DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 162

[CMS–0032–IFC]

RIN 0938–AQ12

Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions

AGENCY: Office of the Secretary, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: Section 1104 of the Administrative Simplification provisions of the Patient Protection and Affordable Care Act (hereafter referred to as the Affordable Care Act) establishes new requirements for administrative transactions that will improve the utility of the existing HIPAA transactions and reduce administrative costs. Specifically, in section 1104(b)(2) of the Affordable Care Act, Congress required the adoption of operating rules for the health care industry and directed the Secretary of Health and Human Services to ''adopt a single set of operating rules for each transaction * * * with the goal of creating as much uniformity in the implementation of the electronic standards as possible.''

This interim final rule with comment period adopts operating rules for two Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions: eligibility for a health plan and health care claim status. This rule also defines the term ''operating rules'' and explains the role of operating rules in relation to the adopted transaction standards. In general, transaction standards adopted under HIPAA enable electronic data interchange through a common interchange structure, thus minimizing the industry's reliance on multiple formats. Operating rules, in turn, attempt to define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more, in order to facilitate successful interoperability between data systems of different entities.

DATES: *Effective Date:* These regulations are effective on June 30, 2011. The incorporation by reference of the publications listed in this interim final rule is approved by the Director of the Office of the Federal Register June 30, 2011.

Compliance Date: The compliance date for this regulation is January 1, 2013.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2011.

ADDRESSES: In commenting, please refer to file code CMS–0032–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0032–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0032–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT: Shannon Whetzel (410) 786–3267. Matthew Albright (410) 786–2546. Denise Buenning (410) 786–6711.

SUPPLEMENTARY INFORMATION:

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

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Introduction

The background discussion below presents a partial statutory and regulatory history related only to the statutory provisions and regulations that are important and relevant for purposes of this interim final rule with comment period. For further information about electronic data interchange, the complete statutory background, and the regulatory history, see the proposed rule entitled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,'' published in the **Federal Register** on August 22, 2008 (73 FR 49742).

Congress addressed the need for a consistent framework for electronic health care transactions and other administrative simplification issues through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), (Pub. L. 104–191), enacted on August 21, 1996. HIPAA amended the

Social Security Act (hereinafter referred to as the Act) by adding Part C—Administrative Simplification—to Title XI of the Act requiring the Secretary of the Department of Health and Human Services (hereinafter referred to as the Secretary) to adopt standards for certain transactions to enable health information to be exchanged electronically and to achieve greater uniformity in the transmission of health information. Electronic Data interchange (EDI) enables providers and payers to process financial and administrative transactions faster and at a lower cost than manual transactions.

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

In the January 16, 2009 **Federal Register**, we published a final rule entitled, ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' (74 FR 3296) (hereinafter referred to as the Modifications final rule), that, among other things, adopted updated versions of the standards [(ASC X12 Version 5010 (hereinafter referred to as Version 5010)] and NCPDP Version D.0) for the electronic health care transactions originally adopted in the Transactions and Code Sets final rule. Covered entities are required to comply with the updated standards for electronic health care transactions on January 1, 2012. Table 1 lists HIPAA standard transactions.

TABLE 1—CURRENT ADOPTED STANDARDS FOR HIPAA TRANSACTIONS

Standard	Transaction
ASC X12 837 D	Health care claims—Dental.
ASC X12 837 P	Health care claims—Professional.
ASC X12 837 I	Health care claims—Institutional.
NCPDP D.0	Health care claims—Retail pharmacy drug.
ASC X12 837 P and NCPDP D.0	Health care claims—Retail pharmacy supplies and professional services.
NCPDP D.0	Coordination of Benefits—Retail pharmacy drug.
ASC X12 837 D	Coordination of Benefits—Dental.
ASC X12 837 P	Coordination of Benefits—Professional.
ASC X12 837 I	Coordination of Benefits—Institutional.
ASC X12 270/271	Eligibility for a health plan (request and response)—dental, professional, and institutional.
NCPDP D.0	Eligibility for a health plan (request and response)—Retail pharmacy drugs.
ASC X12 276/277	Health care claim status (request and response).
ASC X12 834	Enrollment and disenrollment in a health plan.
ASC X12 835	Health care payment and remittance advice.
ASC X12 820	Health plan premium payment.
ASC X12 278	Referral certification and authorization (request and response).
NCPDP D.0	Referral certification and authorization (request and response)—retail pharmacy drugs.
NCPDP 5.1 and D.0	Retail pharmacy drug claims (telecommunication and batch standards).
NCPDP 3.0	Medicaid pharmacy subrogation (batch standard).

