organization health care providers under the authority of sections 1173(b) and 1175(b) of the Act. It also accommodates 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 final rule sets 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 adopts the HPID as the standard unique identifier for health plans and defines the terms ''Controlling Health Plan'' (CHP) and ''Subhealth Plan'' (SHP). The definitions of these two terms differentiate health plan entities that are required to obtain an HPID, and those that are eligible, but not required, to obtain an HPID. This rule requires 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, we established requirements for CHPs and SHPs in order to enable health plans to obtain HPIDs to reflect different business arrangements so they can be identified appropriately in standard transactions.

This rule also adopts a data element to serve as an other entity identifier. The OEID will function 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 final rule, other entities are not required to obtain an OEID, but they could obtain and use one if they need 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 an identifier for other entities will increase efficiency by facilitating the use of a uniform identifier.

b. NPI

This rule requires an organization covered health care provider to 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 changes the compliance date for ICD–10–CM and ICD–10–PCS 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. Summary of 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, Indian Health Service (IHS), and Veterans Health Administration (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 the HPID requirements to be overly burdensome. Many entities have indicated that they have delayed regular system updates and maintenance, as well as the issuance of new health plan identification cards, in order 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 $1.3 billion to $6 billion. (This estimate includes savings resulting from the ongoing effects of adopting the HPID rather than the immediate and direct budgetary effects.)

b. NPI

The addition to the requirements for the NPI will 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, the threshold specified in the Unfunded Mandates Reform Act (UMRA).

c. Change of Compliance Date of ICD–10

According to a recent survey conducted by the Centers for Medicare & Medicaid Services (CMS), up to one quarter of health care providers believe they will not be ready for an 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 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 are allowing more time for covered entities to prepare for the transition to ICD–10 and to conduct

[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).

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 will 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 final rule, we estimate that there would be a cost avoidance of approximately $3.6 billion to nearly $8 billion in this regard. This range of estimates reflects the avoidance of two costly consequences that could occur should the compliance date remain October 1, 2013: (1) both health care providers and health plans could have to process health care claims manually in order for claims to be paid; and (2) small health care providers could 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 billion 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 final 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 $6.6 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 solicited comments on our assumptions and conclusions in the RIA.

B. Background

1. Legislative and Regulatory Overview

In the April 17, 2012 **Federal Register** (77 FR 22950), we published a proposed rule titled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets'' (hereinafter referred to as the April 2012 proposed rule). The April 2012 proposed rule provides an overview of the statutory provisions and regulations that are relevant for purposes of the April 2012 proposed rule (77 FR 22952 through 22954) and this final rule. We refer readers to that discussion.

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

Section 1104(c)(1) of the Affordable Care Act 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). Congress created the NCVHS to serve as an advisory body to the Secretary on health data, statistics, and national health information policy. 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 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 currently no requirement for consistency in the use of identifiers for health plans. The transaction standards implementation guides, though, do provide for the use of the HPID once its use is mandated and during a phase-in period. Prior to this rule, health care providers, health plans, and health care clearinghouses consequently could use EINs, TINs, NAIC numbers, or health care 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 group health plans, and provider- or hospital-run health plans to perform claims administration, premium collection, enrollment, and other administrative functions. As explained later in this final rule, we are adopting 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)

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, the Secretary is directed to conduct rulemaking to establish a unique health plan identifier based on input of the NCVHS.

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.).

For a full discussion of the key topics and recommendations from the July 19 through 21, 2010 NCVHS hearings, we refer the reader to the April 2012 proposed rule (77 FR 22950). For the complete text of the NCVHS' observations and recommendations, go to *http://www.ncvhs.hhs.gov/100930lt1.pdf.*

E. Definition of Health Plan

The regulatory definition of health plan at 45 CFR 160.103 was initially adopted in the August 17, 2000 Standards for Electronic Transactions final rule (65 FR 50312) (hereafter Transactions and Code Sets final rule). The basis for the additions to, and clarifications of, the definition of health plan is further discussed in the preamble to the December 28, 2000 final rule (65 FR 82478 and 82576) titled ''Standards for Privacy of Individually Identifiable Health Information'' (hereinafter referred to as the Privacy Rule). For additional information on the definition of health plan, we refer readers to these rules.

F. The April 2012 Proposed Rule and Analysis of and Responses to Public Comments

In the April 2012 proposed rule, we proposed the following:

- The adoption of the standard for a national unique HPID for use in all transactions for which the Secretary has adopted a standard (hereinafter referred to as standard transactions).
- An OEID for use by entities that do not meet the definition of a health plan, but that need to be identified in the standard transactions.
- Requirements and provisions for the implementation of both the HPID and OEID.
- Additions to the NPI requirements mandating that covered health care providers require certain noncovered individual health care providers who are prescribers to obtain NPIs.
- To change the compliance date for ICD–10 code sets from October 1, 2013 to October 1, 2014.

In the April 2012 proposed rule, we solicited public comments on a number of proposals. In response to our solicitation, we received approximately 536 timely pieces of correspondence. Summaries of the public comments that are within the scope of the proposed rule and our responses to those comments are set forth in the various sections of this final rule under the corresponding headings.

II. Adopting a Standard for a Unique Health Plan Identifier (HPID)

A. The Health Plan Identifier

We proposed HPID as the standard unique identifier for health plans. We also proposed: (1) Instructions and guidance concerning how health plans may obtain an HPID; (2) the requirements that covered entities will have to meet to use the HPID in standard transactions; and (3) provisions for the HPID in a new subpart (subpart E) at 45 CFR part 162.

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 proposed and are adopting in this final rule, to categorize health plans as controlling health plans (CHPs) and subhealth plans (SHPs).

The definitions of CHPs and SHPs are established in 45 CFR 162.103 as follows:

a. Controlling Health Plan (CHP)

A 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), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

We suggested that the following considerations may be helpful in 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 would meet the definition of CHP. We proposed that an entity that meets the definition of CHP would be required to obtain a health plan identifier.

b. Subhealth Plan (SHP)

We proposed that a SHP means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

We suggested that 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 business 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 proposed 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.

Comment: We received a few comments on the proposed definitions of CHP and SHP. Some commenters liked the proposed definitions, believing they would aid health plans in determining the appropriate enumeration level. A few commenters suggested alternatives to either broaden or narrow the definition of CHP. Commenters that requested a broader definition were generally concerned that the definition was not sufficiently broad to encompass the legal structures utilized by various third party payors. As a result, ambiguity in the standard transactions occurs because of the numerous different ways in which health plans functions are performed by different entities and the numerous ways the term ''health plan'' is interpreted. These commenters suggested that HHS expand the definition of CHP to encompass any and all potential legal relationships between holding companies and their subsidiaries that hold health insurance licenses. These commenters also requested that after HHS broadens the definition of CHP, that the CHP be required to obtain a separate HPID for each of the health plans' subsidiaries involved in the healthcare delivery system, specifically for the entities that are involved as fiduciaries with legal responsibilities for paying claims, any administrator responsible for administering any aspect of the benefits, and any holder of the participation contract with the physicians or other health care providers. These commenters suggested that HHS revisit the definition of health plan at 45 CFR 160.103 to include each of the intermediaries involved in the multitude of transactions that occur in administering payment.

Response: HHS was tasked with creating a unique health plan identifier. The term ''health plan'' is defined in section 1171(5) of the Act and at 45 CFR 160.103 of the regulations. We do not believe Congress intended to include in the definition of health plan entities that solely perform the functions of third party administrators or repricers. In addition, while we recognize that health plans and other entities that perform health plan functions may be identified in similar fields in the standard transactions, they are distinctly different organizations with different purposes. Furthermore, we proposed the adoption of a data element that will serve as the OEID discussed in section II.B. of this final rule to meet industry's need for a standard identifier for entities that do not meet the definition of health plan, but that perform related functions.

Comment: A commenter suggested that HHS narrow the definition of a CHP so that it means ''a health plan that—(1) controls its own business activities, actions, *and* 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, *and* policies.''

Response: We believe that a narrow definition of CHP would not capture all of the ''parent'' organizations that should be required to obtain HPIDs for themselves and be authorized to obtain HPIDs for their subhealth plans, to accomplish the goals at this stage of standardization. We distinguish between CHPs and SHPs because health plans have different business structures and arrangements that determine how they are identified in the standard transactions. We recognize that different organizations may divide business responsibilities in various ways. For example, a ''parent'' organization that meets the definition of health plan may dictate some business activities, actions, or policies, but may not control all business activities, actions, or policies of entities that they own or operate that also meet the definition of health plan. Given the variations in structures and relationships, we used the word ''or'' rather than ''and'' to provide more flexibility to health plans and ensure that ''parent'' organizations are classified as CHPs and are required to obtain HPIDs.

After consideration of the public comments received, we are finalizing the definitions of CHP and SHP without modification.

2. Use of the HPID

In 45 CFR 162.510, we proposed that all covered entities would be required to use an HPID where a covered entity identifies a health plan in a covered transaction. We proposed further that, if a covered entity uses a business associate to conduct standard transactions on its behalf, the covered entity must require its business associate to use an HPID to identify a health plan where the business associate identifies a health plan in all covered transactions.

We proposed in § 162.506 that the HPID could also be used for any other lawful purpose, and provided some examples of permitted uses including 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 nonstandard 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.

Comment: Many commenters requested further clarification of the purpose, intent, and use of the HPID, specifically if and how the HPID should be used in the standard transactions. For instance, they suggested more guidance on if and where the HPID should be used in the standard transactions and on the ISA envelope.

Response: We direct these commenters to the adopted transaction standards, the relevant implementation guides, and as appropriate, adopted operating rules, for direction on if and when to use the HPID. We note that the only required use of the HPID is that a covered entity must use an HPID to identify a health plan that has an HPID in the standard transactions where the covered entity is identifying a health plan in the standard transaction. This final rule does not require that health plans now be identified in the standard transactions if they were not identified before this rule. For instance, if a covered entity is currently identifying a health plan as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1—information source name, the covered entity will be required to use an HPID to identify that health plan as the information source once the HPID is required. If a covered entity is currently identifying a third party administrator as the information source, the covered entity can continue to identify that third party administrator as the information source using whatever identifier the third party administrator uses after the adoption of the HPID. We anticipate we will provide additional examples of how the HPID can be used in the standard transactions outside of this final rule.

In their request for clarification, some of these commenters appeared confused regarding the affirmative obligation in 45 CFR 162.510 for covered entities to use an HPID to identify a health plan in standard transactions, when a SHP may not have its own HPID. In those cases, covered entities would use the HPID that the SHP indicates should be used to identify that SHP, which may be the HPID of its controlling health plan. If an entity has in good faith sought to identify the HPID that should be used for a SHP that has no HPID and has been unsuccessful, then it obviously cannot use an HPID to identify that SHP. However, we would anticipate that those circumstances would be rare. Nevertheless, consistent with these commenters' request to clarify the requirement, we have inserted ''that has an HPID'' immediately after ''health plan'' in § 162.510(a) and (b). We consider a health plan as ''having an HPID'' if that health plan communicates with its trading partners that it consistently uses a particular HPID, even if the HPID it uses is associated with another health plan, such as its controlling health plan.

Comment: A few commenters stated that they saw the primary purpose of the HPID as a way to eliminate the ambiguity that currently exists in the covered transactions. They note that various nonhealth plans perform certain administrative functions currently performed by health plans.

Response: These comments imply that the Department should expand the definition of ''health plan'' to include entities that are not health plans as defined by statute and regulation. Previously, we addressed why this rule does not expand the definition of health plan, and further, why we take an incremental approach in the adoption of the HPID and OEID. We seek to allow the industry time and flexibility for implementing these unique identifiers. We created the other entity identifier to provide standardization for these entities that do not meet the definition of health plan, for instance. While the use of the OEID is voluntary, its use can facilitate the standardization of electronic administrative and financial transactions.

Comment: Some commenters expressed concern that the HPID requirements and provisions are not clearly defined for industry implementation. Commenters recommended that pilot testing occur prior to the adoption of the HPID, to ensure proper and consistent implementation. Some commenters suggested that the Department work with the NCVHS to determine if operating rules for the use of HPID are necessary to clarify any implementation issues that arise following HPID implementation.

Response: We anticipate this rule serving as a first step in standardizing the way health plans are identified in the standard transactions. We note that the only required use of the HPID is to identify a health plan that has an HPID where a health plan is identified in the standard transactions. Health plans, except small health plans, have until 2 years after the effective date of this rule to obtain HPIDs. Small health plans have until 3 years after the effective date of this rule to obtain HPIDs. Covered entities are not required to use HPIDs in the standard transactions until 4 years after the effective date of this rule. (For further discussion of the HPID compliance date see section II.E. of this final rule.) The rule provides ample time for covered entities to develop their own implementation timelines, which we suggest could include pilot testing, and milestones to ensure they meet the compliance dates.

As we explained in the April 2012 proposed rule, a health plan may need to be identified in different fields in the transactions and these fields may not always require the use of a health plan identifier. For instance, the information source, in the eligibility response transaction (271), Loop 2100A, Segment NM1, may be a health plan, or an other entity that performs health plan functions, like a third party administrator. So after the applicable compliance date of the HPID, if a covered entity is identifying a health plan as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1, then the covered entity will be required to use an HPID to identify that health plan in the standard transactions. However, if after the adoption of the HPID, the covered entity is identifying a third party administrator as the information source in the eligibility response transaction (271), Loop 2100A, Segment NM1, the covered entity can use whatever identifier it was using previously or an OEID to identify that third party administrator. This final rule does not impose any new requirement for when to identify a health plan that has an HPID in standard transactions. It merely requires the use of the HPID where the health plan is identified. We did provide an example of a use of the HPID in transaction standards in the April 2012 proposed rule (77 FR 22961).

Comment: Some commenters question what the HPID will actually accomplish.

Response: The establishment of the HPID and the requirement to use it in the standard transactions to identify health plans is another step towards standardization. In standard transactions, the HPID will replace proprietary identifiers for health plans which have different lengths and formats. In addition, it will provide public access to information necessary to accurately identify health plans. This will save providers time when verifying a health plan's identity. Standardization of the health plan identifier is also expected to ameliorate some electronic transaction routing problems. The HPID and OEID will add consistency to identifiers, may 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 may allow reconciliation of claims with the claim payments to be automated at a higher level. While the implementation of HPID, in and of itself, may not immediately provide significant monetary savings for covered entities, it is expected to provide significant time savings by immediately resolving certain transaction routing problems.

Comment: Commenters raised issues about whether the early use of the HPID in the standard transactions could result in denied or misrouted claims with the potential to cause privacy or security breaches.

Response: We believe the HPID will reduce denied and misrouted claims once fully implemented, given that all HPIDs and information related to HPIDs will be available in one database. While we recognize that there is the potential for misrouted or denied claims during the transition to the HPID, we believe that privacy or security breaches can be avoided, particularly with prior implementation planning. We believe there is more than adequate time between the compliance date for when health plans obtain HPIDs and when covered entities are required to use HPIDs in the standard transactions, which will allow industry ample opportunity to make system changes and perform extensive testing with trading partners. This additional time and phased-in approach to compliance should reduce denied or misrouted claims during the early use of the HPID.

Comment: Some commenters requested more specific guidance about how the HPID should be used in business models, for instance in situations where one health plan may be adjudicating the claim and a separate health plan may hold the actual contract with the provider.

Response: The implementation of the HPID does not require a change to health plans' business models. Changing a health plan's current identifiers to an HPID does not change the structural organization and/or its contractual relationships with other entities, or whether it is identified in the standard transactions. For example, if the health plan that adjudicates the claim needs to be identified in a standard transaction, then the HPID of that health plan should be used. If the health plan that holds the actual contract with the provider needs to be identified in a standard transaction, then the HPID of that health plan should be used.

Comment: Several commenters raised concerns about the use of the HPID on health plan members' ID cards. Commenters were split between making the use of the HPID on member ID cards mandatory or optional. Others raised concerns that the cost of re-issuing all member ID cards far outweighs any benefit.

Response: In this rule, we only require the use of the HPID in the standard transactions. The HPID is permitted to be used for any other lawful purpose and inclusion of the HPID on health plan members' ID cards is just one example of an optional use of the HPID. While health plans are permitted to put the HPID on member ID cards, we do not require it, so the determination of whether to reissue cards, and the associated costs, lie with the health plans.

Comment: Other commenters recommended that health plans be required to comply with the health plan ID card standards set forth in the Workgroup for Electronic Data Interchange (WEDI) Health ID Card Implementation Guide, Version 1.0 (November 30, 2007).

Response: We did not address or propose the adoption of a standard format for a health plan identification card. The goal of this rule was to adopt a standard health plan identifier for use in the standard transactions. While the use of the HPID on a health plan ID card is a permitted use, we did not require it in this rule because further analysis and industry feedback is needed on standard identification cards after the implementation of the HPID.

After consideration of the public comments, we are finalizing the required and permitted uses of the HPID with the minor clarifying modifications to § 162.510(a) and (b), adding ''that has an HPID'' immediately after ''health plan.''

3. Health Plan Identifier Requirements

a. Requirements and Options for Obtaining an HPID

This final rule discusses how CHPs and SHPs will obtain an HPID from the Enumeration System. In 45 CFR 162.512, we proposed to require a CHP to obtain an HPID for itself from the Enumeration System. In addition, we proposed that a CHP may obtain an HPID from the Enumeration System for its SHP, or direct a SHP to obtain an HPID from the Enumeration System. We proposed that any SHP would be able to obtain an HPID regardless of whether or not its CHP directed it to obtain an HPID. While a CHP could only obtain one HPID for itself, a CHP could use the HPID of its SHPs for any lawful purpose.

While a CHP would be required to obtain an HPID, there would be different options available for the enumeration of SHPs based on a CHP's organizational structure and business needs. The CHP would analyze its organizational structure to determine if and which of its SHPs need an HPID based on whether the SHP needs to be identified in covered transactions. We encouraged CHPs and SHPs to coordinate their HPID applications to prevent duplication and possible confusion. See Table 1 for a comparison of requirements for obtaining an HPID.

TABLE 1—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.

For further illustrations and examples of enumeration options to demonstrate the ways a CHP could choose to enumerate itself and its SHPs, see the April 2012 proposed rule (77 FR 22957 through 22962).

In the proposed rule, we clarified that self-insured group health plans are included in the definition of health plan in § 160.103 and therefore will need to obtain a health plan identifier if they meet the definition of a CHP. We specifically mentioned 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 often need to be identified in the standard transactions. Some industry stakeholders noted that 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. Therefore, many in the industry suggested not requiring self-insured group health plans to obtain HPIDs, while others recommended requiring these plans to obtain HPIDs because they are typically the financially responsible party. Given that self-insured group health plans are included in the definition of health plan and potentially need to be identified in the standard transactions, we proposed that they be required to obtain an HPID if they meet the definition of a CHP. We solicited comments on this issue.

b. Options for Enumeration of Health Plans

As discussed previously in this final rule, stakeholders at the NCVHS hearings expressed differing 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 policies associated with HPID adoption and implementation.

In the April 2012 proposed rule, we considered multiple uses for the HPID. We determined that the primary purpose of the HPID was for use in standard transactions in order to identify health plans in the appropriate loops and segments and to provide a consistent standard identifier for covered entities to use when identifying health plans in standard transactions. 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 a loop or segment conveys when a health plan is being identified. We also carefully considered the information that industry stakeholders reported was missing in covered transactions, such as information related to patient financial responsibility.

We determined that much of the information testifiers wanted to obtain from the HPID might already be available in other parts of the transaction standards and associated operating rules. To illustrate this point, in the proposed rule, we discussed the CAQH CORE 154 Eligibility and Benefits 270/271 Data Content Rule, which we adopted through an interim final rule with comment period in the July 8, 2011 **Federal Register** (76 FR 40458). That operating rule is 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. The operating rule requires certain additional information to be included in the Version 5010 270/271 eligibility inquiry/response transaction 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. Moreover, we believe that the transaction standards themselves could more appropriately address many of the other issues raised by stakeholders about the appropriate level of enumeration. Therefore, HPID does not need to provide the level of detail that some testifiers suggested.