In general, the transaction standards adopted under HIPAA enable electronic data interchange using a common interchange structure, thus minimizing the industry's reliance on multiple formats. While the standards significantly decrease administrative burden on covered entities by creating greater uniformity in data exchange, and reduce the amount of paper forms needed for transmitting data, gaps created by the flexibility in the standards permit each health plan to use the transactions in very different ways, which remains an obstacle to achieving greater health care industry administrative simplification. These gaps include all of the following:

• Performance and system availability. Because the standards permit the flexibility of conducting the transactions in batch mode or real-time, in order to minimize the number of different implementations, some submitters have resorted to contracting with clearinghouses for transaction exchanges that require batch submissions, and simultaneously are utilizing internal resources for real-time submissions. Some batch submissions are only conducted overnight. Typically batch submissions can be substantially slower than real-time transmissions, and systems may be available only at certain times for conducting certain transactions.

• Connectivity and transportation of information. In traditional trading partner agreements, health plans specify their connectivity options for conducting the standard transactions. These options can vary from plan to plan. For example, some payers only conduct the transactions through a contracted clearinghouse. Others offer a direct connection to their system. Still others use both—contract with a clearinghouse for some transactions, and offer direct connect solutions for other transactions. Also, there are some plans that offer a number of options, and negotiate a choice with each trading partner, including providers.

• Security and authentication. Currently, security standards do not prescribe requirements for levels of security and authentication when conducting the standard transactions and accessing protected health information. A covered entity's level of security and authentication requirements is determined by the individual entity's periodic assessments for security risk and vulnerabilities. Organizations have latitude to determine and document the number and types of security safeguards that they implement. Although this flexibility supports the implementation

of security safeguards that are consistent with the uniqueness of various organizations, it also limits standardization for security compliance.

• Business scenarios and expected responses. The standards do not define methods by which trading partners, including providers, establish electronic communication links, or types of hardware and software to exchange EDI data. Each trading partner, including providers, separately provides specific requirements; for example, the number of transactions that are submitted in a file. Transaction processing in each entity's system will vary from one trading partner, including providers, to another. The responses to compliantly implementing these various transaction processing systems are identified by trading partners, including providers, in documentation that is in addition to the adopted implementation guides. These types of documented business requirements can vary in terms of number and complexity.

• Data content refinements. In accordance with trading partner agreements, plans can ignore certain data that are submitted if not needed by them to conduct the transaction. They also can refine certain data elements and require their submission. Trading partner agreements and additional documentation that plans develop permit plans to define specific types of data and to clarify the specific data that is required to be submitted for successful completion of a transaction. Although the standards limit the number of data elements that can be defined or optionally submitted, a plan's individual business flow and operations may impose specific data definition and submission requirements.

These gaps, among other challenges in the implementation of the standards, have spurred the creation of companion guides by health plans. Health plans have created these companion guides to describe their unique implementation of HIPAA transactions and how they will work with their business partners. Historically, companion guides have been used to establish business practices such as response time, system availability, communication protocols, hours of operation, amount of claim history available for inquiries and real-time adjustments, security practices, and more. Health plans' companion guides vary in format and structure. Such variance can be confusing to trading partners (those entities, including providers, who exchange HIPAA compliant electronic transactions), who must implement them in addition to the specifications in the transaction standard implementation guides. Further, each companion guide is unique for each different health plan.

Currently, according to the American Medical Association (AMA) there are over 1,200 such companion guides in existence (*http://www.ama-assn.org/ama1/pub/upload/mm/368/hipaa-tcs.pdf*). As mentioned previously, companion guides require providers and trading partners, including providers, to adhere to different transaction implementation rules for different health plans. Therefore, the widespread proliferation of health plan companion guides is particularly burdensome to health care providers, and we believe has subverted the goal of administrative simplification.