We discussed in the April 2012 proposed rule how requiring health plans to enumerate at 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. For example, health care providers would need to update their software and systems frequently to ensure the accuracy of information. A failure of either health care providers or health plans to ensure that the HPIDs and the corresponding health plan information is up-to-date could result in increased time spent by health plan and health care provider staff to ensure the most accurate information is being used for eligibility determinations and claim payments.

As discussed in the April 2012 proposed rule, we developed the policies associated with HPID adoption and implementation 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 transaction standards and the adoption of associated operating rules.

We received many comments on the enumeration requirements for CHPs and SHPs.

Comment: Some commenters generally supported our proposal that a CHP be required to obtain an HPID, while a SHP would be eligible but not required to obtain one. These commenters supported the flexibility this approach provided to a health plan to determine the appropriate level of enumeration for its organization and enumerate itself in a way that supports its business needs.

Response: We thank commenters for their support.

Comment: Some commenters emphasized that it is critical that the approach in the proposed rule be finalized so that health plans have the flexibility to determine how the health plan chooses to enumerate itself for use in the standard transaction. For instance, whether it chooses to have one HPID for its entire organization or whether it chooses to obtain separate HPIDs for its subhealth plans. While these commenters supported the proposed enumeration requirements and required uses of the HPID, they expressed concerns that future rulemaking could result in requiring divisions within health plans to be enumerated.

Response: While we appreciate the commenters' support for our proposed approach to establishing an HPID, we find the concerns expressed about future rulemaking to be outside the scope of this rule. Nevertheless, we anticipate that future changes in the requirements or prohibitions will be aligned with industry business needs and experience.

Comment: A commenter expressed concern about limiting a health plan to a single HPID. This commenter was concerned that a single HPID may present issues from a routing perspective because a single health plan may use multiple processing systems or administrators. The commenter also noted that if a health plan were limited to being enumerated with a single HPID, there would need to be intelligence associated with the HPID, such as a data element to redirect incoming transactions from the single receiving site to the multiple processing sites. This commenter further suggested that a health plan be able to obtain and use subordinate identifiers for routing purposes.

Response: This final rule limits CHPs to obtaining one HPID for themselves. Permitting a CHP to obtain multiple HPIDs would lead to unnecessary complexity and potential confusion for no discernible benefit. Any additional information necessary for the transaction should be included within the transaction standard, implementation specifications, or associated operating rule. However, we note that we do allow CHPs to obtain HPIDs for their subhealth plans based on their business needs and arrangements and allow CHPs to use the HPID of their SHPs in the standard transactions.

Comment: Some commenters supported not enumerating at a more granular level of enumeration because certain information about patient eligibility or financial information can be provided in other data fields in the transactions. They stressed that a more granular approach would add significant administrative costs to the implementation of the HPID and would require the creation of a clearinghouse to maintain the various separate identifiers and this would not benefit vendors, health care providers or health plans.

Response: We agree with these commenters that a greater level of granularity has the potential to be unnecessarily burdensome and expensive for all segments of industry. If the industry determines that additional information is needed for certain electronic transactions, changes to the transaction standards would likely be more appropriate.

Comment: Commenters recommended that HHS work with the Operating Rules Authoring Entity for the applicable transactions if additional information is needed in the future.

Response: The Affordable Care Act authorized the Secretary to establish a review committee to conduct hearings to evaluate and review the adopted standards and operating rules. The review committee will provide recommendations for updating and improving such standards and operating rules. We believe that the industry will have sufficient opportunities to provide information about developing needs and ways to address those needs with possible changes to standards and operating rules.

Comment: Some commenters suggested that HHS provide additional guidance on enumeration to support health plans in making informed decisions on the most appropriate approach for enumeration. These commenters cautioned that, without more guidance, the proposed enumeration approach would result in health plans enumerating their organizations in different ways and this lack of consistency across health plans would impact the industry.

Response: We do not believe additional guidance on enumeration is needed at this time. This final rule seeks in large part to substitute the use of proprietary and other non-standard identifiers with a unique standard health plan identifier in HIPAA standard transactions. Covered entities nevertheless retain certain flexibility to use identifiers in ways that best serve their own business needs, even within standard transactions. As health plans are enumerated, HHS will monitor the industry and assess whether any clarification or guidance is necessary. More likely, the industry will quickly identify best practices for health plan enumeration and HHS will seek to facilitate the dissemination of this information.

Comment: Commenters urged HHS to require a greater level of health plan enumeration granularity. For example, some commenters suggested that a patient-specific benefit plan ID is needed. They stated that an identifier should include this information because from the perspective of patients, physicians, and other health care providers, the patient-specific benefit plan information is routinely necessary prior to the patient encounter. They also stated that while the current set of adopted operating rules will ensure additional information is available, they will not provide all the information associated with the patient-specific benefit plan the commenters believe is needed. They suggested that the need for a patient-specific benefit plan ID will only increase as the number of people purchasing coverage directly from Exchanges grows. According to these commenters, this information is needed at the point of service, on the eligibility response, and on the electronic remittance advice (ERA). Currently this information is only required to be provided on the ERA in text, which makes automation difficult. These commenters suggested that having specific benefit plan information associated with the HPID would improve automation.

Response: Given our gradual approach to standardization, a patient-specific benefit plan identifier is a more specific requirement than we believe would be appropriate to impose at this early stage. As other commenters have suggested, a more granular level of enumeration has the potential to cause ongoing administrative burden and would need to be continually updated by both the health plans and the providers to ensure accuracy. We understand that this first step of standardization for the identification of health plans is not going to achieve as much transparency initially as some commenters state is needed in the transactions. After experience with the implementation and use of the HPID, we will work with industry to explore next steps of enumeration that may include patient-specific benefit plan information. We also want to caution that we do not believe a standard identifier alone will be the final solution to all of the transparency challenges in standard transactions. The health plan identifier is foundational and will allow the gradual move towards greater utility.

Comment: Some commenters emphasized the need to enumerate each SHP because there are situations where the specific benefit package of that health plan under which services were performed needs to be identified, such as with coordination of benefit transactions or laboratory services.

Response: For this phase of implementation of HPID, we determined that it would not be necessary to require each SHP to obtain an HPID because health plans are essentially transitioning their multiple proprietary identifiers to HPIDs. We are not changing what is required to be identified in the standard transaction so if there are situations where the SHP may need to be identified, such as with laboratory services or coordination of benefit transactions, it will be up to the CHP within the limitations of this rule to determine how that SHP is identified in the standard transaction to ensure continuous flow of the transactions. We believe that at this stage of transition, it is wise to allow CHPs to make these decisions based on their business needs and structures.

In a previous response, we provided clarification about the affirmative obligation in 45 CFR 162.510 for covered entities to use an HPID to identify a health plan in standard transactions, when a SHP may not have its own HPID, and we believe the discussion is applicable to this comment. As we explained previously, in those cases, covered entities would use the HPID that the SHP indicates should be used to identify that SHP, which may be the HPID of its controlling health plan. If an entity has in good faith sought to identify the HPID that should be used for a SHP that has no HPID and has been unsuccessful, then it obviously cannot use an HPID to identify that SHP. While we anticipate those circumstances would be rare, we have inserted ''that has an HPID'' immediately after ''health plan'' in § 162.510(a) and (b). We consider a health plan as ''having an HPID'' if that health plan communicates with its trading partners that it consistently uses a particular HPID, even if the HPID it uses is associated with another health plan, such as its controlling health plan.

Comment: It was also suggested by commenters that there be a national standard fee schedule identifier that is separate from the HPID. A payer-assigned fee schedule identifier and a mandate that each entity that serves as a contracting agent issue a unique fee schedule identifier in conformance with that standard for each separate fee schedule would allow physicians and other health care providers to automatically post and reconcile claims payments from multiple payers for multiple products.

Response: For this rule, we decided to take a gradual approach towards standardization of the health plan identifier and not attempt to address all information needs that industry wants from the standard transactions with a health plan identifier. We understand that other types of identifiers, such as a payer-assigned fee schedule identifier may be useful in the future to move towards a system where health care providers can automatically post and reconcile payments. For some of the suggested identifiers, we may not have the necessary legal authority to adopt them, and regardless, we believe this final rule provides a foundation that can be built upon in the future.

Comment: We received numerous comments on enumeration of self-insured group health plans. Some commenters supported the requirement because self-insured group health plans may need to be identified as the financially responsible entity in the standard transactions. A majority of commenters recommended that only self-insured group health plans that are conducting the standard transactions directly should be required to be enumerated since few self-insured group health plans directly conduct transactions. These commenters recommended that if business needs are identified that require the identification of a self-insured group health plan, changes to the standards or operating rules should be considered to address these issues.

Response: The definition of health plan at 45 CFR 160.103 specifically includes the self-insured group health plans. While self-insured group health plans will be required to obtain an HPID to the extent they meet the definition of a CHP, the HPID of a self-insured group health plan will *only need to be used* by covered entities *if* that self-insured group health plan is identified in the standard transactions. While many commenters recommended that a self-insured group health plan only be required to obtain an HPID if it needs to be identified in the standard transactions, we believe it is important that the requirement to obtain an HPID extend to any entity that meets the definition of CHP. Therefore, we require self-insured group health plans to obtain an HPID to the extent they meet the definition of CHP.

Comment: Some commenters also discussed operational challenges that health plans functioning as TPAs would encounter because of the requirement that self-insured group health plans obtain an HPID. These commenters stated that self-insured group health plans would need to enumerate on behalf of their plan sponsors so that they can be identified in the standard transactions.

Response: We are not requiring that the HPID of the self-insured group health plan be used to identify that self-insured group health plan, if the transaction standard does not require it. For example, if a covered entity is identifying the self-insured group health plan in the standard transaction, then the covered entity must use the HPID of the self-insured group health plan. If, however, the covered entity *was not* identifying the self-insured group health plan prior to this final rule, because, for example, it was identifying either another health plan or an entity such as a TPA, then the covered entity *would not* be required to identify a self-insured group health plan. This rule *does not* require that a self-insured group health plan be identified in the standard transactions.

Comment: Commenters also requested clarification about what identifier a health plan should use in the standard transaction if it is functioning as a third party administrator.

Response: The primary purposes of this rule include adopting a unique health plan identifier and establishing the enumeration system for the HPID. While we recognize that health plans have various business structures and arrangements, health plans need to be identified with a unique identifier using a standardized format. HPIDs will therefore need to be used in standard transactions to identify health plans in accordance with the requirements of the implementation guides for the relevant transaction standards. We would also note that because health plans are eligible to obtain an HPID, they are ineligible to receive an OEID.

Comment: A number of commenters requested additional guidance on enumeration for various business arrangements. A commenter specifically requested additional guidance on situations where the holding companies/controlling entities for multiple affiliated health plans do not meet the definition of health plan and consider allowing affiliated CHPs to share a single HPID in certain clearly defined circumstances.

Response: While each CHP is required to obtain an HPID, these comments suggest it may be helpful and more efficient for affiliated CHPs to share an HPID in limited circumstances in the standard transactions based on their unique organizational structures and business arrangements. We appreciate these comments and will provide further guidance in the near future. We would note that the regulation text broadly states that a covered entity must use an HPID to identify a health plan that has an HPID.

Under this latter requirement, we envision that a health plan would be considered to ''have an HPID'' if it communicates to its trading partners that it should be identified with a particular HPID of an entity with which it is associated, such as its CHP. A CHP for instance could direct its SHPs to use its own HPID for all HIPAA covered transactions. Presuming that the SHPs have communicated with their trading partners that they use their CHP's HPID, the SHPs would be considered to ''have an HPID'' which the trading partners must use to identify the SHPs.

Comment: A few commenters stated that they already have health plan identifiers that are identical in format and are consistent with ISO 7812, like the HPID and OEID. These identifiers had been assigned by a private firm. These commenters recommended that these existing identifiers be incorporated in the Enumeration System so they do not have to reissue health insurance cards.

Response: We regret that entities may have already obtained identifiers from other parties that were not issued through the Enumeration System. However, this final rule requires that HPIDs only be obtained from the Enumeration System. This requirement ensures that HHS oversees the issuance of all HPIDs, that the HPIDs meet the requirements in this rule, and that necessary information about the health plan is available in the Enumeration System database. To grandfather in existing numbers could cause confusion among industry, a lack of integrity in the database, and disproportionate burden on health plans that do not have a current number that can be grandfathered in. While health plans are permitted to put the HPID on health insurance cards, we do not require it so the determination to reissue cards lies with the health plans.

Comment: One commenter requested that expatriate health plans, which they defined as plans whose principal purpose is covering those lives outside their country of citizenship and their dependents, be exempted from complying with the HPID requirements. This commenter alleged that compliance would be an added burden on U.S.-based insurers of expatriate plans and would competitively disadvantage them vis-à-vis their non-U.S. competitors.

Response: As discussed previously, this rule adopts the HPID as the standard unique health plan identifier for all health plans covered by HIPAA. Section 162.504 provides that all health plans that are not small health plans have until 2 years after the effective date of this rule and small health plans have until 3 years after the effective date of this rule to obtain an HPID and comply with the other provisions of § 162.512. To fully implement the HPID, all covered entities have until 4 years after the effective date of this rule to use an HPID to identify a health plan that has an HPID in standard transactions and comply with the other provisions of § 162.510. (For more information regarding the HPID compliance dates, see section II.E. of this final rule.) We believe that these dates provide covered entities, including ''expatriate plans'' that are health plans covered by HIPAA, sufficient time to meet the requirements of this rule. Moreover, we note that if a category of health plans were exempted from obtaining an HPID, other covered entities needing to identify those health plans would be adversely affected when attempting to conduct standard transactions with such exempted entities. Furthermore, neither HIPAA nor the Affordable Care Act authorizes

HHS to exempt health plans from complying with these adopted regulations simply because those health plans also conduct certain financial and administrative transactions electronically outside of the United States or are also covering individuals that are not U.S. citizens.

c. Changes to a Health Plan's HPID in the Enumeration System

In the April 2012 proposed rule, we proposed to require each health plan to disclose its HPID, upon request, to any entity that needs the HPID to identify that health plan in a standard transaction. We proposed to require each health plan to communicate changes (updates, corrections, etc.) to its own data to the Enumeration System within 30 days of the date of the change. We proposed that 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.

Comment: We received comments about CHP and SHP responsibilities for obtaining HPIDs and maintaining information related to the HPID in the Enumeration System. Some commenters suggested that HHS should clarify the respective obligations of CHPs and SHPs and that there should be a clear and defined responsible party for both the HPID application process and the HPID maintenance process to avoid the need for coordination. For instance, these commenters suggested that a CHP have responsibility for application and maintenance of HPIDs for itself and its SHPs. These commenters believe this would prevent duplicate numbers that could cause confusion and costly manual intervention in the claims process. Some commenters recommended that rather than have the SHP be responsible for updating its own information in the Enumeration System, the responsibility for updating information associated with an HPID should be left to the CHP and SHP to determine based on their business practices.

Response: We allow a CHP or SHP to obtain the HPID for a SHP because we recognize there are different arrangements that impact what entity may control the business actions, activities, or policies of an organization. For example, a CHP may dictate or manage the data and information systems for all of its SHPs and choose to obtain HPIDs on behalf of their SHPs to ensure coordination. On the other hand, a CHP may instruct its SHPs to obtain HPIDs. While we wanted to ensure flexibility during the application process, we also wanted to be sure that the responsibility to update the information rested with one entity and was clearly delineated. We believe that the simplest way to ensure the integrity of the data is that each entity be responsible for updating the information linked to its HPID. We anticipate that entities may delegate the update responsibility to other entities, although the health plan identified by an HPID still retains the responsibility to update its required data elements in the Enumeration System.

Comment: A few commenters recommended that changes to information associated with an identifier should be required within 5 days of the change, rather than the proposed 30 days. Another commenter recommended that an enumerated entity provide a minimum of 60 days' notice *prior* to the effective date of any change that would impact the HPID and OEID under which that entity is enumerated, which would be sufficient time to allow providers and their vendors or clearinghouses to make adjustments in their systems to avoid transaction rejections or failures.

Response: We have considered the comments about notification of changes and believe that entities should be given up to 30 days to make changes during this initial implementation stage. We recognize the operational challenges often associated with organizational changes or restructuring, and believe that 30 days strikes a good balance between the need to update the information in the Enumeration System and the entity's competing operational responsibilities. With that said, we encourage entities to make any necessary changes in a shorter timeframe when possible.

After consideration of the public comments, we are finalizing the policy regarding health plan requirements without modification.

4. HPID Standard Format

a. Introduction

Per the NCVHS recommendations, which were based on stakeholder testimony from a wide range of potential HPID users, in the April 2012 proposed rule, we proposed to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit. 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. We sought 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 proposed 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 10th digit, be adopted as the standard for the HPID. We proposed that the HPID format will essentially be an intelligence-free identifier, except that the start digit of the identifier would signal that the identifier is assigned to a health plan, as opposed to an ''other entity'' or a health care provider, which each have a different start digit. In the proposed rule, we explained that the number of digits of the HPID will not exceed the number permitted for identifiers in the relevant data fields of the standard transactions.

Comment: We received many comments regarding the proposed HPID format. The majority of the commenters supported the proposed format. A few commenters offered additional suggestions and questions, many of which were technical. One commenter responded to the following language in the proposed rule: ''that 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.'' (77 FR 22962). The commenter suggested that HHS adopt a format that would exceed capacity but was concerned that HHS would then expand the number of digits in the format identifier past 10 digits to increase capacity. Increasing the number of digits in the identifier though would not meet the Luhn check digit. This commenter emphasized that HHS should adopt a format with ample capacity in order to avoid the need to perform additional programming and testing of systems in the future.

Response: In the proposed rule, we did not intend to suggest that we would be increasing the length of the identifier when we stated we would add additional numeric digits. Instead, we meant that we would increase capacity by introducing a new start digit that still met the Luhn check digit logic; therefore, we believe that this commenter's concern has been adequately addressed.

Comment: A commenter supported the rule's proposal to adopt the ISO Standard 7812 format for the HPID and OEID, similar to the NPI. The commenter suggested that it may be helpful to provide more information about the ISO Standard 7812. For instance, information that the full identifier number under the ISO 7812 Standard is a composite of the ISO 80840 Issuer Identification Number (IIN), a number assigned by the holder of the IIN, and the Luhn modulus −10 check digit. The commenter stated this information is clearly provided in the NPI final rule.

Response: We appreciate the comment regarding the importance of providing information about the ISO 7812 Standard. For those readers interested in more background on the ISO 7812 Standard, we recommend that they refer to the discussion in the NPI final rule (69 FR 3442).

After consideration of the public comments received, we are finalizing the policy to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit without modification.

B. Adoption of the Other Entity Identifier (OEID)

In addition to proposing the adoption of an identifier for health plans, in the April 2012 proposed rule we proposed to adopt a data element that will serve as the OEID, which would be an identifier for other entities for use in standard transactions. We proposed that the OEID would be optional—other entities could choose to obtain one or not.

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 identified in standard transactions in the same fields and using the same type of identifiers as health plans. 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 recommended that HHS consider making these entities eligible to obtain an HPID when there is a clear case for them to be enumerated. Based on the NCVHS recommendation, we found that a clear case does exist for these other entities to be enumerated.

We proposed that the OEID would serve as an identifier for entities that are not health plans, health care providers, or individuals,[3] yet need to be identified in standard transactions. We proposed that these other entities would not be required to obtain an OEID, but that they could obtain one from the Enumeration System and use it where they need to be identified in covered transactions. We proposed that the OEID could also be used for any other lawful purpose. If they obtained an OEID, other entities would be expected to disclose it upon request to entities that need to identify the other entities in covered transactions.

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 proposed to adopt, the OEID would also follow ISO standard 7812, and be a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit. Consequently, entities would not need to significantly modify their information technology systems to accommodate the OEID since they would follow the same ISO standard as the HPID.

We solicited industry and stakeholder comments on the enumeration of other entities and adoption of the OEID for use in the standard transactions.

We received many comments on our proposal to adopt the OEID for use in the standard transactions.

Comment: Commenters requested that we provide greater clarification about the definition of an OEID as it relates to the eligibility to obtain an OEID. For example, a few commenters questioned whether or not a non-individual health care provider qualifies for an OEID and whether non-covered entities, such as auto liability and workers compensation carriers, are able to obtain OEIDs. A few other commenters suggested that the definition of OEID be further limited to entities that perform functions of a health plan and should not include healthcare clearinghouses because they state the only place the health care clearinghouse could be identified independently in the existing transactions is on the ISA envelope.

Response: The intent of the proposal for an OEID is to provide a mechanism that facilitates standardization to provide greater transparency in electronic transactions. Thus, we have proposed that the definition and eligibility for the OEID include a wide variety of entities, and have provided few limits on the types of entities that can obtain OEIDs. One limit is that it cannot be an individual. Another limit is that the entity cannot be eligible to obtain either an HPID or an NPI. The reason is to avoid having multiple and differing types of identifiers for the same entity. Therefore, if the non-individual health care provider is eligible for an NPI, it would not be eligible to obtain an OEID. On the other hand, HIPAA non-covered entities, such as auto liability and workers compensation carriers, would be eligible to obtain an OEID as long as they need to be identified in a HIPAA covered transaction. They are entities that are not individuals and not eligible to obtain an HPID or NPI. We included clearinghouses as an example in the proposed rule as our goal was to keep the definition broad so that use and requirements for the OEID in the standard transactions could be further developed in the future.

Comment: A few commenters requested clarification about whether specific entities are eligible to obtain an OEID, specifically atypical providers, accountable care organizations (ACOs), and clearinghouses. Some commenters recommended that we state clearly whether atypical providers are eligible to obtain an OEID. A few of these commenters stated that if atypical providers obtained OEIDs, they should be required to disclose them and use them to identify themselves in all standard transactions. A commenter stated that the OEID should be available to any entity that performs the functions of a payer but acts as an independent third party.

Response: We appreciate the comments about atypical providers. Atypical providers are individuals or organizations that furnish atypical or nontraditional services that are indirectly health-care related, such as taxi, home, and vehicle modification, insect control, habilitation, and respite services. We encourage entities to review the definition of health care provider in § 160.103 and the discussion of atypical providers in the NPI final rule (69 FR 3437) in determining their

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

eligibility to obtain an OEID. We decided to place few requirements on entities that obtain an OEID, because we wanted to allow industry business needs to drive industry use of the OEID, presumably through contractual arrangements.

A determination of eligibility for an OEID will be specific for each entity based on individual factors.

Comment: A commenter cautioned that if atypical providers are eligible to obtain OEIDs, the Health Care Provider Taxonomy code should not be included as a data field in the OEID application. These commenters stated that if all atypical non-individual providers qualify for an OEID and taxonomy code(s) are included in the data elements for the OEID application, it will require adding new taxonomy codes for this purpose, which will create a potential problem due to the structure of the code set.

Response: We are still developing the required data elements but do not anticipate using this taxonomy code.

Comment: A number of commenters requested that we provide clarification on the use of the OEID in the standard transactions. A commenter requested clarification on whether the OEID could be used in the provider identifier field, in some instances.

Response: We will provide further examples of potential ways the OEID can be used in the standard transactions outside of this final rule. In the meantime, we encourage those commenters and others to review the directions within the relevant implementation guides to determine the appropriateness of using an OEID in particular data fields.

Comment: Some commenters requested that the Department work with the appropriate standard development organizations to determine where the OEID should be included in the standard transactions. They emphasized that it is important to specify that the OEID should be used in all places in the standard transactions where the HPID can be used to avoid confusion and inconsistency. Other commenters suggested that there should be a pilot test of the OEID to determine if and what changes are needed to the standard transactions and the operating rules to clarify OEID use and requirements.

Response: We appreciate the commenters' interest in the development and use of the OEID. Our intent was to create a standard identifier and allow business needs and efficiencies to drive its adoption and uses. At this initial stage of implementation, we do not believe it is necessary yet to work with standards organizations to address this question or conduct independent pilot tests.

Comment: We received many comments regarding our proposal that the OEID be voluntary. Some commenters supported that the OEID be voluntary, while others advocated that the OEID should be mandatory. Supporters of a voluntary OEID believed that business needs will drive the use of the OEID and industry can refine OEID requirements as experience with the OEID is gained. In addition, some commenters believed that if the OEID were required it may result in entities that have no current business need to use an OEID nevertheless obtaining an OEID. Those commenters in support of the OEID being mandated advocated that the OEID requirements match the HPID requirements to limit system requirement variability. They believed that this approach promotes administrative simplification and encourages a greater return on investment. They suggested that a voluntary OEID would result in additional changes to existing connections as some entities replace their current identifiers and thus would introduce another level of complexity. They added that a voluntary enumeration system would add just another identifier option for other entities to use in the standard transactions and would not necessarily lead to standardization. One commenter even suggested that the Tax Identification Number be required rather than create a new identifier.

Response: We created the OEID based on industry input and NCVHS recommendations that it would be helpful to have a standard identifier for entities that need to be identified in the standard transactions but that do not meet the definition of a health plan. The value of the OEID would be to create greater standardization in the transaction so that all parties that needed to be identified in the transactions would have a standard identifier that would be listed in a publicly available searchable database. Because of the diversity of entity types that may need an OEID and potential new uses for the OEID, we believe it would be helpful to begin with a voluntary approach that allows for gradual implementation and improvised use based on industry needs and practices. We recognize this approach may have certain risks associated with it, but we believe the risk of harm to the industry is relatively low and the potential benefit quite high.

Comment: A commenter suggested that the Secretary should require all covered entities to require any trading partner that would qualify for an OEID to be enumerated by contract, trading partner agreement, or business associate agreement to require that the identifier be used according to the transaction standards.

Response: We reiterate that covered entities could require their trading partners and business associates to obtain and use an OEID, and we believe that entities will take advantage of that approach if it is appropriate for them.

Comment: A few commenters suggested that other entities be able to obtain more than a single OEID for use in the standard transactions.

Response: At this point, we believe this proposed approach has the potential to lead to significant confusion while undermining the goal of having one unique number tied to each entity.

After consideration of the public comments received, we are finalizing the OEID requirements without modification.

C. Assignment of the HPID and OEID—The Enumeration System

We proposed in 45 CFR 162.508, that the Enumeration System would assign unique HPIDs and OEIDs to eligible health plans and eligible other entities, respectively. Once operational, the Enumeration System will be a comprehensive system for uniquely identifying and enumerating all eligible health plans and other entities. It will collect and maintain certain identifying and administrative information about CHPs, SHPs, and other entities. The Enumeration System will also disseminate information through a publicly available searchable database or through downloadable files.

HPIDs and OEIDs will 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, will be required to provide certain identifying and administrative information for verification and eligibility determinations during the application process. For assistance, a help desk or other applicant assistance functions will be available to assist with and troubleshoot the online application process.

We proposed that the Enumeration System would also be able to deactivate or reactivate an HPID or OEID based on receipt of sufficient information to justify deactivation or reactivation. Deactivation of an HPID may occur in the event of fraudulent or unlawful use of the HPID by the health plan itself or another 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 for the fraudulent or unlawful use of an OEID by itself or another 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 example, 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 a SHP determines that it again needs its HPID.

With that said, upon further reviewing the proposed regulation text in the April 2012 proposed rule, we noticed that while we had discussed having the Enumeration System be able to reactivate a deactivated OEID or HPID in the preamble of the April 2012 proposed rule, we unintentionally omitted ''or OEID'' in the proposed § 162.508(c) that would have enabled the Enumeration System to deactivate an OEID, as it would an HPID. Because this reflects a technical drafting error that was obviously inconsistent with the preamble discussion at (77 FR 22963), and further, § 162.508(d) clearly presupposes that the Enumeration System would have that authority, we are finalizing § 162.508(c) with ''or OEID'' inserted.

We solicited stakeholder comment on our proposals regarding the enumeration system and process.

Comment: We received numerous comments on the type of information to be collected in the Enumeration System. Some commenters recommended that HHS collect only ''minimally necessary'' information that does not include confidential business information in order to decrease burden. These commenters recommended collecting data elements, such, as name of health plan, tax identification number, address, EDI contact phone number, email address, other legacy identifiers, and the BIN/IIN or PCN number associated with that health plan. Other commenters suggested collecting a robust amount of information in the Enumeration System. These commenters suggested collecting routing and demographic information. For example, all demographic information related to that health plan and all information necessary to enroll with the health plan to send and receive standard transactions as well as transmit standard transactions to the correct destination. In addition, they recommended that the database include information to identify the health plan type, the health plan's relationship with any other entity serving in a health plan role, and if the health plan utilizes a different network of physicians through a rental network of the physician network by region. These commenters also suggested that specific routing information for each standard transaction for each mode of transaction (that is, nearly real-time batch) be included in the database. Many commenters stated they could not provide detailed feedback on the design and information collected in the Enumeration System because they were not in the proposed rule and they would like the opportunity to review and comment on this information.

Response: We appreciate commenters' suggestions regarding the type of information to be collected in the Enumeration System. The purpose of the Enumeration System is to provide an identifier and collect only that amount of information that is necessary to uniquely identify a health plan and ensure that a link exists between a CHP and its SHPs. We have not at this point developed the data fields or identified the specific information we will need to collect to achieve the purpose of the Enumeration System. At this point, we believe that only minimally necessary information will be collected in the Enumeration System, based on the current limited purpose of the Enumeration System. When we develop the data fields, we will take into consideration the comments offered to the proposed rule and further consult industry. In the future, if and when the purpose and use of the Enumeration System expands, we will work with industry to identify other data elements that will need to be collected.

Comment: A commenter requested specific guidance that would clarify when an HPID that has been issued for a health plan can continue to be used after that health plan has undergone a business merger or acquisition.

Response: If a health plan wants to retain its HPID after a merger or acquisition, it should update its health-plan related data in the Enumeration System. If the health plan does not want to retain its HPID, it should deactivate its HPID. We anticipate that there will be more guidance available on operational questions, such as these, as the Enumeration System is implemented.

Comment: Some commenters stressed the importance of the Enumeration System having both a look-up capability, similar to that for the NPI, and downloadable files to easily disseminate information about HPIDs and OEIDs.

Response: We anticipate that both a look-up function and downloadable files will be available in the future.

Comment: Some commenters asked when entities could apply for identifiers from the Enumeration System.

Response: While we anticipate entities may access the system and learn more about the application process and Enumeration System on October 1, 2012, we anticipate providing additional information about the Enumeration System in the near future.

Comment: A few commenters provided other suggestions about system design and specific system features. For instance, a commenter stated that all user activity should be conducted through an ''account'' and a user is granted access to the system by a system administrator. Through the establishment of an ''account'' in the system, the user would have the ability to apply for identifiers, maintain information associated with identifiers, download reports, establish users who could access or perform activities related to the account, transfer control over an identifier to another account, and upload batch files. The benefit of this ''account'' approach is that it would enable an administrator to access and manage all identifiers for itself and subordinate plans and other entities. It would also enable the Enumeration System administrator to deal with fewer entities, reduce phone calls, and increase accuracy and efficiency. Another commenter suggested that the Enumeration System have a listserv function so entities could be notified of any changes in identifier information. Another commenter suggested that the database have the capability to provide near real-time updates and the ability to electronically ping databases from a practice management system or other provider administrative systems based on selected search criteria.

Response: We are still in the process of collecting information and developing the Enumeration System and will take these comments into consideration in the process.

After consideration of the public comments received, we are finalizing the Enumeration System policies without modification with the one minor exception of inserting ''or OEID'' in § 162.508(c).

D. Other Considerations

1. Pharmacy Transactions

In the April 2012 proposed rule, we noted that currently, the pharmacy industry utilizes two unique identifiers to identify entities responsible for administering claims 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.

The BIN/IIN and PCN 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. We took note of the NCPDP's testimony from the July 20120 NCVHS Subcommittee on Standards meeting that the use of these two identifiers has been very effective in ensuring efficient, timely prescription claim processing.

We also considered testimony from the July 2010 NCVHS meeting 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. We considered the claims 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 and cards would need to be re-issued with the HPID, with no direct patient or pharmacy benefit.

There was also testimony 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 intentionally not defined in the standard. However, the use of the BIN and PCN fields is mandatory.

We reviewed the September 30, 2010 NCVHS recommendation letter to the Secretary, where the NCVHS observed that retail pharmacy transactions utilize the BIN/IIN and/or PCN identifier to facilitate their transaction processing, and that changing to another 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.

We further considered the NCVHS recommendation 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 use of HPID be required on the HIPAA-named standard transactions for retail pharmacy.

In the April 2012 proposed rule, we did not propose any changes to the NCPDP Version D.0 standard. So where the D.0 calls for the BIN/IIN and PCN to be used, this final rule has no impact or effect because health plans are not being identified in those fields. We clarified that we do not believe that the HPID should be required in place of the existing BIN/IIN and PCN identifier in retail pharmacy transactions.

We received a few comments regarding the use of the HPID in pharmacy transactions.

Comment: Several commenters did not believe the HPID should be used in place of the BIN/IIN and PCN in pharmacy transactions, but that the HPID be required on the HIPAA-named standard transactions for retail pharmacy.

Response: We thank commenters for their comments.

After consideration of the public comments received, we are finalizing the policy regarding the use of the HPID in pharmacy transactions without modification.

2. Definition of Covered Health Care Provider

We proposed to move the definition of ''covered health care provider'' from 45 CFR 162.402 to 45 CFR 162.103 because the term has a broader application beyond just Subpart D. We did not receive any comments on the proposal to move the definition of ''covered health care provider'' from 45 CFR 162.402 to 45 CFR 162.103, and therefore, we are finalizing this change as proposed.

E. Effective Date and Compliance Requirements 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. The effective date would mark the beginning of the implementation period for the HPID, which we indicated in the proposed rule is the day we expect would be the first day health plans could apply to obtain an HPID and the first day an entity could apply to obtain an OEID from the Enumeration System. We would like to clarify that entities will not be able to obtain identifiers on that date, but that they may begin to access the Enumeration System and learn more about the application process. We proposed 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 proposed, would be October 1, 2014. The compliance date for small health plans would be October 1, 2015. Neither small health plans nor other covered entities would be prohibited from using HPIDs in their transactions at any time before their respective compliance dates.

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 date by which an entity had to obtain and use an NPI in the standard transactions. We consequently interpreted section of the 1104(c)(1) of the Affordable Care Act as specifying October 1, 2012 as the effective date of the final rule, the date on which the policies take effect and the implementation period for the HPID begins.

We solicited comment on the effective and compliance dates for the HPID.

Comment: We received extensive comments on the compliance dates and implementation requirements of HPID. The majority of commenters emphasized the need for additional time to test and implement HPID, and requested that we establish a date by which health plans should obtain their HPIDs in advance of the date by which covered entities are required to use the HPID in standard transactions. These commenters emphasized that health plans must obtain their identifiers and communicate them to all covered entities well in advance of the required use of the HPID in the standard transactions. This additional time would allow for internal system changes to accommodate the HPID and for extensive testing among trading partners. Commenters explained that ample time to perform system changes and testing is critical to the successful implementation of the HPID by all covered entities. Implied in many of these comments was that because covered transactions virtually always involve multiple parties, a single ''go-live'' date by which all covered entities must use the HPID should be established.

Response: We have considered the significant operational challenges described by commenters that occur as a result of a single compliance date for both the health plans to obtain HPIDs and covered entities to use the HPIDs to identify health plans in the standard transactions. We agree that the successful implementation of HPID could be jeopardized. Therefore, in this final rule we are changing the approach to compliance with new implementation requirements shown in Chart 1.

Comment: Commenters warned that if ICD–10 and the HPID have the same compliance date of October 1, 2014, it will be financially and administratively burdensome. In addition, commenters suggested that it would be difficult to determine the cause of any claim delays or problems with implementation.

Response: We agree that implementation of these two initiatives at the same time could impose technical and operational problems, which would be difficult to diagnose and address.

Comment: Some commenters suggested that there be a dual use period for implementation of HPID, during which time both legacy health plan identifiers and the new health plan ID is permitted in the transactions. These commenters suggested that the dual use period would assist industry during simultaneous compliance for both ICD–10 and HPID. A dual use period was allowed in the transition to NPI and this provided the ability to validate crosswalks and resolve any implementation issues prior to full transition. Finally, these commenters stated that a dual use period would allow CMS to monitor the rate of adoption and readiness of the industry through metric reporting.

Response: While we believe that a period of dual usage would be helpful, we do not believe it necessary to mandate such a dual use period. The new HPID compliance dates will address many of the concerns raised by these commenters. The compliance date for HPID to be used in the standard transaction, which we are now referring to as the full implementation date, is no longer the same date as for ICD–10. In addition, in contrast to the single compliance date for NPI, the new phased-in approach for HPIDs, where there is lag time between when health plans are required to obtain an HPID and when covered entities are required to begin using HPIDs in the standard transactions, will allow the opportunity for dual use and sufficient time for a successful transition. The additional time will allow industry the opportunity to perform extensive testing of the HPID prior to full implementation.

Comment: Commenters recommended that large and small health plans have the same full implementation date by which all covered entities must use the HPID should be established.

Response: Based on the comments above regarding the compliance dates for HPID, the following changes have been made to the implementation requirements to ensure a smooth transition to the HPID. The effective date of this final rule is 60 days after the publication date of this rule. Compliance with the implementation specifications for obtaining the HPID will be 2 years after the effective date of this rule, except for small health plans, which will have 3 years after the effective date of this rule. Full implementation of the HPID—or the date by which all covered entities must use HPIDs to identify health plans that have an HPID—will be 4 years after the effective date of this rule. To reflect our intention of having a single date by which all covered entities must have fully implemented the HPID, we are referring to 4 years after the effective date of this rule) as the full implementation date for the HPID. We determined that 2 years after the time health plans (other than small health plans) are required to have obtained their HPIDs and 1 year after the time when small health plans are required to have obtained their HPIDs provides more than sufficient time for all covered entities to make any necessary system changes prior to the full implementation date of 4 years after the effective date of this rule. In Chart 1, we provide the actual HPID compliance and implementations dates based on the timeframes discussed in this section of the final rule. These dates are also reflected in the **DATES** section of this final rule.

CHART 1—HPID IMPLEMENTATION

Entity type	Compliance date for obtaining HPID	Full implementation date—for using HPID in standard transactions
Health Plans, except small health plans	November 5, 2014	November 7, 2016.
Small Health Plans	November 5, 2015	November 7, 2016.
Healthcare Clearinghouses	N/A	November 7, 2016.
Healthcare Providers	N/A	November 7, 2016.

After consideration of the public comments received, we are modifying the compliance requirements of the HPID and have made changes to the regulation text to reflect these new dates. We have revised § 162.504(a) to reflect the new policy that all covered entities are required to use HPIDs in the standard transaction by 4 years after the effective date of this rule and removed references to compliance dates for covered health care providers and health care clearinghouses that are no longer necessary.

III. Addition to the National Provider Identifier Requirements

A. Background

As discussed in section I of this final 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 proposed an addition to the requirements in 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 when 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 final 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 published in the April 12, 2012 **Federal Register** (77 FR 22072) and is hereinafter referred to as the April 2012 final rule), CMS requires Part D sponsors to include an active and valid prescriber NPI on prescription drug event records (PDEs) that they submit to CMS beginning January 1, 2013. This change 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 by paying the claim and obtaining the valid NPI afterwards (77 FR 22075).