Over the past 5 years, this proliferation of health plan companion guides has given rise to the development of operating rules. To facilitate successful interoperability between data systems of different entities, operating rules more clearly define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more. Operating rules have been shown to reduce costs and administrative complexities as will be described later in this interim final rule with comment period.

The use of operating rules is widespread and varied among other industries. For example, uniform operating rules for the exchange of Automated Clearing House (ACH) payments among ACH associations are used in compliance with U.S. Federal Reserve regulations (12 CFR Part 370), and maintained by the Federal Reserve and the Electronic Payments Network. Additionally, credit card issuers employ detailed operating rules (for example, Cirrus Worldwide Operating Rules) describing types of members, their responsibilities and obligations, licensing and display of service marks, *etc.*

B. Operating Rules Mandated by the Affordable Care Act

Congress sought to address the aforementioned problems in the health care industry by requiring the adoption of operating rules for the health care industry as outlined in the Patient Protection and Affordable Care Act (Pub L. 111–148), enacted on March 23, 2010, and by the Health Care and Education Reconciliation Act of 2010, (Pub. L. 111–152), which was enacted on March 30, 2010 (hereinafter referred to as the Affordable Care Act). Section 1173(g)(1) of the Act, as added by section 1104(b)(2) of the Affordable Care Act, requires the Secretary to ''adopt a single set of operating rules for each transaction * * * with the goal of creating as much uniformity in the implementation of the electronic standards as possible.''

The role of operating rules is to support the adopted standards for health care transactions in order to foster and enhance uniform use of the adopted standards and implementation guides across the health care industry. Standards and operating rules overlap in their functions to increase uniformity, but differ in their purposes. While standards are mainly concerned with the content transmitted in a transaction, operating rules provide for the method of how the information should be transmitted, as well as the elimination of certain situationality in the use of data content contained in the standards. Situationality refers to the fact that many transaction requirements only apply if the situation is presented. For example, in the 271 eligibility response transaction, the health plan name is only required when a specific plan name exists for the plan for which the individual has coverage.

Operating rules augment the standards in the following three important ways:

• They contain additional requirements that help implement the standard for a transaction in a more consistent manner across health plans. For example, when a provider currently sends an eligibility for a health plan inquiry to a health plan, the standard allows responses ranging from a simple ''yes'' or ''no'', to the inclusion of a complete range of information. The operating rule requires the health plan to return patient eligibility and financial responsibility for a specified list of service type codes including, but not limited to, dental, vision, medical, hospital inpatient, and emergency care. This requirement ensures that a provider, who submits the same inquiry to multiple payers, receives a consistent response for an eligibility for a health plan inquiry. This reduces the number of customized transactions when dealing with multiple health plans, thus saving both time and money.

• They address ambiguous or conditional requirements in the standard and clarify when to use or not use certain data elements or code values. For example, the standard may leave it to the discretion of the health plan whether or not to return the health plan's name in a particular field, creating the possibility of inconsistency in health plan responses. An operating rule may require that the health plan name always be returned and that it

always be returned in one particular specified manner. This encourages uniformity and alleviates the problem of providers receiving inconsistent information.

• They specify how trading partners, including providers, should communicate with each other and exchange patient information, with the goal of eliminating connectivity inconsistencies. Currently, individual health plans specify the transmission methods they expect each of their trading partners, including providers, to use for electronic transactions. Mandating one uniform method decreases the amount of work and inconsistencies providers experience when dealing with multiple payers with differing transmission methods.

The Affordable Care Act presents a definition of operating rules and provides a great deal of guidance about the role Congress envisioned for operating rules in relation to the standards. Operating rules are defined by section 1171(9) of the Act (as added by section 1104(b)(1) of the Affordable Care Act) as ''the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.'' Additionally, section 1173(a)(4)(A) of the Act (as added by section 1104(b)(2) of the Affordable Care Act) requires that—

> The standards and associated operating rules adopted by the Secretary shall—
> (i) to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care;
> (ii) be comprehensive, requiring minimal augmentation by paper or other communications;
> (iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and
> (iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).''