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. However, Part D sponsors and pharmacies generally have no regulatory leverage or other recourse over prescribers who do not have NPIs or do not disclose them. In the latter case, the sponsors and pharmacies 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. This final rule addresses the problems that are presented by prescribers who do not have NPIs or do not disclose them, by proposing an additional requirement in the NPI regulations.

B. Provisions for a Requirement To Obtain and Use NPIs

We proposed 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 we proposed 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). For example, if the final rule was effective on October 1, 2012, covered organization health care providers would have to meet the requirement by April 7, 2013.

We proposed that 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 requirement represents a narrow exception to the position we took in the 2004 NPI final rule. In 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.''

We still do not consider noncovered health care providers that are prescribers to be subparts of organization health care providers, and we did not propose that they would not be legal entities in their own right. This final rule closes a gap in the NPI rule by virtue of the types of relationships that covered organization health care providers have with noncovered individual health care providers.

The providers we intend 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, which does not identify them as individuals, or are using no identifier.

We believe this final rule 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 final 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.

We proposed that 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 have 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 this final rule, as we believe it encompass virtually all prescribers who are not currently required to obtain and disclose an individual NPI. Very limited 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-paying patients. Even with respect to these prescribers, we hope this final rule highlights the importance of voluntarily obtaining NPIs to facilitate their patients' access to prescribed items.

We believe this final rule 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 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, this final rule will 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. This, in turn, would support program integrity efforts described in the April 2012 final rule 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. Dummy and 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 final rule further improves 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 final rule makes such action by Part D sponsors unnecessary by virtually ensuring the availability of prescriber NPIs for PDEs.

This final rule 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 is lessened. Pharmacies and payers should no longer have to cross-check provider identifier databases to determine if the prescriber has an NPI when an alternate identifier was used, or contact the prescriber. Moreover, pharmacies and prescribers should no longer have to respond to inquiries from payers regarding the existence of an NPI because an alternate prescriber identifier is used.

The final rule 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. This final rule accommodates 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.

This final rule takes into account the particular needs of pharmacies for an NPI.

While some prescribers will have to apply to obtain an NPI under this requirement, the NPI is free of charge and requires only the completion of a three-page application form that primarily seeks identifying and location information. Thus, we believe the reduction in administrative burden that will be achieved by this final rule 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 submitted through January 2012 contained valid prescriber NPIs even though alternate prescriber IDs are currently permitted. Less than 1 percent of PDEs were submitted without a valid identifier. Nevertheless, while the vast majority of Medicare Part D claims contain individual NPIs, 10 percent do not. We note that this submission rate increased incrementally through the latter months of 2011, likely due to the issuance of the CY 2012 Part D final call letter on April 4, 2011, signaling that CMS was considering only accepting individual prescriber NPIs on PDEs for CY2013, the subsequent CMS outreach to sponsors and pharmacies, and the CMS April 12, 2012 final rule requiring individual prescriber NPIs be submitted with PDEs. This final rule, coupled with the CMS April 12, 2012 final rule, will help ensure this last 10 percent is addressed.

After discussions with representatives of the provider data industry in the fall of 2011, we estimated at that time that there were approximately 1.4 million active prescribers in the United States, of which approximately 160,000 did not have an NPI. It is these prescribers who will have to obtain an NPI under this final rule.

Comment: A national and a state hospital association, several health care provider associations, a standards organization and a company offering connectivity solutions to health care providers, supported our proposal. The state hospital association stated that it was aware of patients being unable to fill pharmacy prescriptions because the prescriber NPIs were not available and had already encouraged its members to obtain NPIs for interns, residents and other prescribers. One provider association specifically acknowledged that our proposal would improve coordination of patient care, increase anti-fraud detection capabilities, and is in line with the goal of modernizing and reforming the health system at large. The company agreed with our statement that, because there are few health care providers who do not already have an individual NPI, our proposal would have little impact on health care providers and the industry at large.

Response: We appreciate and agree with these comments. We are concerned about any pharmacy claims being denied for lack of a prescriber NPI, for instance, because the payer requires an individual NPI to be submitted on the pharmacy claim, especially when the payer is not required to pay the claim and obtain the NPI later. We believe this final rule will address this issue.

Comment: Two prescription health plans/pharmacy benefit managers supported the proposal, but encouraged us to go further and require all prescribers to obtain and disclose individual NPIs. Another commenter, a hospital association, echoed the idea that all prescribers be required to obtain and disclose individual NPIs. A third commenter recommended expanding the requirement to all individual referring, ordering, and rendering providers. In the alternative, one of the commenters expressed the hope that our rule would highlight the importance of health care providers voluntarily obtaining individual NPIs to facilitate their patients' access to prescribed items.

Response: We appreciate the support for our proposal and also hope that all health care providers who do not currently have an individual NPI will voluntarily obtain them and not wait to be directed to do so by an organization covered health care provider of whom they are a member, are employed by, or with whom they have a contractual relationship. We note that HIPAA does not give us direct authority over health care providers who are not covered entities.

In addition, our proposal was intended to address specific problems that are presented by prescribers who do not have NPIs or do not disclose them. Therefore, our proposal was designed in consideration of our authority under HIPAA and narrowly tailored to address these specific problems.

Comment: A commenter, expressed concern about the compliance burden placed on hospitals, stating that significant staff time would be required to mandate, track and disclose NPIs for all prescribers who are a member, employee, or contract with a hospital, because it would necessitate the maintenance of a central database that would have to provide 24-hour staffing to disclose these NPIs to retail pharmacies. Another commenter, urged us not to underestimate the impact of this final rule on software vendors and their customers, especially those in the hospital systems market, without providing any specific details about the concerns. However, another commenter agreed with our statement that organization covered health care providers may have several alternatives for compliance.

Response: The proposed rule did not specify how organization covered health care providers should impose the requirement on individual health care providers who are prescribers. We tried to be very clear in the preamble of the proposed rule that organization health care providers may have a number of alternatives for doing so, for example through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures. Organization covered health care providers may choose a proactive approach to ensure the requirement it imposes upon individual prescribers is followed by the prescribers. Other organizations may choose to take action upon any inquiries or complaints that a prescriber does not have an NPI or has not disclosed it on prescriptions, for instance. With respect to the latter, organization covered health care providers may want to also voluntarily impose an additional requirement on prescribers to proactively disclose their individual NPIs, so the organization covered health care provider receives as few inquiries or complaints as possible. In addition, we note that pharmacies and payers have access to prescriber NPI databases which are routinely consulted at point-of-sale, to which the additional NPIs that must be obtained under this final rule will be added. In this regard, we fully expect that prescribers will abide by an organization covered health care provider's requirement to obtain an NPI, if they have not already done so voluntarily. We do not expect hospitals to respond to NPI inquiries on a 24-hour basis, but rather, to respond in a reasonable timeframe to what we believe will be infrequent inquiries about prescriber NPIs, or virtually no inquiries, if the prescribers proactively disclose them on the prescriptions they write. We note that such action by prescribers will assist their patients in obtaining the medications they have prescribed for them.

With respect to hospital computer updates, we note that individual NPIs are already obtained by prescribers, who are members of, employed by, or contracted with, hospitals, and disclosed to pharmacies. Our proposal merely marginally expands the pool of prescribers who will be required, by virtue of certain relationships with organization covered health care providers, to obtain individual NPIs and disclose them. While some hospitals may desire to implement computer updates to prevent the use of an alternate prescriber identifier on a prescription, it is not required by this final rule. Thus, we do not believe compliance with this new requirement will necessarily be burdensome.

Comment: A commenter responded to our specific request for comments on whether our proposal would reach residents and interns by stating that it would. Another commenter expressed concerns about our proposal's applicability to residents, interns and medical students, stating that residents and interns are not in full control of what is ordered and are typically acting upon an attending physician's directive, and that medical students would not order or prescribe without counter signature. This commenter suggested that residents obtain an NPI for use during their training tenure and later, a different one for actual practice. A third commenter requested that we require residents, medical students, and prescribers coming from abroad to obtain their NPIs before they leave training/school and before they enter the United States, respectively.

Response: With respect to the concerns expressed about the applicability of our proposal to resident, interns, and medical students, and what their authority is to prescribe, our proposal applies to all health care providers who are prescribers. Thus, to the extent a resident, for example, is a prescriber under applicable state law, and is reached by this new NPI requirement by virtue of his or her relationship with an organization covered health care provider, such resident will have to obtain and disclose his or her individual NPI. While there is currently no NPI type that identifies a person as being in his or her residency, for purposes of data analysis, a physician can identify the period of time during which they are/were a resident with certainty in any outlier analysis. In addition, the NPI is intended to be a lasting identifier for the health care provider to which or whom it has been assigned. In the 2004 NPI final rule (69 FR 3441), we stated that, ''[f]or health care providers with an 'Entity type code' of 1, the NPI will be a permanent identifier, assigned for life, unless circumstances justify deactivation.'' Residents and other health care providers en route to this country should be reached by this final rule by virtue of their relationships with the organization covered health care providers pursuant to which they are prescribers. If they are not prescribers, they will not be reached by this final rule.

Comment: A commenter suggested that we replace ''NPI'' in the regulation text with ''Type 1 NPI.'' The commenter also suggested that, in order to be more precise as to our intent, we add the word ''proactively'' before ''disclose'' in § 162.410(b)(2) so that the regulation would read ''To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, proactively disclose the NPI * * *''

Response: We disagree with the commenter about the suggestion to add ''Type 1'' to the regulations text. Only individuals may obtain a Type 1 NPI, so adding ''Type 1'' to the regulation text as the commenter suggested would be redundant. With respect to the comment that urges us to add the term ''proactively'' to the regulation, we do not require other covered health care providers to proactively disclose their NPIs, and we do not believe it would be appropriate to single out individual prescriber health care providers to do so. We did not propose such a change, but we do encourage organization covered health care providers to require prescribers who are members, employees, or with whom they have a contractual relationship, to proactively disclose their Type 1 NPIs on the prescriptions they write, so the pharmacy has it for the claim and there will be no need for additional follow-up by the pharmacy or payer.

Comment: A commenter stated that there appears to be a loophole in the regulation text, when a provider who is not contracted (for example, out of network), but who bills a health plan, would not need to obtain an individual NPI.

Response: We believe the commenter misunderstands the applicability of our proposal. Our proposal applies to organization covered health care providers. Health plans are not organization covered health care providers. In addition, to the extent a health care provider bills a health plan, such health care provider, if a covered health care provider, would be required to obtain an NPI under HIPAA. If the prescriber is not a covered health care provider but is, for example, a member of a group practice that does bill health plans, this final rule will reach that prescriber by virtue of his or her relationship with the group practice.

Comment: A few commenters made a number of suggestions concerning data enhancements to the NPPES data base and NPI registry.

Response: Our proposal was very limited. We consider these comments, suggesting the creation of new types of NPI numbers and data base enhancements, to be beyond the scope of our proposal, although we appreciate suggestions for future improvements.

After consideration of the public comments received, we are finalizing these provisions as proposed

C. Effective and Compliance Dates

We proposed 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 60 days after the date of publication; then 180 days after the effective date, 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, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

Comment: A commenter stated that the NPI implementation date of October 1, 2013 is not attainable. Other commenters requested that the compliance deadline be delayed until 1 year after the publication of the final rule so that organization covered health care providers have sufficient time to implement the requirement.

Response: We are not certain why the other commenter is referring to a compliance date of October 1, 2013. We proposed that the compliance date for the modification to the NPI rule would be 180 days after the effective date of the final rule. This final rule is effective on 60 days after the date of publication, which means that the compliance date is 180 days after the effective date of this final rule. In other words, by 180 days after the effective date of this final rule, a organization covered health care provider that has 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 obtain an NPI from NPPES and, 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.

Comment: A few commenters requested that CMS align the compliance date of this NPI requirement with the compliance date in the Medicare Part D program requirement that PDEs be submitted with individual NPIs beginning January 1, 2013.

Response: The Medicare Part D Program PDE requirement that PDEs must include a valid and active NPI is effective on January 1, 2013. In order to align the compliance date of the Part D requirement with the NPI requirement adopted in this final rule, CMS would have to delay the new requirement for PDEs or we would have to provide a compliance date for the NPI requirement that is substantially shorter than 180 days. We are not willing to shorten the 180-day compliance date in order to give covered organization health care providers sufficient time to comply with this final rule. Further, the CMS Medicare Part D program requirement is not within the scope of this regulation. Therefore, we cannot accept the commenter's suggestion.

After consideration of the public comments received, we are finalizing these provisions as proposed.

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

A. Background

As discussed in section I. of this final 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 ''2009 ICD–10 final rule''). The 2009 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 2009 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 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 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 2009 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 2009 ICD–10 final rule. The analysis in the 2009 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 2009 ICD–10 final rule (74 FR 3334), ''[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.'' Based on NCVHS recommendations and industry feedback received on the 2009 ICD–10 final rule (74 FR 3334), 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.'' In the 2009 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 the implementation of Version 5010 have affected ICD–10 planning and transition timelines.

2. Providers' Concerns That Other Statutory Initiatives Are Stretching Their Resources

Since publication of the 2009 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 (ARRA) (Pub. L. 111–5). Medicare and Medicaid incentive payments are available to eligible professionals and hospitals for adopting 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 (PQRS) is currently a voluntary reporting program that provides incentive 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. However, eligible professionals and group practices who do not meet the reporting requirements will start receiving penalties in 2015. The Electronic Prescribing (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 2.

CHART 2—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.
4 years from effective date of this rule (For more information see section II.E. of this final rule.).	• 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 proposed to extend the compliance date for ICD–10.

B. Public Comments on the 1-Year Delay of ICD–10

Faced with growing evidence that a group of providers would not be ready to transition to ICD–10 on October 1, 2013, and the possibility that payment for millions of health care claims would be delayed, we considered the following options before proposing a 1-year delay of the compliance date in the April 2012 proposed rule:

Option 1: Maintain October 1, 2013 deadline
Option 2: Maintain the October 1, 2013 compliance date for ICD–10–PCS (procedure codes) and only delay the compliance date for ICD–10–CM (diagnosis codes)
Option 3: Forgo ICD–10 and wait for ICD–11
Option 4: Mandate a uniform delay of the compliance date for ICD–10

We proposed Option 4, mandate a uniform delay for 1 year of the ICD–10 compliance date, because we believed it would be the most effective way to mitigate the significant systemic disruptions and payment delays that could result if a large percentage of providers are not ready to implement ICD–10 on October 1, 2013. In addition, as the Regulatory Impact Analysis (RIA) in this final rule indicates, Option 4 is most likely to minimize the costs of delay and to maximize the benefits to providers who need more time to implement.

Of the more than 500 public comments submitted, there was some support for each of the options considered. The compliance date of October 1, 2014, as proposed in the April 2012 proposed rule, was supported by the highest number of public comments in comparison to the other options. We summarize the

[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.

options from the April 2012 proposed rule below, present the public comments related to them, and provide our responses. We also summarize and respond to additional options and suggestions commenters presented that were not considered in the April 2012 proposed rule. Finally, we summarize some of the comments that address issues outside the scope of this regulation.

1. Option 1: Maintain October 1, 2013 Deadline

Segments of the health care industry expressed support for staying the course regarding the October 2013 compliance 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.''[8]

Comment: Some commenters recommended maintaining the October 1, 2013 deadline. Some commenters argued that considerable expense has been expended by many entities in order to meet the October 1, 2013 deadline, and any delay will be costly. Another commenter described the investment of time and resources that has been spent on education, outreach, and policy discussions in order to meet the October 1, 2013 compliance date. Some commenters noted the costs that would be incurred by coders, students, teaching institutions, and training programs if the compliance date were delayed. Students and teaching programs have invested much in training geared toward an October 1, 2013 compliance date.

One commenter noted that, among the downsides to delaying implementation of ICD–10, if we continue to use current codes, the ability to progress population-based healthcare and improve patient care will be limited. Commenters suggested that a delay prolongs the period until industry can use the improved code sets that support the improvement of quality and outcomes data, cost-effective approaches to delivering care, and information for better research.

Another commenter urged no delay, noting that the U.S. health care industry has known for at least 15 years that ICD–10 would be adopted as a replacement for the severely outdated and broken ICD–9. The commenter stated that the industry has had 3 years to prepare, since the publication of the ICD–10 final rule, and, therefore, it does not seem likely that the provision of more time, by itself, will be sufficient to ensure those lagging in ICD–10 will be ready by a delayed compliance date.

Other commenters recommended that if a delay is necessary, that it be for less than 1 year, citing similar reasons to those already described.

One commenter suggested that maintaining the October 1, 2013 compliance date would be difficult because the ICD–10 project timelines for both physicians and vendors—on which physicians are often dependent—were affected by the obstacles associated with the implementation of Version 5010. Another commenter argued that the survey results used in the RIA that indicated that 25 percent of physicians did not think they were prepared for IC–10 may well overestimate the percentage of physicians who would be well-prepared for an October 1, 2013 compliance date, and that maintaining the October 1, 2013 date would be ill-advised.

Response: We recognize that many individual entities that were on target to meet the October 1, 2013 deadline will be financially impacted by a delay. We also recognize that there are opportunity costs associated with a delay, such as a delay in taking advantage of the improved code sets that support the improvement of quality and outcomes data, cost-effective approaches to delivering care, and information for better research. But we believe that the risk of a major disruption in physicians' reimbursements nationwide and the possible effects on patient care outweighs those costs.

As we indicated in the April 2012 proposed rule, it is clear to us that a significant number of health care entities will not be prepared to meet an October 1, 2013 compliance date. Reasons for this include that entities may not have altered their systems, thoroughly analyzed their processes, changed their forms, prepared for training their personnel, begun testing their internal systems, or are not in a financial position to begin these preparations.

While we cannot project precisely what percentage of certain sectors of the health care industry would not be prepared for an October 1, 2013 deadline, the studies we have used in the RIA of this final rule reflect that the numbers are significant enough to cause a disruption in health care claim payments. We project a number of quantifiable negative consequences of such a disruption in the RIA and believe that there may be a number of unanticipated costs as well, including possible indirect economic impacts on related industries and the economy at large.

It is also likely that health care entities have stopped or slowed their preparations for an October 1, 2013 deadline since the Secretary announced in February 2012 that a delay would be considered through rulemaking. Because of this, there may be more entities that would be unprepared for an October 1, 2013 deadline than what we predicted in the April 2012 proposed rule.

We believe a delay of the ICD–10 compliance date will increase the readiness of the industry at large, and thus avoid a large disruption in health care claim payments. Entities that were not on schedule to be ready by October 1, 2013 can use the time to become prepared, and entities that are on schedule can use the delay to conduct more thorough testing and work with their trading partners to decrease the possibility of unforeseen obstacles to implementation and increase the possibility of a smooth transition.

We recognize that the 1-year delay in compliance date does not guarantee that entities will use the time to become better prepared to meet the original compliance date of October 1, 2013. However, additional activities are planned to mitigate this risk. During the 1-year delay, we expect to increase education and outreach events and to work with industry on improvements to the overall standards implementation process.

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

In the April 2012 proposed rule, we considered a split implementation alternative: Maintaining the compliance date for ICD–10–PCS, which is used for inpatient hospital procedure coding, 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–

[8] See ''Survey: Industry Reaction to Potential Delay of ICD–10—A Delay will be Costly, but Manageable * * * Unless it's more than a Year,'' Edifecs, February 27, 2012: *http://www.edifecs.com/downloads/EdifecsSurvey-ICD10Delay.pdf.*

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.

Comment: Some commenters believed that a split implementation of the ICD–10 procedure versus diagnosis codes would be an appropriate approach. Moving first to adopt ICD–10–PCS for the inpatient setting, commenters stated, would permit HHS and the industry to evaluate the impact on a defined part of the health care system and better inform challenges and solutions before moving the broader health care industry to ICD–10–CM codes.

One commenter noted that moving to adopt ICD–10–PCS for the inpatient setting first would alleviate the issue of the lack of granular coding for inpatient procedures, a concern vocalized by both hospitals and device manufacturers.

Other commenters argued against mandating different compliance dates for procedure and diagnosis codes. One commenter stated that a split approach would result in significant increases in costs to vendors because they would have to support dual systems. These costs would then be passed on to clients. Another commenter noted that a split approach would be costly with regard to the coordination of concurrent payer rules for ICD–9 and ICD–10 as applied to adjudication, duplicate claims checking, and fraud and abuse. The same commenter stated that there would be added complexities for clearinghouses because they would be running dual systems.

Other commenters argued that splitting the compliance date could confuse certain providers because of the overlap of hospitals and ambulatory sites of services in some contexts. Another commenter argued that splitting the implementation date would have three consequences: Added cost to support dual coding systems and the analyses, coding, and testing that each of the two code sets would require before implementation; increased provider confusion because the industry is supporting both code sets; and the need for a complete rewrite of CMS' diagnostic related groups (DRGs). This would eventually have an impact on revenue neutrality, the commenter suggested. Staggered implementation would also make interpretation of data difficult, the commenter added.

Response: We agree with commenters that argue against a phased-in approach to implementation of ICD–10–PCS followed at a later date by ICD–10–CM. We believe that different compliance dates for diagnostic and procedure codes would burden the health care industry with a substantially greater cost than a uniform implementation because many sectors of the health care industry would have to run dual systems. This option would also place considerably more burden on hospitals because they would effectively have to implement ICD–10 twice: once in 2013 for ICD–10–PCS and then again at a later date for ICD–10–CM, increasing their implementation costs.

Further, there is a risk that a split implementation of procedure and diagnostic codes would render an operationally difficult implementation of the new code set even more difficult. These operational complexities would translate into added costs for all parties. Also, where a split-compliance approach contributes its own implementation challenges—that is, complexities in terms of dual processing and dual payer rules—we do not believe that HHS would easily be able to derive useful lessons that could applied to a successive implementation of ICD–10–CM.

Given that the costs of such an approach would be greater than a uniform delay of ICD–10–PCS and ICD–10–CM, and that the experience of a phased approach would yield few beneficial lessons that could be applied to implementation of ICD–10–CM for the broader industry, we do not support such an approach.

Comment: Some commenters suggested a related option of adopting ICD–10–PCS and ICD–10–CM both, but only in the inpatient setting. One commenter stated that this would mirror the approach taken by other nations, and would capture much of the nation's public health data. Commenters noted that moving to ICD–10–CM in the inpatient setting would provide data that would inform a decision whether to move to ICD–10–CM in outpatient settings.

One commenter suggested implementing a small ''subset'' of ICD–10–CM in the outpatient setting and excluding certain providers from detailed requirements. The commenter referred to Germany's approach in this regard.

Response: Both these approaches would appear to have the same costs and involve the same complexities as implementing ICD–10–PCS first and ICD–10–CM later: (1) Many entities would be required to maintain dual processing, which is costly and adds complexity; (2) there would be confusion among providers that are in settings where there is overlap between inpatient and outpatient environments or environments where ICD–9 and the small subset of ICD–10–CM would be used; and (3) concurrent sets of payer rules would have to be followed.

The suggestion that data could be garnered from using ICD–10 in the inpatient setting to inform a decision whether to move the code set to outpatient settings, implies that the decision to mandate ICD–10–CM in outpatient settings has not yet been made, but could be made based on the experience of implementing ICD–10 in the inpatient setting only. This is incorrect. The decision to require ICD–10 to be used by covered entities has already been made, and it was based on years of industry discussions, consensus building, and government rulemaking. Before publishing the proposed rule that proposed to require covered entities to implement ICD–10–CM and ICD–10–PCS, the Secretary considered recommendations of the NCVHS, as well as input from Federal and State agencies, private and professional organizations, and industry stakeholders, including organizations representing providers, health plans, clearinghouses, and vendors. For a history of the adoption of ICD–10, see the proposed rule titled ''HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'', published on August 22, 2008 (73 FR 49796) (hereinafter referred to as the August 2008 ICD–10 proposed rule). After the August 2008 ICD–10 proposed rule was published, HHS considered over 3,000 public comments on the proposed mandate. (See the January 16, 2009 final rule titled ''HIPAA Administrative Simplification Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS'' (74 FR 3328).)

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

The option to forego a transition from ICD–9 to ICD–10, and instead wait for ICD–11, was another alternative that was considered. This option was eliminated from consideration because the World Health Organization (WHO), which creates the basic version of the medical data code set from which all countries create their own specialized versions, is not expected to release the basic ICD–11 medical data 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.[9]

Comment: A number of commenters referred to an article titled ''There are Important Reasons for Delaying Implementation of the New ICD–10 Coding System,'' published in *Health Affairs* in May 2012, using it to support their opinion that the United States should forgo ICD–10 and wait for ICD–11.[10] Commenters noted a number of highlights from the article, including the following:

• Reference to a study that found that ICD–10 codes failed to outperform ICD–9 codes in capturing clinical data.

• Reference to an analysis of ICD–10 codes that found a lower percent of codes dedicated to diseases, compared to ICD–9 codes.

• Deficiencies in the ICD–10 code set, including a lack of genomic information such as family history.

• Reasons why SNOMED–CT, on which ICD–11 is based, is a superior clinical coding language.

• Reasons why ICD–10 is nearing obsolescence.

One commenter pointed out that, if ICD–11, as scheduled for release by the WHO, should be accepted without further modifications as the reporting standard for the U.S., ICD–11 could be ready for adoption before the 2020–2022 date estimated in the April 2012 proposed rule. Another commenter argued that we should forgo ICD–10 because implementing ICD–10 in 2013 or 2014 would delay the eventual adoption of ICD–11 given the time it takes for code sets to be implemented in the U.S. This would again put us behind the rest of the world because we would be using an obsolete code set—ICD–10—for 13+ years after the WHO adopts ICD–11.

One commenter recommended moving to ICD–11 in the same timeframe as the rest of the world in order not to defeat the primary purpose of having the interoperability to exchange the most accurate health care data.

Other commenters argued against waiting for ICD–11 and argued for preceding with ICD–10 as mandated. Some of these commenters quoted an article that was published in the July 2012 *Journal of AHIMA* that rebutted the article Chute et.al. point by point. (One commenter submitted the entire article as her comment.)[11] Some commenters argued against waiting for ICD–11 because the current code set, ICD–9–CM, is not adequate to support health information and data needs. ICD–9 does not allow for clinically relevant or robust data, commenters wrote, and its continued use reduces physicians' ability to assess patient outcomes, track public health risks, and exchange meaningful data with other health care organizations and reporting entities. It could also slow the adoption of value-based purchasing and other payment reform models, according to the commenter.

Some commenters noted that the structure of ICD–10 was designed to allow for the eventual changeover to ICD–11, and that failure to have this structure in place for ICD–11 would result in retrofitting many more health care systems at catastrophic costs. One commenter noted that, while ICD–11 may hold great promise, the commenter believed that claims about ICD–11's benefits were speculative, at best, because so much of it had yet to be developed.

Another commenter noted that, despite the appeal of putting off the cost and disruption of transitioning to a new code set indefinitely, the disruption and costs of transitioning to ICD–11 are highly unlikely to be less those of transitioning to ICD–10.

Response: We recognize that there is a debate within the health care industry as to the value of ICD–10 compared to ICD–11. We do not participate in this debate in this rule, except to say that we are convinced of the benefit of ICD–10 to health care delivery in this country. One of our responsibilities is to consider costs and benefits. We can make some rough calculations as to the investment that would be lost if we were to forgo ICD–10. In the RIA, we estimate the cost of a 1-year delay to be $1 to $6.6 billion. This represents what we believe to be approximately 10 to 30 percent what has been invested or budgeted, to date, into implementation of ICD–10. Forgoing ICD–10 translates into a loss of up to $22 billion for the U.S. health care industry. This does not take into account the projected fiscal and public health benefits that would be lost every additional year that we use ICD–9.

Given the considerable financial investment made by entities in preparation for ICD–10, and the timelines and uncertainties regarding a possible adoption of ICD–11, we cannot forgo ICD–10 in the hopes that a future, more effective code set will be adopted.

Comment: One commenter recommended that October 1, 2014 remain the compliance date for ICD–10–PCS since this is the area that has run out of ICD–9 procedure codes. HHS should then set October 1, 2016 as the compliance date for ICD–11 diagnosis codes, using ICD–11 as established by the WHO without the clinical modification. This would allow the industry to spend the time prior to October 1, 2016 preparing for ICD–11.

Response: This approach appears to require the processing of three different code sets over a 2-year period: ICD–10–PCS and ICD–9–CM from October 1, 2014 to October 1, 2016; ICD–10–PCS and ICD–11 from October 1, 2016 on. It is unlikely that any version of ICD–11 would be adopted in the timeframes suggested and, as we have noted, dual processing is a more costly and complex approach than a uniform implementation. We do not believe that this is an appropriate approach.

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

The fourth option considered was a uniform delay of the compliance date for both ICD–10–CM and ICD–10–PCS. The advantage to an across-the-board delay is that it will 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?

In the proposed rule, we considered a 1-year and a 2-year delay of the compliance date. We believed a 1-year delay achieves a balance between the needs of those who have already taken the initiative to plan for one-time compliance with ICD–10 and the need for other entities 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 October 1, 2013 date, delaying ICD–10–CM and ICD–10–PCS by one year does the least to disrupt existing implementation efforts, while affording the small provider community an additional year to become compliant.

a. 2-Year Delay

Comment: Some commenters suggested extending the ICD–10 compliance date 2 years, until October 1, 2015, or beyond. In general, these

[9] 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, 2012, *http://www.icd10watch.com/,* ''ICD–10 Frequently Asked Questions,'' American Health Information Management Association (AHIMA), *http://www.ahima.org/ICD10/faqsall.aspx#36.*

[10] C. Chute, S. Huff, J. Ferguson, J. Walker, and J. Halamka, ''There are Important Reasons for Delaying Implementation of the New ICD–10 Coding System,'' *Health Affairs,* May 2012, Vol. 31, No. 5.

[11] R. Averill and S. Bowman, ''There are critical reasons for not further delaying the Implementation of the new ICD–10 coding system,'' *Journal of AHIMA,* vol. 83, no. 7, July 2012.

commenters stated that an additional 2 years is needed to perform system testing, staff training, further analysis, and outreach and education by both the federal government and the private sector to those entities that experience difficulty implementing ICD–10.

One commenter suggested that 2 years would be preferable in order for front line care providers to ''buy into'' the change and integrate ICD–10 into their day-to-day operations. One commenter suggested that, given the interdependency between implementing Version 5010 and implementing ICD–10, HHS should monitor the implementation of Version 5010 carefully, as an additional delay in its implementation may require a delay longer than one year for ICD–10.

One commenter noted that its state Medicaid program would incur substantial costs if the delay was 1 year instead of 2 years due to the schedule in which it Medicaid Management Information System MMIS would be updated.

Another commenter stated that the uncertainty over the compliance date had caused resource planning challenges because organizations have put on hold their partially complete planning and implementation efforts. A 2-year delay would allow organizations to more effectively re-plan their efforts. One commenter noted that a 2-year delay would better align resources and spread costs out over time.

One commenter noted that a 2-year delay is necessary because federal mandates and independent business initiatives were straining already constrained resources in health services delivery and health plan administration. The commenter's organization had committed significant resources in EHR development, Meaningful Use certification, PQRS creation and ACO design and development. Two years would also give the commenter's entity time to implement significant business model changes in 2013 to accommodate provisions of the Affordable Care Act.

One commenter argued that a 2-year delay would give worker's compensation (WC) and third party liability (TPL) insurances time to implement ICD–10 voluntarily because of industry pressure to do so. The commenter further argued that a 2-year delay would enable further study demonstrating the positive impact of ICD–10 for providers who have yet to be convinced.

Some commenters suggested that a delay longer than 2 years was necessary, citing some of the same reasons given for a 2-year delay.

Many commenters agreed with the assumption that implementation costs would increase with every year of a delay, while there were no commenters that argued otherwise. Commenters reported that a 2-year delay would increase costs to maintain implementation efforts, staff training, and systems changes. One commenter stated that a delay in ICD–10 beyond 1 year would result in higher implementation costs for insurers and ultimately for customers. They stated that a delay beyond 1 year would require costly and time-consuming work, including conducting systems inventories that will have become outdated and would need to be completely reassessed.

Some commenters noted that each year of delay prevents the industry from realizing the anticipated benefits of implementing ICD–10.

Some commenters also suggested that any delay beyond 1 year would result in the industry losing momentum in implementation efforts, which could ultimately jeopardize the implementation of ICD–10. One commenter argued that, in the case of a 2-year delay, the staffing and financial resources that were dedicated to the implementation would likely be diverted elsewhere. Some commenters expressed concern about the system implications of moving to ICD–10 the same year some may implement Stage 2 of Meaningful Use.

A commenter stated that our analysis did not include some categories of additional costs of a 2-year delay associated with the ICD–9–CM code set, including ''inaccurate diagnosis and clinical decisions, administrative inefficiencies due to manual processes, coding errors due to outdated codes, worsening imprecision of the ICD–9–CM code (due to stasis if the code freeze is not lifted), and ongoing maintenance of both ICD–9–CM and ICD–10–CM/PCS code sets.''

Response: 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. Therefore, we can assume that a 2-year delay would be at least double the cost.

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 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, the existing and outdated ICD–9 medical code set. 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. 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 could also signal a lack of HHS' commitment to ICD–10, 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.

We agree that a 2-year delay would provide more time for entities to coordinate implementation with other federal mandates and programs and would give the entire industry more time to conduct system testing, training, further analysis and outreach and education. However, as illustrated in the RIA and as reflected in many of the comments, every year carries considerable costs for those that have already invested resources in order to meet an October 1, 2013 deadline. As well, the entire health care industry will suffer the opportunity costs of not moving to a more effective code set. We also believe there is a risk that ICD–10 could be abandoned altogether if a 2-year delay was established. We do not believe the benefits of more time outweigh the costs and risks of a 2-year delay.

b. 1-Year Delay

Comment: Of all the options, the highest number of commenters supported the proposed 1-year delay of ICD–10. Commenters supported the proposed delay for a number of reasons. Some stated they would benefit from the additional time for implementation given that they are in the process of implementing numerous other competing priorities during the same time frame. Some commenters believed a 1-year delay would ensure that all industry segments had ample time to transition to ICD–10 and would be ready to do so on the same date.

One commenter supported the 1-year delay because it would allow additional time for planning, testing, training, and price negotiation with vendors, the opportunity for additional business impact assessments, and implementation of appropriate workflow changes, additional time for vendor and payer readiness, and alignment with other health system-wide initiatives.

Some commenters supported the proposed 1-year delay because of the financial advantages. One commenter noted that the 1-year delay would be helpful in order to recover from the cash outlay that was made in order to transition to Version 5010. Some commenters argued in support of the 1-year delay because they believed that their organizations could not support the financial investment necessary to make the ICD–10 transition by the original compliance date.

One commenter supported a 1-year delay because the delay effectively balances the interests and current implementation status of multiple stakeholders. The commenter described the range of opinions and readiness of physicians in the commenter's state, noting that some physicians preferred a longer delay due to competing initiatives, lack of resources, and other mitigating factors, while others preferred no delay because of their early investment in staff and resources to support the effort.

Many commenters did not agree that a 1-year delay was a reasonable approach, arguing for one of the other options or arguing for options that we did not consider in the proposed rule. We have included their arguments under those options.

Response: We agree with commenters that believe a 1-year delay would be helpful operationally, financially, and in terms of planning and coordinating with other initiatives. We agree that a delay beyond one year carries costs and risks that do not outweigh the benefit of a longer delay.

5. Options Not Considered in the April 2012 Proposed Rule

Comment: Some commenters suggested a staggered approach to implementation based on covered entity type. These commenters recommended that clearinghouses and health plans should comply with ICD–10 first and then providers should comply at least 12 months later. Commenters argued that implementation by health plans must be thoroughly vetted before involving providers in the implementation. They believed this would allow providers to fully test with trading partners before their compliance date. These commenters stated that separate compliance dates would minimize the disruption to health care delivery and claims payment processes.

One commenter recommended against any dual implementation period for ICD–10. The commenter argued that such an approach would be nearly impossible to implement from an operational perspective and would cause great challenges both in the development of health plan and provider contracts as well as the implementation of quality improvement strategy reporting, which depends on ICD–10 diagnostic and procedure codes. It would also add significant costs and marketplace confusion to the implementation of ICD–10.

Response: With respect to health plans, all analysis, design and development has been done according to the initial requirement of a cutover implementation. This means health plans have not prepared for processing both ICD–9 and ICD–10 code values on initial claims with dates of service received after the cutover date, as would be expected if health plans were required to be ICD–10 compliant before providers. The strategy to require ICD–10 codes as of a specific date of service has been reinforced in industry outreach and education by HHS, and vendor contracts have been based on this strategy. Some entities have recently indicated a change in this foundational requirement would effectively require them to start over, which would cause a multiyear delay. We assume that the same would be true for many entities were we to change approaches.

A specific compliance date for health plans, followed by another date a year later for providers' compliance, is effectively a 2-year delay of the date when the health care industry as a whole ''goes live'' with ICD–10. In practice, therefore, an argument for a different compliance date for providers and health plans/clearinghouses is an argument for a 2-year delay of the compliance date. We have estimated that a 2-year delay of the compliance date of ICD–10 carries with it considerable costs. We do not believe that the benefits of a 2-year compliance delay would be worth the costs.

Comment: Some commenters made suggestions that went beyond consideration of a delay in compliance date of ICD–10 and questioned the implementation of ICD–10 in general. Commenters stated that the initiative should be abandoned completely because it represents an enormous burden on medical practices with no benefit to patients or no improvement to quality of care. Another commenter argued that ICD–10 will not enhance the process of reporting medical claims.

Response: Beyond stating the basic thesis that there is no benefit to implementing ICD–10, the commenters did not provide detail as to how they arrived at this conclusion. We respectfully disagree with these commenters' conclusion. Although the benefits of ICD–10 have been reiterated in many studies and articles, we emphasize a number of the benefits here: standardized medical data for research, accessing and interpolating global health data in any language, drug discovery for complex diseases, individualized medicine (both predictive and preventative), clinical decision support, improved patient outcomes, optimized billing, and accurate insurance administration, leading to lower health care costs. ICD–10 will allow for better monitoring of patients with chronic conditions such as asthma, diabetes, and sickle cell disease, and will permit better tracking of injuries that can lead to improved preventive and safety measures. For a comprehensive discussion of the expected benefits of ICD–10, and the reasons why we adopted it, see the ICD–10 proposed and final rules (August 22, 2008 (73 FR 49796) and January 16, 2009 (74 FR 3328), respectively.)

6. Other Suggestions From Commenters on How Best To Implement ICD–10

(a) Increased Education and Outreach

Comment: Many commenters urged increased education and outreach on ICD–10, both from the federal government and from industry resources and organizations. One commenter urged HHS to continue to engage the 30+ organizations that are working on ICD–10 education and to leverage their tools and resources. One commenter noted that industry surveys continue to show the lack of awareness of ICD–10 among providers and that education and outreach might mitigate this. Another commenter suggested that HHS educate providers on the synergies between Meaningful Use and ICD–10. The commenter suggested that private sector firms and entrepreneurs should be engaged in education and outreach tasks. One commenter suggested that HHS reach out to health care professions and trade organizations to assist the health care industry, including local and state providers, plans, and payers—governmental and private.

One commenter suggested that HHS create an education plan and conduct education in a wide range of formats, including webinars, handouts, podcasts, frequently asked questions, and a variety of other formats.

Some commenters suggested that HHS develop and publish specific milestones or benchmarks on the implementation of ICD–10 so that industry could measure its own progress toward ICD–10 readinesss.

One commenter stated that, while large providers many not need assistance, small providers will need assistance to determine if their current documentation practices will enable the selection of an appropriate ICD–10 code.