Section 1104(b)(2) of the Affordable Care Act also amended section 1173 of the Act by adding new subsection (a)(4)(B), which states that, ''[i]n adopting standards and operating rules for the transactions* * *, the Secretary shall seek to reduce the number and complexity of forms (including paper and electronic forms) and data entry required by patients and providers.''

Section 1104(b)(2) of the Affordable Care Act added section 1173(g)(1) to the Act, which states that, ''[s]uch operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.''

New sections 1173(g)(2)(D), (g)(3)(C), and (g)(3)(D) of the Act also clarify the scope of operating rules. They provide that,

> In adopting operating rules under this subsection, the Secretary shall consider recommendations for operating rules developed by a qualified nonprofit entity that meets the following requirements * * * (D) The entity builds on the transactions issued under Health Insurance Portability and Accountability Act of 1996. * * * The National Committee on Vital and Health Statistics shall * * * (C) determine whether such operating rules represent a consensus view of health care stakeholders and are consistent with and do not conflict with other existing standards; (D) evaluate whether such operating rules are consistent with electronic standards adopted for health information technology

We take from the statutory context the following information about operating rules to be adopted under HIPAA:

• They are business rules and guidelines;
• They are necessary for the electronic exchange of information;
• They are not defined by a standard;
• They do not conflict with the existing HIPAA standards;
• They are consensus based;
• They are consistent with HIPAA and Health Information Technology (HIT) standards adopted by the Secretary; and
• Together with standards they encourage the use of electronic transactions by reducing ambiguities currently permitted by the standard, resulting in better-defined inquiries and responses that add value to provider practice management and health plan operations.

II. Provisions of the Interim Final Rule With Comment Period

A. Definition of Operating Rules

Section 1171(9) of the Act, as added by section 1104(b)(1) of the Affordable Care Act, defines operating rules as ''the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.'' We are adding the term ''operating rules'' to the definitions in regulations at 45 CFR 162.103, and defining it just as it appears in the statute. We note that, in the statutory reference, ''this part'' refers to Part C of Title XI of the Act, Administrative Simplification. In the regulation at 45 CFR 162.103, ''this part'' refers to Part 162 of the CFR, the part in which the definition appears, which contains the regulations that pertain to, among other things, the HIPAA transactions and code sets. The following discussion further explains operating rules and their scope, in light of their relationship to the standards.

Business rules and guidelines are not defined by the statute, nor has the health care industry specifically defined business rules or guidelines for itself. These are very broad terms and there are many ways to define them. Generally, business rules and guidelines are statements that refine and specify. For purposes of operating rules, business rules and guidelines are statements that refine and specify.

While operating rules may have a very broad scope as business rules and guidelines in order to cover the full spectrum of data content, from data elements to standards, we believe there are limitations. To meet the definition of operating rules, business rules and guidelines must be ''*necessary* * * * for the electronic exchange of information that are not defined by a standard or its implementation specifications.'' We interpret the term ''necessary'' to be those operating rules needed to facilitate better communication between trading partners, including providers, to fill gaps in the standards, and to fulfill the purposes and principles set out in sections 1173(a)(4)(A)(i) through (iv) and (B) of the Act.

If a business rule or guideline is necessary for the electronic exchange of information, it must also be one that is ''not defined by'' a HIPAA standard or its implementation specifications in order to meet the definition of an operating rule. We consider a business rule or guideline that does not duplicate what is in the standard to be one that is not defined by the standard. Business rules and guidelines that duplicate what is in the standard are not operating rules under our interpretation.