Response: We will continue to work with industry to provide outreach and education. We will continue to engage stakeholders on a wide variety of ICD–10 implementation issues, including reduction of burden on physicians and other healthcare segments.

Comment: One commenter urged HHS to engage a national Coding Authority to provide a recognized source of accurate and timely coding information. The Coding Authority for ICD–10, such as the Cooperating Parties, would provide the needed awareness and timely answers for ICD–10 transition questions.

Response: We note that the Cooperating Parties, which includes CMS, the Centers for Disease Control and Prevention (CDC), the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), serve as the national coding authorities on both the ICD–10 and the ICD–9–CM code sets. CMS has the lead on ICD–9–CM and ICD–10–PCS procedure code maintenance. CDC has the lead on ICD–9–CM and ICD–10–CM diagnosis maintenance. AHA has established a Central Office on ICD–9–CM coding and will continue that role with ICD–10. The AHA's Editorial Advisory Board for Coding Clinic is already addressing ICD–10 coding issues for inclusion in their publication Coding Clinic for ICD–9–CM. All of the Cooperating Parties serve on the Editorial Advisory Board. We are confident in the Cooperating Parties continuing role as the national authorities on both ICD–9–CM and ICD–10.

(b) Code Freeze

Comment: Some commenters suggested the ICD–10 code freeze be extended an additional year or until October 1, 2015. One commenter requested clarification on when the code freeze would be lifted.

Response: The issue of the partial code freeze was discussed over several meetings of the ICD–9–CM Coordination and Maintenance Committee. Based on these discussions it was decided to make the last regular update to ICD–9–CM and ICD–10 codes on October 1, 2011. Beginning on October 1, 2012, only codes for new technologies and new diseases would be considered for code updates. The committee decided that, 1 year after the initial compliance date of October 1, 2013, regular updates to ICD–10 would begin and no further updates to ICD–9–CM would occur upon the implementation of ICD–10. The Committee is the public forum for discussions on the maintenance and updates to both ICD–9–CM and ICD–10 code sets and will therefore be the source of discussion and any decisions on the implementation of any further code freeze based on the provisions of this final rule.

(c) Crosswalks

Comment: One commenter argued that, even with a delayed compliance date, the lack of a single forward crosswalk from ICD–9–CM to ICD–10–CM and a single backward crosswalk from ICD–10–CM to ICD–9–CM that is more specific than the General Equivalence Mappings (GEMs) will hamper implementation. According to the commenter, the GEMs are not actual crosswalks that are sufficiently specific to be useful for forward or backward cross-walking in automated billing systems. The commenter suggested that HHS establish true forward and backward crosswalks that eliminate the ambiguity of the GEMs for billing and reimbursement purposes while providing a single authoritative standard for the industry.

Another commenter urged that HHS not endorse a single crosswalk that enhances GEMs with one-to-one mapping forward and backward. ICD–10 creates many-to-many mappings, the commenter noted, and, in contrast to relying on national crosswalks established by HHS, health plans should build rules and medical policy and ensure their use of ICD–10 supports that policy. Another commenter urged that HHS take a lesson from the Canadian transition to ICD–10: ''don't crosswalk.''

Response: We are aware that there is not an exact one-to-one match in the forward or backward translation between ICD–9 and ICD–10. However, we believe that our General Equivalency Mapping (GEMs) is a useful tool to assist with transitioning between ICD–9 and ICD–10. Furthermore, we believe that the training materials posted to the CMS Web site, as well as the scheduled outreach and educational opportunities which are periodically provided by CMS, suffice for training and technical support.

(d) Implementation and Testing Plan and Certification

Comment: Some commenters recommended that HHS develop an implementation and testing plan that expands outreach and education, ensures adequate testing, and develops milestones/timelines to ensure the new compliance date is met. Some commenters discussed the need for HHS to apply lessons learned from Version 5010 implementation when designing a testing plan. Many commenters suggested that there was a false sense of readiness with regard to the transition to Version 5010. True readiness could only be realized through adequate testing.

One commenter suggested that a consistent testing approach be applied by all stakeholders. Another commenter suggested that an ICD–10 Pilot Test could include a representative number of covered entities that, after testing, could establish regional solution centers that would identify best practices on problem solving, obstacles to avoid, and concrete solutions in the implementation of ICD–10. The commenter also recommended standardizing the ICD–10 testing process, which should also include end-to-end testing, so that a national approach could be used for each particular category of entity.

Another commenter suggested we work with NCVHS to develop an ICD–10 testing and implementation plan. The plan should include milestones and metrics that would provide a better understanding of the state of the industry.

Another commenter suggested we tap the Workgroup for Electronic Data Interchange (WEDI), to identify and coordinate pilot participants, liaise with CMS, and work with the agency to disseminate the results to industry.

One commenter suggested that, along with certification, HHS should survey and publish the expected downstream costs that health plans, clearinghouses, Medicare Intermediaries, and Medicare Advantage contractors intend to transfer to their internal and external customers.

One commenter argued against the development of a certification program, and urged HHS to leverage and adopt existing best practice guides and schedules.

One commenter suggested HHS require the certification of all health plans and clearinghouses to be able to accept ICD–10 codes. The commenter suggested that provider management systems (PMS) and billing systems should be certified by a private entity. Certification of these products, the commenter stated, would greatly assist physician practices in identifying the software necessary to comply with federal mandates and in taking advantage of the various administrative simplification initiatives. The commenter added that certification can also drive implementation by standardizing software requirements and leveraging market forces to ensure practices can meet federal requirements.

Response: We agree that implementation and testing plans are essential for a successful transition to ICD–10. We recognize the need for a shared, industry-wide definition and understanding of ''readiness'' based on testing. We are evaluating methods to establish that common understanding and will issue guidance and offer general assistance on timelines and testing protocols through education and outreach.

(E) PM and Billing Software Vendors

Comment: Some commenters emphasized the integral role PMS and billing software vendors play in covered entities' abilities to meet compliance dates. Commenters noted that vendors needed to provide ICD–10 products and services in a timely manner in order to achieve timely compliance and functionality for all ICD–10 processes. Some commenters therefore suggested that there be compliance tracking and testing of practice management and billing software vendors.

One commenter agreed that software vendors played an important role, but urged that vendors self-report readiness to implement ICD–10. The commenter believed that the self-reporting approach affords an organization more time than a full-blown certification process that will likely increase the cost of implementation for providers and vendors. One commenter suggested that HHS aggressively educate and monitor billing software vendors for the reasons given above.

Response: We agree with commenters that software vendor readiness impacts covered entities' ability to meet compliance dates. While certification of software vendors is not within our authority in this rule, we will issue guidance on expected deliverables and timelines for vendors, and work to establish effective communication, education and outreach for vendor support in realizing these objectives.

(f) Coordinating With Other CMS and Federal Initiatives

Comment: Some commenters emphasized the need for CMS to expedite the availability of a mainframe version of the DRG grouper.

One commenter urged CMS to provide specific guidance on how Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) should approach claim submission and medical necessity documentation, specifically when an initial claim is made in ICD–9 and subsequent claims are made in ICD–10.

One commenter recommended that CMS evaluate and alleviate the financial impact of implementation on state Medicaid programs. The short-term and long-term financial cost associated with ICD–10 will place excessive stress on safety net payer systems that are already under duress, the commenter said.

Some commenters argued that CMS should modify the Medical Loss Ratio (MLR) rule. According to the commenters, in the MLR final rule published on December 7, 2011, CMS recognized that ICD–10 conversion implementation costs are quality improvement activities, and the rule ''proposed to limit the amount of ICD–10 conversion costs to only those incurred in 2012 and 2013. The commenter suggested that the MLR final rule should adjust the 0.3 percent cap on ICD–10 costs to reflect the proposed changes' costs and extend the ability to take costs into account beyond 2013 into 2013.

One commenter requested that all references within the Meaningful Use Stage 2 regulations from both CMS and the Office of the National Coordinator (ONC) be adjusted to align with the ultimate decision on the timing of ICD–10 compliance, including the availability of and flexibility in certification to clinical quality measure specifications that reference ICD–10.

Another commenter suggested that ONC require that all certified EHRs be required to include the capabilities necessary for the use of ICD–10–CM and ICD–10–PCS in the 2014 certification requirements.

Another commenter suggested that CMS use its Quality Improvement Organizations to assist providers in the implementation and testing of ICD–10.

Another commenter brought forward a number of concerns about ICD–10 and CMS' policies regarding the payment system and classification criteria for inpatient rehabilitation units of general hospitals (IRH/Us) and access to care for the patients they serve.

One commenter suggested leveraging existing programs, such as Regional Extension Centers, to enhance provider outreach and education (ONC has implemented a set of Regional Extension Centers (RECs), which are defined as organizations that receive funding under the Health Information Technology for Economic and Clinical Health Act to assist health care providers with the selection and implementation of electronic health records). The commenter suggested that we work with ONC to create and disseminate educational and operational programs, tools, and other ICD–10 resources.

Other commenters addressed specific impacts of ICD–10 on other CMS programs and requested guidance or changes to the policies of those programs based on a delay of ICD–10 implementation.

Some commenters urged that HHS harmonize federal programs with regard to ICD–10. Lack of a coordination of multiple overlapping initiatives could threaten ICD–10 implementation, one commenter stated. Another commenter stated that it was critical that we align the ICD–10 deadline with any dependencies built into all other federal and state programs, such as those involving clinical quality measures that reference ICD–10 codes. Another commenter stated that existing federal health information technology mandates on physicians, such as meaningful use, e-prescribing and quality reporting, must be evaluated in the context of the enormous burden and cost of ICD–10.

Response: We appreciate these observations and suggestions. However, these programs, regulations, and initiatives are the purview of the CMS and other federal agencies and are, therefore, outside of the scope of this regulation. We cannot represent CMS' policy decisions or the programs of other federal agencies.

Comment: Some commenters suggested that HHS review upcoming administrative simplification deadlines and other federal deadlines to see if some of them should be adjusted. One commenter suggested that HHS work with the NCVHS to determine if the compliance dates for operating rules related to the electronic remittance advice, electronic funds transfers, and future operating rules related to enrollment, authorizations, and referrals, and claims should be adjusted. One commenter stated that the HPID compliance date being on the same date as the compliance date of ICD–10 (October 1, 2014) would create a potentially difficult situation in the industry.

Response: We appreciate these observations. We are working to improve future regulatory alignment, timetables and scheduled deliverables within the limits of our authority. For instance, with HPID, we believe we accommodated some commenters' concerns about the timeframe for compliance by mandating in this final rule that October 1, 2016 be the date by which covered entities must use HPID in standard transactions.

Comment: One commenter recommended that the ICD–10 mandate be extended to noncovered entities, such as workman's compensation and auto insurance, to eliminate the duplicity of administrative processes and systems for health care providers. Otherwise, health care providers will have to maintain dual processes and system capabilities to perform transactions using ICD–9 and ICD–10, which will result in increased administrative burden for providers.

Response: We agree with commenters that some noncovered entities create duplicate processes for health care providers. For purposes of this rule, however, workman's compensation and auto insurance companies are not required to implement ICD–10.

Comment: Commenters urged that, once the final rule is published, HHS not introduce any further delays to ICD–10 implementation, including ''discretionary enforcement periods'' like those used after the Version 5010 compliance date. Further delays would impact other areas of health care such as the successful implementation of electronic health records and reporting that will be required as part of state based exchanges. One commenter noted that further changes in the compliance date would cause significant costs for health plans and ultimately for their customers at a time when the industry will be preparing for the implementation of health insurance exchanges and other Affordable Care Act-mandated changes. This is because systems naturally evolve for a number of reasons over time and an extended delay will require an extension of testing activities and prolonged maintenance of the testing environment.

Other commenters suggested that, as the delayed compliance date draws closer, HHS assess industry readiness and, if necessary, postpone compliance further. One commenter suggested establishing a delay, but delaying still further at a later date if the industry continues to struggle with Version 5010.

Response: We agree with commenters that further delay of the ICD–10 compliance date would be costly to the industry at large. We do not expect any further delays of the ICD–10 compliance date.

(g) Further Analysis

Comment: One commenter suggested that an analysis of the costs of ICD–10 implementation for providers should be conducted by HHS, including how those costs would contribute to the cost of total health care delivery. The commenter wanted the study to include an analysis of whether the ''costs have any benefit to the nation's health,'' and stated that, once the study was conducted, HHS should consider whether implementation of ICD–10 was still in the best interests of the country or if alternatives or an extended timetable for further study would achieve the best results.

Some commenters suggested additional studies and analysis be undertaken before HHS mandate any compliance date for providers. For one, commenters suggested that, as an interim step, HHS fully examine the current ICD–9–CM code development allocation process and make the necessary changes to permit the full utilization of the current code set and the rapid assignment of necessary codes.

Some commenters suggested an analysis be conducted that compared the costs to industry of using ICD–9 for another few years before transitioning to ICD–11 to the industry costs of using ICD–10 for those years. Commenters suggested HHS conduct a further analysis of the cost of requiring two code conversions—to ICD–10 then to ICD–11—over the next 15 years. These analyses, commenters stated, are necessary in order to make a better-informed decision (ostensibly about whether to implement ICD–10).

Some commenters urged that HHS complete a comprehensive cost-benefit analysis to determine the impact of ICD–10 implementation on each health care industry sector before mandating ICD–10. The commenters stated that this analysis should include consultations with appropriate provider organizations and HHS advisory groups, and a final report should be issued that includes the benefits to physician practices and other sectors. The commenters suggested that the analysis include costs for information system changes, rate negotiations, recalculation of reimbursement methodologies, training, and changes to forms. Further, the analysis should consider the timing of the transition, including the impact of timing options on costs and benefits, potential return on investment, and interaction with other major health information investment tasks, including participation in other CMS HIT and quality initiatives. The commenters stated that the analysis should identify immediate and future costs and benefits on physician practices and others of improved data for, but not limited to, patient safety, outcomes analysis, reimbursement, disease management, utilization review and health statistics.

Response: A common assumption of these suggestions is that, after a particular analysis, HHS would consider the merits of implementing ICD–10 and whether to mandate its use or not. In terms of this assumption, we make the following observations:

• The decision to mandate ICD–10 for covered entities has already been made, and it was based on years of industry discussions, consensus building, and government rulemaking. Before publishing the proposed rule that proposed to require covered entities to implement ICD–10–CM and ICD–10–PCS, the Secretary considered recommendations of the NCVHS as well as input from federal and state agencies, private and professional organizations, and industry stakeholders, including organizations representing providers, health plans, clearinghouses, and vendors. For a history of the adoption of ICD–10, see the ICD–10 proposed rule and final rules (August 22, 2008 (73 FR 49796) and January 16, 2009 (74 FR 3328), respectively).

• A number of studies have been conducted with regard to the costs and benefits of ICD–10. The April 2012 proposed rule listed a number of analyses in this regard. A robust analysis of the cost and benefits of ICD–10 was provided in the August 2008 ICD–10 proposed rule, and public comments on the analysis were subsequently incorporated or responded to in the January 2009 ICD–10 final rule. As well, there have been numerous other academic studies, analysis, and articles related to ICD–10. All of these studies have demonstrated costs and benefits with implementation.

Given these points, there is little evidence that another study would, itself, convince HHS to overturn years of rulemaking (or, in the likelihood of it approximately concurring with the results of previous studies, serve any use whatsoever). However, it is clear that further analysis or study means more delay and uncertainty for the health care industry. Because ICD–10 has been mandated, many entities have invested considerable resources to comply. As our RIA—and many of the comments we received—illustrate: Every day that we delay—or create uncertainty around—the implementation of what has been mandated translates to considerable cost to the health care industry.

We do not believe that further analysis of ICD–9 or ICD–10 would be a responsible use of stakeholders' and the federal government's resources.

Comment: Another commenter suggested that a 2-year delay would provide us with the time to analyze the costs and benefits of implementing ICD1–10 on physician practices. The commenter suggested that, at the same time, we should engage all stakeholders to assess whether an alternative code set approach is more appropriate than the full implementation of ICD–10. The commenter noted that other countries implemented ICD–10 with a modified version of the code set. The commenter argued that stakeholders should reach consensus on the question of costs, scope, and whether a modified version is appropriate within the 2-year delay; otherwise, the industry should not implement ICD–10.

Response: We reiterate that further analysis of the costs and benefits of ICD–10 is probably not a responsible approach given the substantial rulemaking and analysis conducted to date and the fact that a significant proportion of the health care industry has already spent resources implementing ICD–10. While we appreciate the suggestion that this analysis take place within a limited time; that is, a 2-year period, and that the analysis is narrowed only to the impact on physician practices, we do not believe the health care industry would participate in a cost/benefit analysis on the current version of ICD–10 while at the same time participating in a decision on whether to create a modified version, as the commenter suggests. This would send contradictory messages to the industry as to what is being proposed or mandated and, again, the delay and uncertainty would be costly, whatever the outcome of these discussions.

It is unclear from the commenters' comments how the concept of consensus is defined and whether consensus refers to stakeholder agreement on the costs of ICD–10 on physicians, stakeholder agreement on the decision to modify ICD–10, or stakeholder agreement on a suggested modified version itself. Regardless, it is questionable whether some defined methodology for achieving consensus would be a valid or appropriate mechanism for agreeing on cost estimates or a decision to modify ICD–10, and whether such a process could or should override years of industry input and government rulemaking that has been used to arrive at the current mandate.

Given the obstacles and uncertainties that we envision 2 years of analysis and decision-making would engender, it is unlikely that any consensus could be made with regard to costs or a proposed modification of ICD–10 within 2 years. For reasons stated earlier, however, it is clear that there would be tremendous costs for the both government and commercial entities.

7. Summary

After analysis and consideration of these comments, we are finalizing the policy to delay the ICD–10 compliance date by 1 year to October 1, 2014.

IV. Provisions of the Final Rule

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

- In 162.504, we have revised the term ''dates'' to read ''requirements''.
- In 162. 504(a), we have revised the term ''specifications'' to read ''requirements''.
- In 162.504(a), we have revised the term ''Covered health care providers'' to read ''Covered entities''.
- In 162.504(a), we have revised the year ''2014'' to read ''2016''.
- In 162.504(b), we have removed the reference to ''162.510''.
- In 162.504, we have deleted paragraph (c).
- In 162.508 (c), we have inserted ''or OEID'' after the phrase ''deactivate an HPID''.
- In 162.510, we have inserted the term ''Full'' before implementation and revised the term ''specifications'' to read ''requirements''.
- In 162.510(a), we have inserted ''that has an HPID'' immediately after ''health plan''.
- In 162.510(b), we inserted the phrase ''that has an HPID'' immediately after ''health plan''.

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 solicited 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 final 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 seeks to obtain 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 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 that has an HPID 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 3.

CHART 3—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
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 which we used in the calculations in section V. of this final rule. This is because self-insured group health plans are required to obtain HPIDs if they meet the requirements of a CHP under this final 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 an HPID or OEID is a one-time burden, although we anticipate health plans will need to update any information changes in the Enumeration System. In future years, the burden to apply for HPIDs and OEIDs will impact only new health plans and other entities that choose to obtain an OEID as described in the section V of this final rule. While health plans will need to update their information in the Enumeration System, we anticipate the burden associated with this requirement will be negligible as health plans will already have access to the Enumeration System and the information collected about the health plan is minimal so little information will need to be updated on a regular basis. 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 for application and update of information in the Enumeration System 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 proposed accepting electronic applications and updates over the internet. We explicitly solicited 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.

We did not receive any comments on these [requirements?] and we are finalizing these provisions as proposed.

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

We proposed 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

[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.

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 final 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 as of the fall of 2011 there were approximately 1.4 million prescribers in the United States, of which approximately 160,000 did not have an NPI. It is these prescribers who would have to obtain an NPI. 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 2 shows the estimated annualized burden for the HPID and NPI PRA in hours.

We did not receive any comments and we are finalizing these provisions as proposed.

TABLE 2—TOTAL 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 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 final 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–F; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

VI. Regulatory Impact Statement (or Analysis)

A. Statement of Need

1. NPI for Non-Covered Health Care Providers

The compliance date for use of the NPI by health care providers was May 23, 2007. As of the fall of 2011, we believe there were 160,000 prescribing 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 final rule 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. of this final rule and in the summary Tables 20 and 21 of the RIA.

2. HPID

As noted in section I of this final 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 in this rule is to create a standard 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 in the April 2012 proposed rule for a list of HIPAA standard transactions, and Table 2 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. With the adoption of the HPID, such a health plan will likely use one identifier, thereby making it easier for the covered health care provider to

[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.*

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 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.

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.'' [14] 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.[15] The association went on to contend that fee schedules and plan and product types would need to be identified with this health plan identifier.

We did not propose that the HPID or the OEID contain intelligence that would include fee schedules or benefit plans or product types. However, we view the adoption of the HPID and the 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 final rule changes 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 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. 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 percent of providers surveyed indicated that they are at risk for not meeting the October 1, 2013 compliance date.[16] 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.[17] 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 that numerous practices were not 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

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

[15] Ibid.

[16] ''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.

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

of organizations, 37 percent of respondents stated that a 1-year delay would be beneficial for them.[18] 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.'' [19]

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 final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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

The RIA on the delay of ICD–10 follows the RIA on the 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 believe 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.C. of this final 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 are in this rule. The NPI is the standard identifier for health care providers under HIPAA. 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 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, and considered comments regarding those alternatives. The summary of the alternatives, the comments, and our responses to the comments are included in the preamble and will not be repeated for the RIA.

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 adoption of the HPID in this final rule will have an impact on a substantial number of small entities and that a regulatory flexibility analysis, an analysis on the impact of this final rule on small entities, is required. The regulatory flexibility analysis on the impact of the adoption of HPID will come after the RIA. The regulatory flexibility analysis for HPID concludes that, although a significant number of small entities may be affected by this final rule, the economic impact on small entities will not be significant.

We have also determined that the delay of the compliance date for the use of the ICD–10 medical code set will have an impact on a substantial number of small entities and this regulatory flexibility analysis will follow the RIA for the delay of ICD–10. The regulatory flexibility analysis for the delay of ICD–10 concludes that small entities will be positively impacted economically by the 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

[18] ''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 Medicaid (9%), medical claim clearinghouses (6%), and other healthcare industry organizations (17%).

[19] Ibid.

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 final rule, with regard to the HPID, ICD–10, and NPI provisions, is being finalized under title XI, part C, ''Administrative Simplification,'' of the Act, and, therefore, does not apply. However, we assume that the impact to small rural hospitals will be similar to that of other small providers in terms of the HPID, NPI, and ICD–10 provisions; that is, implementation of the provisions will either not have a significant economic impact, in the case of HPID and NPI provisions. Or, in the case of the ICD–10 provision, there will be a positive impact.

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 final rule contains mandates that would likely impose spending costs on State governments and the private sector, of more than $139 million. We will therefore 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. We will also illustrate the costs of the 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.

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 with whom they contract, 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.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State laws, or otherwise has Federalism implications. The adoption of the HPID in this final rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications. The delay of compliance with ICD–10 in this final rule will not have a substantial direct effect on State or local governments, does not preempt States, or otherwise have Federalism implications.

In the RIA for implementation of the HPID in the April 2012 proposed rule, we used the proposed provision that the HPID would be implemented for use starting in October 2013. In that RIA, we used data projected for 2013 as our baseline, and 2014 as the first year when benefits attributable to use of the HPID would begin. We also assumed that 2013 would be the year in which most of the costs would be incurred, with 2014 and 2015 as the years in which transition costs would be incurred. We projected those benefits and costs out until 2023.

Because this final rule has established a date 4 years from effective date of this rule as the date by which all covered entities will be required to use HPIDs to identify health plans in the standard transactions, we have changed the year that we will use as a baseline from 2013 to 2016. (See section II.E. of this final rule for more information regarding effective and compliance dates.) For the RIA in this final rule, we assume, as we did in the proposed rule, that benefits from the use of the HPID will occur over a ten-year period beginning the first full year covered entities are required to use the HPID in standard transactions. That 10-year period will begin in 2017 and continue through 10 years (that is, through 2026) and transition costs will be incurred in the years 2017 through 2018.

Because we have shifted our costs and savings forward three years, our conclusions on costs and benefits are different from those in the RIA of the April 2012 proposed rule.

B. Consideration of Public Comments Regarding the Impact Analysis

In the April 2012 proposed rule, we solicited additional data that would help us determine more accurately the impact on the various categories of entities affected by the April 2012 proposed rule. We received numerous comments on our analysis of the costs and benefits of implementing the HPID and the delay in the compliance date of ICD–10. We have provided summaries of those comments and our responses.

Some of our assumptions in the April 2012 proposed rule have changed because of new information we received through public comments. However, the assumptions that we changed were based on comments that were qualitative or anecdotal. The comments did not contain new data or estimates that would impact the quantitative estimates with regard to the impact of implementation of HPID and delay of ICD–10 that were made in the April 2012 proposed rule. Therefore, none of the comments we received required us to change the calculations and conclusions of the RIA that we provided in the April 2012 proposed rule with regard to both the HPID and ICD–10 provisions.

We will summarize those comments and the changes we made to the assumptions.

We have maintained or summarized sections of the RIA that we provided in the April 2012 proposed rule in which comments were made or new information was provided within the comments. We removed or summarized sections of the RIA where we received no comments.

Although we have not changed any of the calculations or conclusions of the RIA that we provided in the April 2012 proposed rule with regard to the ICD–10 provisions of that rule, we have duplicated the summary tables from the April 2012 proposed rule that illustrate those calculations for reference.

C.

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 solicited public and stakeholder comments. As noted, we did not consider alternatives to the addition to the NPI requirements.

We did not receive comments with regard to the alternatives considered in the April 2012 proposed rule regarding the HPID and the NPI. For more detail about the alternatives we considered, please refer to the April 2012 proposed rule. Having received no comments meriting a change in policy, we are finalizing the policy to adopt an HPID that is a 10-digit, all-numeric identifier with a Luhn check-digit as the 10th digit.

D. Impacted Entities—HPID and NPI

All HIPAA covered entities may be affected by the HPID standard as detailed in this final rule although, as we estimate, only a segment of covered entities will have substantive cost or benefits associated with the adoption of the HPID. Impacted 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 3 outlines the estimated number of entities that may be affected by the

HPID and OEID, along with the sources of those data.

TABLE 3—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 x 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.
Pharmacy Benefit Managers (PBMs)	60	National Council for Prescription Drug Programs (NCPDP) May 17, 2012 letter to Centers for Medicare & Medicaid Services, Re: CMS–0040–P.

E. 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 final 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 asked for comments on this approach.

Comment: A commenter expressed concerns about the burden placed on hospitals that would be incurred in order to meet the addition to the NPI requirements. The commenter noted that NPI requirements would require hospitals and other organization health care providers to maintain a central location where prescribers' NPIs would be tracked as well as provide 24-hour staffing to provide pharmacies with these NPIs.

Response: The preamble makes clear that the rule does not specify how organization covered health care providers should impose the requirement on individual health care providers and that they may have a number of alternatives to do so, for example, through a written agreement, an employment contract, or a directive to abide by the organization health care provider's policies and procedures. Thus, we do not believe compliance with this new requirement will necessarily be burdensome.

In this RIA, we do not analyze the impact of implementation and use of the OEID. The OEID, as finalized herein, is 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 group health plans. The range of total entities that may apply for and use an OEID is from zero to approximately 1,000 entities (750 Third party administrators + 169 transaction vendors + 60 Pharmacy Benefit Managers). Therefore, using the methodology employed in this RIA, the cost for implementation of the OEID for other entities ranges from no cost to over $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 an 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. In the proposed rule, we welcomed stakeholder comment on the number and kind of entities that may apply for and use an OEID.

Comment: A commenter noted that he was unable to ascertain whether Pharmacy Benefit Managers (PBMs), TPAs, transaction vendors and other entities that might want to obtain OEIDs were included in the RIA.

Response: We limited our RIA to the analysis of costs and benefits in relation to the HPID, and not the costs or benefits of the OEID. We concluded that there was no way of projecting how many other entities would ultimately obtain and use an OEID as it is a voluntary enumeration. As such, we did not consider costs or benefits to entities that might want to obtain OEID.

However, we assume that there will be some impact to PBMs, just as we assume that there will be some impact to other entities that may obtain and use an OEID. We have included PBMs in Table 3 as a category of impacted entities, even as we are unable to quantify the impact on PBMs.

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 HPID and enumeration 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 application, updating, and data dissemination activities. We 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 final 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 HPID will affect a broad range of health care providers, as illustrated in Table 3, we only examine the costs and benefits of implementation and use of the HPID on two types of health care providers: hospitals and physician practices. We did 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: First, 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.[20] Second, we assume that the greatest benefits will be gained by hospitals and physician practices as they conduct the majority of standard transactions. In our proposed rule, we welcomed comment from industry and the public as to our assumptions.

We did not include an analysis of the impact on pharmacies because the HPID will not be used extensively in electronic transactions by the pharmacy industry. Therefore, we assume no impact of the HPID on pharmacies.

Comment: A commenter disagreed with the assumption that there would be no impact to pharmacies with regard to implementing and using the HPID. The commenter noted that the HPID/OEID would be used in other areas as defined by the NCPDP and ASC X12. The commenter noted that the pharmacy industry has presented recommendations to NCVHS on specific fields in the NCPDP Telecommunication VD.0 Standard and ASC X12 5010 in which the HPID/OEID might be used, and the commenter included a list of recommendations for where and under what circumstances an HPID might be required to be used.

Response: While the commenter's recommendations of where and under what circumstances the HPID might be used in future ASC X12 and NCPDP standards appear reasonable, they were not considered in the context of the RIA because they went beyond the provisions of the April 2012 proposed rule, and, subsequently, this final rule with regard to required use of the HPID. The commenter did not argue that the pharmacy industry would use the HPID in the manner in which it is required in the provisions of this final rule. Therefore, we did not change the assumption we made regarding the pharmacy industry's use of the HPID as noted in the April 2012 proposed rule: ''[T]he HPID will not be used extensively in electronic transactions by the pharmacy industry'' (77 FR 22979).

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 under HIPAA.

We assumed that the HPID may be used to identify health plans in nonelectronic 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 nonelectronic 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 HPID.

We include health care clearinghouses and transaction vendors as affected entities in Table 3. 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 are 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 used the total number of health insurance issuers as the number of commercial health plans that will be affected by this final rule, and used this

[20] ''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.

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

The projection of costs in this RIA is based on the number of health plans that will use the HPID in standard transactions. However, we do not have 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 will use the HPID in standard transactions. We base our cost estimates on the highest number of entities that would likely use the HPID in standard transactions. The number of health plans is used as a factor in our calculation of costs, but not in our calculation for savings. Therefore, we took a conservative approach to the costs to health plans which we believe is warranted given the uncertainties in our estimates. In our proposed rule, we solicited industry and stakeholder comments on our assumptions.

Comment: We received a number of comments that expressed concern regarding the validity of the RIA for the HPID because the commenters believed that the purpose and the use of the HPID was unclear.

Response: We cannot project how individual health care entities might implement and use the HPID given their specific business organization and needs. We also believe that, to the extent that the HPID will be used to facilitate transactions in ways that are beyond what is required by the provisions of this final rule, it is not clear what all the downstream effects of adopting a national health plan identifier may be. We believe that the HPID may be used within and outside of the transactions in ways that we have not required or envisioned. However, the required use of the HPID was specified in the preamble of the April 2012 proposed rule. The only required use of the HPID in this final rule is that if a health plan is identified in the standard transactions, a covered entity must identify a health plan using a HPID.

The RIA put forward in the April 2012 proposed rule is based on the HPID being used as required by the provisions of this final rule. We agree that there is uncertainty in projecting and estimating the benefits and costs, even given this specific usage. We emphasize that the RIA is based on the premise that the HPID is a foundational standard that will facilitate the routing of all standardized transactions, but not necessarily directly related to specific benefits. We deliberately did not claim in the April 2012 proposed rule that the HPID would be directly responsible for cost savings due to its required use in the standard transactions, with the exception of attributing some cost benefit to time savings in routing certain transactions. The cost savings, we believe, are derived from an efficiency in routing transactions which, in turn, will incentivize more health care entities to use those transactions.

Comment: A commenter stated that the cost savings outlined in the April 2012 proposed rule was conducted prior to the implementation of Version 5010 and projected savings are therefore questionable.

Response: While much of the RIA in the April 2012 proposed rule was developed before the January 1, 2012 implementation of Version 5010, some of the baseline assumptions and data were based on the cost and savings estimates of Version 5010 as included in the RIA of the Modifications final rule. The RIA was also written under the assumption that the HPID would be used in Version 5010 standard transactions. That being said, the benefits of the HPID are only tangentially related to the benefits of Version 5010, and we do not believe the implementation of Version 5010 has a direct affect on the savings or costs of implementing and using HPID.

Comment: A commenter suggested that we only move forward to adopt the HPID when the savings to be realized from its use exceeded the cost of its implementation.

Response: As illustrated in Table 12, our analysis concludes that the savings outweighs the cost, so it is reasonable to assume that we should move forward to adopt the HPID. We reiterate that we based many of our calculations on the assumption that the HPID is a foundational standard that will enable other initiatives and efficiencies to be built off of it. HPID cannot be viewed as an individual band-aid that fixes a specific problem. Instead, HPID is part of a broader picture of standardizing billing and insurance-related transactions and tasks.

F. Costs Associated with HPID and NPI

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.

For more detail on the justification for using 25 percent of the cost estimates in the Modifications final rule, please refer to the April 2012 proposed rule.

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 final rule. In our proposed rule, we solicited comments and data from the industry and other stakeholders on this assumption, but received no substantive comments in this regard.

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 2016. Transition costs will occur from 2017 through 2018.

TABLE 4—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 final 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 electronically (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 5 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. In our proposed rule, we invited stakeholder comment on our assumptions and method for estimating the implementation costs, but received no comments in this regard.

TABLE 5—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	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

TABLE 5—HPID COSTS TO COVERED HOSPITALS AND PHYSICIAN PRACTICES *—Continued

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	Estimated cost of implementing HPID (in millions)	Maximum estimated cost of implementing HPID (in millions)
	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

G. Savings Associated With HPID and NPI

1. Savings to Health Plans

In our proposed rule, we 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.

Comment: A commenter disagreed with the savings analysis stating that the savings to be realized are from Version 5010 implementation and not due to use of the HPID.

Response: The savings and benefits associated with the HPID are not the same as the savings that were calculated in the Modifications final rule, although we derive the costs associated with the HPID by using the Modification final rule costs as a baseline.

The savings associated with the HPID are derived from an increase in three transactions and from the number of pended claims that we have projected will be decreased on account of better routing through use of the HPID . In contrast, the savings associated with Version 5010 implementation are based on benefits in three areas: Better standards or savings due to improved claims standards, cost savings due to new users of claims standards, and operational savings or savings due to increased auxiliary standards usage.

In both this final rule and the Modifications final rule, some of the cost savings are based on an increase in electronic transactions. However, the specific electronic transactions that will be affected are different in the two rules, and the calculations used to link savings to the increase are different.

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 as resulting from: data about claims receipts from the trade association America's Health Insurance Plans (AHIP),[21] information about eligibility transactions from the Oregon Provider and Payer Survey,[22] 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.[23] Assuming 6.8 billion claims will be submitted in 2017, as is projected in the Modifications proposed rule, this calculates to about 950 million pended claims (Table 6, Column 2).

We assumed 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 6, 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 1 percent because of invalid codes.[24] The HPID may help alleviate these particular pended claims issues by enabling the automation of the COB process [25] 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 6, 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

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

[22] 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.*

[23] AHIP, 2006.

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

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

multiply the projected number of pended claims (Table 6, 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 starting the first full year the HPID is required for use in standard transactions, 2017, resulting in a savings of approximately $776 million to $1.6 billion. As stated previously, we consider the HPID standard adopted in this final rule to be foundational standards that will be built upon by future operating rules and regulations over the next decade.

TABLE 6—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. 2)	(Col. 3)	(Col. 4)	(Col. 5)	(Col. 6)	(Col. 1)	(Col. 7)
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
2025	1310.9	1.35	65.5	88.5	131.1	177.0
2026	1363.3	1.35	68.2	92.0	136.3	184.0
Total				776		1,551

* 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.

Comment: A commenter stated that the 5 to 10 percent reduction in pended claims was a gross overestimate. The commenter, representing a health plan, stated that the health plan has a front end clearinghouse that verifies eligibility and then routes transactions or rejects them. The commenter stated that they anticipate no reduction in pended claims volume.

Response: We appreciate the commenter's perspective, although we have no certitude as to how widespread this way of filtering claims may be among health plans. We received no other comments about our calculations or assumptions with regard to our estimate on decreased pended claims. Therefore, we are maintaining the estimates and calculations on our assumptions in this regard.

Comment: A commenter expressed concerned that the cost savings analysis did not reflect the efficiency gained by the HPID as proposed by the April 2012 proposed rule and adopted by this final rule. The commenter stated that the time and cost savings as stated in the April 2012 proposed rule could only be achieved if the health plan was enumerated down to the product level. Another commenter stated similarly that the cost savings estimated in the proposed rule could not be realized without the adoption of an HPID that was much more granular; that is, an HPID that identified the entity that holds the participation contract with the physician, an identification of the patient-specific benefit plan, and the claim specific fee schedule identifier.

Response: The provisions in the April 2012 proposed rule and this final rule do not require health plans to enumerate to the product level. However, we do believe that, even at the level in which health plans must enumerate as per this final rule, there will be the savings that we estimate herein. One of the above-referenced commenters noted that, if health plans were enumerated at a more granular level than that which we have adopted in this final rule, then the need for manual processes in 80 to 85 percent of the transactions could be eliminated. The estimated cost savings in this final rule, derived from use of the HPID as it is adopted, is based, partly, on a decrease in a particular manual process—the process that stems from processing pended claims. However, the decrease in this manual process is substantially less than what the commenter envisioned were health plans to enumerate at a lower level.

We estimated a 5 to 10 percent decrease in total pended claims based on the reasoning that a standard HPID used in the standard transactions would improve routing and so decrease a small number of pended claims. We do not presume to infer that the HPID, as it is adopted, will decrease a large proportion of manual processes related to eligibility and claim submissions.

In this final rule, we maintain the range of savings, as presented in the April 2012 proposed rule that is possible through implementation of the HPID.

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 nonelectronic, 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.

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 from 2017 through 2026 as illustrated in Table 7. 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.[26]

For more detail regarding our assumptions and calculations in this regard, please refer to the April 2012 proposed rule.

We estimate that the savings to health plans because of increased usage in three transactions will be at least $850 million within 10 years of HPID use in transactions. Health plan savings are summarized in Table 7.

The results of this calculation are higher in cost savings than the results of the same calculation in the April 2012 proposed rule. We have projected that the number of overall health care information transactions—electronic and nonelectronic—increases with every year. The overall number of health care information transactions is a primary factor in our projection of savings derived from an increase in electronic transactions. Because the cost savings begins in 2017 in this final rule, in contrast to 2014 as was assumed in the April 2012 proposed rule, there is an increase in the cost savings of this rule when compared to the April 2012 proposed rule.

TABLE 7—ANNUAL COST SAVINGS FOR HEALTH PLANS FROM INCREASE DUE TO HPID IN VOLUME OF THREE ELECTRONIC TRANSACIONS *

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 (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)
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
2023	63.4	122.0	12.5	23.8	19.5	52.1
2024	66.0	126.9	13.1	24.9	20.6	58.4
2025	68.6	131.9	13.7	26.2	21.9	61.9
2026	71.4	137.2	14.4	27.5	23.2	65.6

Cumulative Annual Cost Savings:
LOW: $849 million.
HIGH: $1,728 million.
* Based on 2012 dollars.