The National Committee on Vital and Health Statistics (NCVHS) is tasked with reviewing any operating rule developed and recommended to the Secretary for adoption. The NCVHS is to make recommendations to the Secretary and determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other

existing standards under section 1173(g)(3)(C) of the Act. The NCVHS must also determine if such operating rules are consistent with electronic standards adopted for health information technology under section 1173(g)(3)(D) of the Act. From these statutory provisions, we understand that operating rules should be consistent with and not be in conflict with the adopted HIPAA standards and HIT standards (for example, those standards that address governance, funding and infrastructure of controlled vocabularies, value sets and vocabulary subsets to be used primarily to further interoperability between providers and systems). We believe that, if an operating rule imposes a requirement that would make it impossible for a party to comply with both the associated HIPAA standard and the operating rule, then the operating rule conflicts with the standard. This interpretation is consistent with fundamental principles and precedents regarding when a conflict exists. If a party is able to satisfy both the requirements of the standard and the requirements of the operating rule, there is no conflict and the operating rule is consistent with the standard. Table 2 illustrates what we consider to be a conflict by presenting hypothetical scenarios that illustrate when an operating rule could or could not conflict with a standard.

TABLE 2—COULD AN OPERATING RULE CONFLICT WITH A STANDARD?

Statement in the standard	Statement in the operating rule	Does the operating rule's statement conflict with the standard's statement?	Justification
"X is recommended."	"X is "required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is not required."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X cannot be required."	"X is required."	Yes	It is impossible for an entity to comply with both the standard and the operating rule.
"X is required."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule. (However, to the extent that the statement in the operating rule duplicates the statement in the standard, the operating rule statement would not be considered an operating rule.)
"X is at the discretion of person #1. Person #2 cannot require it."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is required."	"X is required, so is Y."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is required. No other can be required."	"X is required, so is Y."	Yes	It is impossible for an entity to comply with both the standard and the operating rule.

Our current definition of standard at 45 CFR 160.103 is very broad. In fact, it is so broad that it could include operating rules as we are defining that term at § 162.103. Therefore, we are revising the definition of standard at § 160.103 to be clear that standards and operating rules are separate and distinct. See the ''Additional Requirements'' section for discussion of this change.

B. National Committee on Vital and Health Statistics and the Affordable Care Act

The National Committee on Vital and Health Statistics (NCVHS) was established by Congress to serve as an advisory body to the Department of Health and Human Services (DHHS) on health data, statistics and national health information policy, and has been assigned a significant role in the Secretary's adoption of operating rules under section 1173(g)(3) of the Act (as added by section 1104(b)(2) of the Affordable Care Act).

In July 2010, the NCVHS' Subcommittee on Standards convened a hearing to discuss the Affordable Care Act's provisions pertaining to operating rules for the eligibility for a health plan and health care claim status transactions. Section 1173(g)(3) requires the NCVHS to do the following:

- Advise the Secretary whether a nonprofit entity meets the requirements for development of operating rules.
- Review the operating rules developed and recommended by such nonprofit entity.
- Determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards.
- Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology.
- Submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules.

The NCVHS engaged in a comprehensive review of health care operating rules and their authors, with the goal of determining whether an entity was qualified to develop operating rules for transactions and to evaluate existing operating rules for purposes of making a recommendation to the Secretary as to whether those operating rules should be adopted. The process consisted of a full day of public testimony on July 20, 2010, with participation by more than 20 stakeholders representing a cross section of the health care industry, including health plans, provider organizations, health care clearinghouses, pharmacy industry representatives, health care industry associations, standards developers, professional associations, representatives of Federal and State health plans, the banking industry, and the entities proposing to serve as operating rules authoring entities.

During the hearing, testifiers reiterated the need for greater consistency and standardization in HIPAA transactions consistent with the Affordable Care Act amendments to the HIPAA, which highlight the need to improve the use of standard transactions, increase industry adherence to the implementation specifications of the standards, encourage greater adoption of electronic transactions, and enable more timely

updates and adoption of the HIPAA standards. Testifiers claimed that all of these could help reduce the clerical burden on the industry in the use of paper and the non-standard use of the current transaction standards.

We believe that the considerable public participation in the NCVHS hearings for adoption of operating rules demonstrates an increasing level of support and interest from broader segments of the health care industry. Per the NCVHS' recommendation, we will work with industry to continue this public exchange of information regarding operating rules, standards and their respective roles in administrative simplification.

Based on the NCVHS testimony (*http://www.ncvhs.hhs.gov/100719ag.htm*) and the NCVHS' analysis of the operating rules and qualifications of the candidate authoring entities, the NCVHS developed a set of recommendations to the Secretary, which are outlined in the following discussions.

C. Operating Rules Authoring Entities

Section 1173(g)(3)(A) of the Act charges the NCVHS with advising the Secretary as to whether a nonprofit entity meets the statutory requirements for developing the operating rules to be adopted by the Secretary. Those requirements, at section 1173(g)(2) of the Act, include all of the following:

- The entity focuses its mission on administrative simplification.
- The entity demonstrates a multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standards development organizations.
- The entity has a public set of guiding principles that ensure the operating rules and process are open and transparent, and supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.
- The entity builds on the transaction standards issued under the Health Insurance Portability and Accountability Act of 1996.
- The entity allows for public review and updates of its operating rules.

Of those organizations testifying at the July 2010 NCVHS hearing, two organizations formally requested to be considered authoring entities for operating rules. These entities were the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE) and the National Council for Prescription Drug Programs (NCPDP).

The CAQH, a nonprofit alliance of health plans and trade associations, supports industry collaboration on initiatives that simplify health care administration (*http://www.caqh.org/about.php*). The CAQH launched the CORE with the goal of giving providers access to eligibility and benefits information before or at the time of service. The CAQH CORE is engaged in the development of voluntary operating rules for the facilitation of administrative health care transactions. It has already developed operating rules for the eligibility for a health plan and health care claim status transactions. The CAQH CORE has also demonstrated that the use of these rules yields a return on investment for both business operations and systems within today's complex health care environment (*http://www.caqh.org/COREIBMstudy.php*).

The NCPDP is a not-for-profit standards development organization (SDO) accredited by the American National Standards Institute (ANSI), with over 1,500 members representing the pharmacy services industry (*http://ncpdp.org/WP.aspx*). It is one of several SDOs involved in health care information technology and standardization, with a focus on retail pharmacy services, and has member representation from the pharmacy services sector of health care (*http://ncpdp.org/about.aspx*). The operating rules the NCPDP brought forth to NCVHS focus on the retail-pharmacy sector.

The July 2010 NCVHS hearings were followed by a request from the NCVHS Subcommittee on Standards to both the CAQH CORE and the NCPDP as authoring entity candidates, to respond to detailed questionnaires about their ability to meet the statutory requirements of the Affordable Care Act as authoring entities for health care operating rules. The NCVHS request solicited specific documentation from the two candidates to validate their previous testimony, including minutes, voting records and copies of bylaws. Both the CAQH CORE and the NCPDP responded to the Subcommittee's request and submitted their respective applicable materials. A synopsis of the candidates' responses can be found on the Internet at *http://www.ncvhs.hhs.gov/100930lt2.pdf.*

Upon review of the CAQH CORE's and the NCPDP's respective responses to the NCVHS questionnaire, the NCVHS determined that both organizations met the statutory requirements to be an operating rules authoring entity. The NCVHS noted, however, that there are still adjustments to process and procedures that may be required of both organizations to enhance transparency, citing the need for more formalized relations with each other and with other SDOs, inclusion of a more diverse cadre of stakeholders, and a more formal public review process. Both the CAQH CORE and the NCPDP acknowledged these issues in their submitted responses to the NCVHS (*http://www.ncvhs.hhs.gov/100930lt2.pdf*).

The NCVHS advised the Secretary in its letter dated September 30, 2010, (*http://www.ncvhs.hhs.gov/100930lt2.pdf*) that the CAQH CORE meets the requirements of section 1173(g)(2) of the Act to be the operating rules authoring entity for the non-retail pharmacy-related eligibility for a health plan and health care claim status standard transactions with additional qualifying requirements. In the same letter, the NCVHS stated that the NCPDP met the requirements to be the authoring entity for operating rules for retail pharmacy-related eligibility transactions (as outlined in the Telecommunications Standard Implementation Guide Version D.0) also with additional qualifying requirements. Those requirements for both the CAQH CORE and the NCPDP are as follows:

- Require authoring entities to maintain minutes, attendance, voting records, and other appropriate documentation that will help the NCVHS conduct verification that the authoring entities have utilized an open, consensus-driven process with broad stakeholder participation and provided an opportunity for public comment in authoring any new operating rules or new versions of existing operating rules, consistent with such processes followed by ANSI-accredited standards development organizations.
- Continue to use the NCVHS and its open process to evaluate, select, and recommend any new qualifying operating rules authoring entities when it comes time to adopt operating rules for other transactions, or for newer versions of the operating rules for the transactions for which the CAQH CORE and the NCPDP are being recommended to be named authoring entities at this time.