TABLE 8—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 in usage of EDI in three transactions		Total savings for health plans	
LOW $776	HIGH $1,551	LOW $849	HIGH $1,729	LOW $1,625	HIGH $3,280

* 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

[26] 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.

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. The 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.[27] 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 or to manually investigate claims that have been rejected by health plans. 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 health plans—could be eliminated if the HPID were implemented.

In our proposed rule, we solicited stakeholder input on our basic assumptions, but we received no comments in this regard. Therefore, we have retained those basic assumptions. For more details on our assumptions and calculations, please refer to the April 2012 proposed rule.

As a result of use of the HPID in the standard transactions, we anticipate that the time physicians in physician practices will spend per week interacting with health plans will slightly decrease, resulting in a cost avoidance of approximately $1.4 to $2.8 billion.

The estimated range of cost avoidance represent an increase in the estimates that were made in the April 2012 proposed rule because the savings in this rule are calculated starting in 2017 while the savings in the proposed rule started in 2014. Due to an increase in the anticipated number of physicians, the cost avoidance is higher in this final rule than it was in the April 2012 proposed rule (Table 9).

Due to a lack of baseline data regarding other providers and physicians working in hospitals, we have not calculated any 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 9—PHYSICIAN SAVINGS THROUGH DECREASE IN TIME INTERACTING WITH HEALTH PLANS

	I	II	III	IV	V	VI	VII
Year	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)
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	389	779	374,688	$146 to $292
2024	60	0.4 to 0.8%	100,263	401	802	378,752	$152 to $304
2025	60	0.4 to 0.8%	103,271	413	826	382,815	$158 to $316
2026	60	0.4 to 0.8%	106,369	425	851	382,815	$163 to $326
Total							$1,413 to $2,826

* In 2012 dollars.

b. Increase in Three Transactions

The second area of savings for health care providers is the per transaction savings of moving from nonelectronic 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 7. However, the savings per transaction for health care providers differ from the savings that health plans will realize, as reflected in Table 14. 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

[27] 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.

next 10 years as illustrated in Table 10. 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.

For a more detailed description of the basic assumptions and calculations we used to arrive at the savings associated with these three transactions, please see the April 2012 proposed rule.

TABLE 10—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)
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
2023	40.68	78.23	7.98	15.21	7.11	19.05
2024	42.31	81.36	8.38	15.97	7.54	21.34
2025	44.00	84.61	8.80	16.77	7.99	22.62
2026	45.76	88.00	9.24	17.60	8.47	23.98

Cumulative Annual Cost Savings:
LOW: $499 million.
HIGH: $985 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 11: 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 11—TOTAL HEALTH CARE PROVIDER HPID SAVINGS *

[In millions]

I	II	III	IV	V	VI
Savings from decrease in provider time spent interacting with health plans		Savings from increase in usage of EDI in three transactions		Total savings for providers	
LOW $1,413	HIGH $2,826	LOW $499	HIGH $985	LOW $1,912	HIGH $3,811

* Based on 2012 dollars.

H. Summary for the HPID and NPI

TABLE 12—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	$1,625	$3,280	$652	$1,297	$328	$2,628
Health Care Providers	1,912	3,811	451	901	1,011	3,360

TABLE 12—HPID SUMMARY TABLE FOR HEALTH CARE INDUSTRY—Continued

	I	II	III	IV	V	VI
Total	3,537	7,091	1,103	2,198	1,339	5,988

* Calculated in 2012 dollars.

I. Regulatory Flexibility Analysis of 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 final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities.

In the April 2012 proposed rule, we used a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities (Table 13).

Table 13, Column II shows the number of small entities as discussed in the April 2012 proposed rule. Table 13, Column III shows revenues that were reported for 2009 in the Survey of Annual Services (*http://www.census.gov/services/sas_data.html*). Table 13, 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 13, Column V shows the percent of the small entity share of implementation costs as a percent of the small entity revenues.

In the April 2012 proposed rule we concluded that the anticipated economic effect of this rule on small entities would not exceed or even come close to meeting the threshold of 3 percent of revenues.

We did not receive any comments regarding the RFA in the April 2012 proposed rule, therefore we make no changes to the assumptions, calculations, and conclusions to that analysis. Based on that analysis, we certify that the HPID provision of this final rule would not have a significant economic impact on a substantial number of small entities.

TABLE 13—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 implementation of HPID (in millions)	Implementation cost revenue receipts (percent)
Physician practices	220,100	$359,853	$288	0.0014
Hospitals	6,500	729,870	645	0.00033

* In 2012 dollars.

J. 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 by October 1, 2013, 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 the April, 2012 proposed rule. We list these options in the preamble and summarize the public comments we received concerning them. Our responses are included in the preamble.

We decided that Option 4 was the most effective in mitigating the significant systemic disruption and payment delays that could have resulted from a large percentage of providers who might not have been ready to implement ICD–10 this October 1; and, in addition, as the RIA in this final rule suggests, Options 4 is most likely to minimize the costs of delay and to maximize the benefits to providers who need more time to implement.

K. Impacted Entities—ICD–10

All HIPAA covered entities may be affected by a delay in the compliance date of ICD–10 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 4 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 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. The ICD codes are used in nearly every sector of the medical and health industry.

Comment: A commenter noted that it was inaccurate to state that workers' compensation programs and automobile and personal liability insurers are not required to abide by HIPAA but may voluntarily do so. The association noted that Medicare has mandatory Medicare Secondary Payer reporting requirements for non group health plans (NGHPs) for liability insurance, no-fault insurance, and workers' compensation. Included in these required data elements for NGHP is the appropriate ICD–9 for the reported injury with mandated transition to ICD–10 when it is implemented.

Response: We agree with the commenter and refine our language to recognize that, while many health care entities are not required by HIPAA to comply with the code sets, standards and operating rules therein, these same health care entities may be required by other state and federal laws or trade agreements to use ICD codes, as is the case with Medicare's reporting requirements.

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

This impact analysis estimates the costs and benefits of a delay in compliance with ICD–10. We are analyzing only the impact of a delay, not the impact of ICD–10 implementation, which we addressed in the 2008 ICD–10 proposed rule (73 FR

49476) and the January 2009 ICD–10 final rule (74 FR 3328).

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 final 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 covered entities. The one area for which 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 previous **Federal Register** ICD–10 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 4, 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.[28] 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 include health care clearinghouses and transaction vendors as affected entities in Table 4. 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 also 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 to 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 group health 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.

In the proposed rule, we stated that ''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'' (77 FR 22991).

Comment: A commenter disagreed with our assumption that software vendors will pass on any incurred costs to their clients. The commenter noted that his organization had incurred costs nearing $1 billion and that further costs would be incurred with a delay. The commenter stated that the update to ICD–10 is part of the normal regulatory update process and that no conversion costs are passed on to the health plans or providers. Another commenter made a similar statement with regard to software vendors, but added that there are clearinghouses as well that make regulatory changes to their software without costs to their clients. Both commenters suggested including the costs to clearinghouses and vendors in the cost analysis.

Response: After consideration of the public comment received, we are revising our assumption with regard to software vendors and clearinghouses passing their costs of ICD–10 changes on to their clients, and recognize that there will be substantial costs associated with any delay for software vendors and clearinghouses in and of themselves. However, beyond anecdotal evidence, we do not have data on the numbers of software vendors or clearinghouses who will be affected or what the financial burden or benefit will be for software vendors or clearinghouses as a group. Therefore, we will not attempt to quantify the impact to software vendors or clearinghouses in this RIA.

M. 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 compliance date of October 1, 2013 than if the compliance date were to be delayed 1 year. 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 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

[28] ''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.

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.

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 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 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.

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. 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 anticipated 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.

We received no substantive comments with regard to our calculations and estimates of the cost avoidance of a 1-year delay in the compliance date of ICD–10 as described in the April 2012 final rule. We have provided the estimates and results of our calculations in the summary Table 17.

While there is a high level of uncertainty in terms of all of our assumptions, we believe it illustrative to make the calculation in order to demonstrate the affect that a delay in payments will have on small physician practices.

Comment: A commenter noted that the cost avoidance calculations are based on the assumption that certain costs will be completely avoided if the compliance date is delayed for 1 year. However, the commenter also noted that if providers are not prepared a year later, then all that will occur will be a delay of these costs, not an avoidance.

Response: We agree that if the delay is not used by the industry to be better prepared for the ICD–10 transition, then there will be no cost avoided by the delay. While there is no guarantee that the delay will translate into better preparation on the part of all health care entities, we anticipate that additional testing, outreach and education efforts will be targeted to help endangered segments, such as small providers, to achieve

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

1. 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.

Table 14 illustrates the calculation of 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.

TABLE 14—COST IN 2014 OF A 1-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 a 1-year delay	HIGH percent of total cost for 1-year delay	LOW estimate of 1-year delay (in millions)	HIGH estimate of 1-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.

2. Cost of a 1-Year Delay for CMS Health Plans

The Medicare program reports that it is prepared to be ICD–10 compliant on October 1, 2013. The 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.

3. Cost of a 1-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.

In Table 15, 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. One State Medicaid program commented that a 1-year delay in the compliance date would add $5 million to the overall cost of implementation, and this supports our assumption of high and low costs.

TABLE 15—COST IN 2014 TO STATE MEDICAID AGENCIES OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10*

# of State Medicaid that would be negatively affected	LOW cost of a 1-year delay per state agency (in millions)	HIGH cost of a 1-year delay per state agency (in millions)	LOW cost of a 1-year delay for Medicaid agencies (in millions)	HIGH cost of a 1-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.

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.

Table 16 illustrates the calculations for the cost to hospitals and large physician practices.

TABLE 16*—COST TO HOSPITALS AND LARGE PHYSICIAN PRACTICES IN 2014 FOR 1–YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 ***

	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

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

Comment: A commenter took issue with assumptions that we derived from the Edifecs poll. The commenter noted that the conclusions of the poll were based on a small sample of representatives from the various categories of health care entities, specifically providers.

Response: We agree with the commenter about the Edifecs poll. However, it is the only information we have, however scant, that specifically addresses the question of a delay and its costs. We used the Edifecs poll to arrive at one assumption in this RIA of the impact of a 1-year delay in the compliance date of ICD–10: A 1-year delay will cost an additional 10 to 30 percent of what commercial health plans and large providers have already budgeted on the ICD–10 transition to date.

Comment: Some commenters questioned the total cost to health care entities of transitioning to ICD–10 that we used as an assumption to calculate the cost of a 1-year delay. One commenter noted that our costs were higher than what was calculated in the January 16, 2009 ICD–10 final rule, and a number of commenters suggested that we conduct a robust survey of how much the transition is actually costing by polling health care entities that are in preparation for the transition. Other commenters also suggested conducting different kind of studies and further analyses in order to better make a decision on an ICD–10 compliance date. For example, one commenter suggested that a full examination be made of ICD–9–CM code development and allocation process and that necessary codes to that code set be assigned quickly.

Response: While we recognize that more robust data and further analysis could better substantiate a cost analysis—and, thus, better inform policy decisions– the purpose of this impact analysis was to help inform whether the health care industry necessitated a delay in the ICD–10 compliance date and, if so, to inform a policy as to the length of that delay. However, a great many of the comments insisted that the regulations that would adopt a compliance date be published as soon as possible in order that unreasonable costs and obstacles not be created while the rule itself was being developed. Thus, it was not deemed prudent to conduct a robust survey in order to obtain what is truly budgeted for the implementation of ICD–10.

We received no data or substantive arguments during the public comment period that our estimated cost of implementation was either too much or too little; only observations and anecdotes that the calculations were less accurate than they could be and based on surveys and polls that had questionable validity. We received some data from commenters on the cost of implementation from specific organizations: One commenter noted that it had dedicated $40 million to date on preparing for the ICD–10 transition. This is considerably above our estimates. Another commenter stated that, although they had started planning and dedicating resources to the transition, they had not expended any funds with regard to training or technical modifications. This is considerably less than our estimates. In light of the fact that there were no substantive arguments—or contradictory data—offered through public comment against our calculations, we continue to rely upon them in this final rule.

O. Summary for ICD–10

Our RIA confirms the need for a delay in the compliance date of ICD–10. In spite of the lack of conclusive data with regard to the overall status of the health care industry's preparation for the transition and the variables inherent in making projections on such a transition, it is apparent that a significant number of providers would not be ready for the original October 1, 2013 compliance date. If a significant number of providers would not be ready, it follows that there could be delays in the payment of health care claims and risk that disrupted cash flow to providers could affect access to health services. We have attempted to quantify a number of the consequences of such a disruption in this RIA, but possible disruptions in patient care are not quantifiable.

Given the risk of disruption in health care claim payments, we sought to measure the negative effects of a delay in the compliance date in this RIA. Although all the data we cite may not be statistically valid, there is a cost to every day that the date of ICD–10 compliance is delayed for entities that have already invested significant resources preparing for the transition. It is also likely that the consequences of a delay would affect entities and industries beyond the HIPAA covered entities that are required to use the code set. The cost to students and educational institutions in the RIA are but one example of this.

Weighing the risks and consequences of a disruption to health care claim payments with an apparent increased cost of delay to the estimated 75 percent of covered entities who would be able to comply October 1, 2013, we believe that a one-year delay in the implementation date strikes the best regulatory balance. It is our best judgment that, to go forward with the original compliance date would risk disruptions on many levels, while a delay of any more than a year would incur costs that could not be justified in the name of avoiding risk.

We summarize the low and high estimates of a 1-year delay in the compliance date for ICD–10 in Table 17.

The total costs and cost avoidance of a 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. 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 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 17, 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 17—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

TABLE 17—SUMMARY OF COST AVOIDANCE AND COSTS IN 2014 OF A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10 *—Continued

	LOW (in millions)	HIGH (in millions)	MEAN (average) (in millions)
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 18—COST AVOIDANCE LESS COST (NET) OF A 1-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.

P. 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 final rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. According to the Small Business Administration's size standards, a small entity is defined as follows according to health care categories: 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).

We stated in the April 2012 proposed rule that there were 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. We also assumed, for purposes of the RFA, that all physician practices and hospitals were small entities. Accordingly, we found in the April 2012 proposed rule that a one-year delay in implementation of the ICD–10 will affect a ''substantial number'' of small entities.

However, as illustrated in Tables 19 and20, we concluded in the April 2012 proposed rule that the 1-year delay in the compliance date of ICD–10 will be more beneficial to small and nonprofit entities than it will be burdensome. Based on that analysis, we certify that the provisions related to ICD–10 in this final rule would not have a significant economic impact on a substantial number of small entities.

Comment: One commenter stated that it was impossible to see how we could arrive at the conclusion that the final rule would not affect small entities when the cost to implement ICD–10 is so high. The commenter noted that it was rather falsehearted for us to state, as we did in the April 2012 proposed rule, that we were only analyzing the impact of the delay, not the impact of the ICD–10 implementation that we addressed in the August 2008 proposed rule. Instead, our latest cost estimates of implementing ICD–10—that the commenter viewed as improperly documented and misleading—should have triggered a re-review of the RIA conducted in the August 2008 proposed rule.

Response: The RIA of the April 2012 proposed rule, and this final rule, are focused on the impact of the provision of the proposed and final rule; that is, a delay in the compliance date of ICD–10. As noted in this RFA, a delay will be beneficial for small entities, otherwise there is no reason to go forward with a delay. We cannot revisit cost/benefits of implementing ICD–10, at least to the extent it was done so in the August 2008 proposed rule, because this rule does not mandate ICD–10; it delays it. As for our estimates on costs and cost avoidance of a delay in the compliance date of ICD–10, we believe that we have been transparent in admitting that our calculations are based on some studies and polls that lack statistical validity. Weighing industry's need for clarity on the ICD–10 compliance date and the need to meet high standards of analysis by conducting a comprehensive study or poll, we believed that an expedient answer on the compliance date would be more beneficial to industry's financial and business needs.

TABLE 19—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

TABLE 19—COSTS AND BENEFITS IN 2014 OF A DELAY IN THE COMPLIANCE DATE OF ICD–10 FOR PROVIDERS—Continued

[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
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.

TABLE 20—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.

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

Table 21 summarizes the impacts of this final rule, including the costs and benefits of implementation of the HPID and the costs and cost avoidance of a 1-year delay in the compliance date of ICD–10. The costs and benefits of implementation of the HPID are calculated over an 11-year period, 2016 through 2026, while the cost avoidance and costs of the delay of the compliance date of ICD–10 will all occur in 2014.

TABLE 21—SUMMARY OF COSTS AND SAVINGS/COST AVOIDANCE, OF IMPLEMENTATION OF HPID, NPI AND A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In millions]*

	LOW	HIGH	MEAN
Total Savings/Cost Avoidance	$7,172	$14,968	$11,070
Total Costs	2,134	8,784	5,459

* Costs and savings of HPID are calculated over 11 years, 2016 through 2026. Costs and cost avoidance of a delay in the compliance date of ICD–10 are calculated over 1 year, 2014. In 2012 dollars.

In Table 22, 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 22—SUMMARY OF NET COST AVOIDANCE/SAVINGS OF IMPLEMENTATION OF HPID, NPI, AND A 1-YEAR DELAY IN THE COMPLIANCE DATE OF ICD–10

[In 2012 dollars]

	LOW NET SAVINGS (cost avoidance/savings less HIGH costs) (in millions)	HIGH NET SAVINGS (cost avoidance/savings less LOW costs) (in millions)	MEAN NET SAVINGS (in millions)
Net Savings/Cost Avoidance	−$1,612	$12,834	$5,611

As required by OMB Circular A–4,[29] Tables 23, 24, and 25 are accounting statements showing the classification of the expenditures associated with the provisions of this final rule. Table 23 provides our best estimate of the costs and benefits associated with the implementation and use of the HPID. Table 24 provides our best estimates of the costs and benefits associated with a 1-year delay in the compliance date of ICD–10. Table 25 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 23—ACCOUNTING STATEMENT FOR HPID IMPLEMENTATION: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2016 TO FY 2026

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$348	$246	$525	RIA.
3% Discount	329	246	506	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.
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 24—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE FOR 2014

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$5,756	$3,635	$7,874	RIA.
3% Discount	5,756	3,635	7,874	RIA.
Qualitative (unquantified) benefits.	Avoidance of returned health care claims.			
COSTS:				
Annualized Monetized costs:				
7% Discount	$3,808	$1,031	$6,586	RIA and Collection of Information.
3% Discount	3,808	1,031	6,586	RIA and Collection of Information.
Qualitative (unquantified) costs.	Downstream costs of a delayed return on investment for covered entities.	None	None.	
TRANSFERS:				

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

TABLE 24—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE FOR 2014—Continued

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
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 25—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR HPID IMPLEMENTATION AND 1-YEAR DELAY OF ICD–10 COMPLIANCE DATE, FROM FY 2014 TO FY 2026

[In millions of 2012 dollars]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, etc.)
BENEFITS:				
Annualized Monetized benefits:				
7% Discount	$916	$613	$1,292	RIA.
3% Discount	795	540	1,134	RIA.
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	$596	$229	$963	RIA and Collection of Information.
3% Discount	493	191	795	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 amends 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)'' 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 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 May 6, 2013.

* * * * *

■ 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. Part 162 is amended by adding subpart E 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 requirements for the implementation of the standard unique health plan identifier.

(a) *Covered entities.* A covered entity must comply with the implementation requirements in § 162.510 no later than November 5, 2014.

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

(1) A health plan that November 5, 2014.

(2) A health plan that is a small health plan–

November 5, 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 must 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 or OEID 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 Full implementation requirements: Covered entities.

(a) A covered entity must use an HPID to identify a health plan that has an HPID when 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 that has an HPID when 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) and (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.

(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.

■ 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: August 21, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: August 22, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–21238 Filed 8–24–12; 12:00 pm]

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