After our own review and analysis of the CAQH CORE and the NCPDP applications for consideration to be authoring entities for their respective developed operating rules, and the NCVHS' recommendation, we have determined that the CAQH CORE is qualified to be the operating rules authoring entity for non-retail

pharmacy-related eligibility for a health plan and health care claim status standard transactions per section 1173(g)(2) of the Act.

At the time of the hearing, the NCVHS based its recommendation to appoint the NCPDP as an operating rules authoring entity on the testimony presented. However, upon further review and consultation, we have determined that the NCPDP's standard provides enough detail and clarity to operationalize the standards to the point where no gaps exist that operating rules would need to fill and no further infrastructure or data content rules need to be adopted. (For a more detailed discussion, see section III. of this interim final rule with comment period).

D. Adoption of Operating Rules

1. Adoption of the CAQH CORE Phase I and Phase II Operating Rules for the Non-Retail Pharmacy Eligibility for a Health Plan and Health Care Claim Status Transactions (Updated for Version 5010)

The CAQH CORE builds consensus among health care industry stakeholders on a set of operating rules that facilitate administrative interoperability between health plans and providers by building on applicable HIPAA transaction requirements, enabling providers to submit transactions from any system, and facilitating administrative and clinical data integration. The CAQH CORE uses a phased approach for developing operating rules. This approach allows for developing rules and implementing them via incremental, achievable milestones, and helps to maximize rule adoption. The CAQH CORE Phase I operating rules were developed in 2006 and focused on the eligibility for a health plan transaction. The CAQH CORE Phase II rules, developed in 2008, added operating rules for the health care claim status transaction, and more rules for the eligibility for a health plan transaction that were not included in Phase I. Both the CAQH CORE Phase I and Phase II operating rules were updated to accommodate the Version 5010 HIPAA standards, which were adopted by the Secretary via the final rule published in the **Federal Register** on January 16, 2009 (74 FR 3296) and with which HIPAA covered entities must be compliant on January 1, 2012.

The CAQH CORE operating rules (updated for Version 5010) include both infrastructure rules and data content rules. The infrastructure rules help improve data content flow between provider and payer. They improve interoperability by addressing all of the following:

- Connectivity—provide a uniform way for stakeholders to connect (through the Internet).
- Response Times—specify that information will be available in real time.
- System Availability—specify systems delivering information be available a certain amount of time.
- Patient Identification—help assure patient matching/identification can occur.

The CAQH CORE's first set of operating rules (updated for Version 5010) are Phase I rules for eligibility for a health plan transaction. They help electronically confirm patient benefit coverage, copay, coinsurance, and base deductible. In addition, through requirements to use common Internet protocols, they allow providers to access needed patient information prior to or at the point of care. The CAQH CORE's second set of operating rules (updated for Version 5010) are the Phase II rules for the eligibility for a health plan and health care claim status transactions. They expand on the first set by adding a requirement for transaction recipients to send back patient remaining deductible amounts, rules to improve patient matching, health care claim status infrastructure requirements (for example, response time) and more prescriptive connectivity requirements.

We have examined each of the CAQH CORE Phase I and Phase II operating rules and are adopting those that we believe further enhance the HIPAA transactions by better facilitating communication between trading partners, including providers, filling gaps in the associated standards, and fulfilling the requirements, purposes, and principles set out in the statute at sections 1173(a)(4)(A)(i through iv) and (B). Of the eight CAQH CORE Phase I operating rules (updated for Version 5010), we are adopting the following six:

- Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.
- Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011.
- Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011.
- Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011.
- Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011.
- Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011.

We are adopting all five of the CAQH CORE Phase II operating rules (updated for Version 5010). They include the following:

- Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.
- Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011.
- Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011.
- Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011.
- Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011.

Both the CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) that we are adopting in this interim final rule with comment period can be found on the CAQH CORE Web site at *http://www.caqh.org/COREVersion5010.php.* Below we briefly describe those operating rules.

The Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule (updated for Version 5010) and CORE Version 5010 Master Companion Guide Template provide a standardized format for health plan companion guides. As mentioned previously, health plans have the option of creating a companion guide that describes the specifics of how they implement the HIPAA transactions. Currently, health plans have independently created companion guides that vary in format and structure, which can be confusing to trading partners, including providers, and providers who must review numerous companion guides along with the Version 5010 Implementation Guides. To address this issue, the CAQH CORE developed the CORE Version 5010 Master Companion Guide Template to ensure that the structure of each health plan's companion guide is similar to every other health plan's companion guide, making it easier for providers to find information quickly.

Developed with input from multiple health plans, system vendors, provider representatives and healthcare and HIPAA industry experts, the CAQH CORE template organizes information into several sections including, general information (sections 1 through 9) and

transaction-specific information (section 10), as well as appendices that provide helpful information, such as an information checklist, descriptions of typical business scenarios, transmission examples, FAQs, and a summary of the changes between companion guides. The CAQH CORE recognizes that different health plans may have different requirements, so the CORE v5010 Master Companion Guide Template gives health plans the flexibility to tailor companion guides to meet each of their own particular needs.

The Phase I CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) addresses usage patterns for both batch and real time transactions, the exchange of security identifiers, and communications-level errors and acknowledgements. It does not define the specific content of the message.

Currently, multiple connectivity methods, some based on open standards, others on proprietary approaches, are in use for administrative electronic transactions in the health care industry. Health care providers and health plans support multiple connectivity methods to connect to different health plans, clearinghouses, provider organizations and others, which add costs for health plans and providers. This rule is designed to provide a ''safe harbor'' that providers and health plans can be assured will be supported by any trading partner, including providers. Safe harbors are essentially connectivity requirements. When trading partners including providers, agree to follow the same connectivity requirements, connectivity is better enabled. This rule is not intended to require trading partners, including providers, to remove existing connections that do not match the rule, nor is it intended to require that all trading partners, including providers, must use this method for all new connections. It is expected that some trading partners, including providers, may agree to use different communication mechanism(s) and/or security requirements than that described by this rule. The rule simply provides a secure connection for those entities that do not currently have one.

The Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) provides more robust and consistent information prior to or at the point of care. It specifies the minimum requirements for using the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271) to inquire about health plan insurance coverage and to respond to such an inquiry using the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271). The requirements address certain situational elements and codes and are in addition to requirements contained in the Version 5010 270/271 implementation guides. This rule provides for not only determination of an individual's eligibility but also his financial responsibility information for co-pay, deductible, and coinsurance prior to or at the point of care. This rule covers, for example, the following content in the Version 5010 271:

- The dates of eligibility under the health plan (contract) level for past and future dates and the dates of eligibility at the benefit level if different from the contract level.
- The patient financial responsibility for each specified benefit at the base contract amounts for both in-network and out-of-network.
- The name of the health plan when it exists in the health plan's system.

Compliance with the requirements of this operating rule will ultimately reduce the time it takes providers to track down such information after the service has been rendered, and decrease the provider's accounts receivable.

The Phase I CORE 155 and 156: Eligibility and Benefits Batch Response and Real Time Response Rules (updated for Version 5010) streamline and improve the flow of transactions by imposing timeframe requirements for when a response is to be submitted for an eligibility for a health plan inquiry.

For a Version 5010 270 batch mode response to a provider's inquiry submitted by 9:00 pm Eastern time of a business day, the response must be returned by 7:00 am Eastern time the following business day. The maximum response time when processing in real time mode must be 20 seconds or less.

The Phase I CORE 157: Eligibility and Benefits System Availability Rule (updated for Version 5010) also streamlines and improves the flow of transactions. It recognizes that many institutional providers need to be able to conduct health plan eligibility activities at any time. It also recognizes that health plans have a business need to take their eligibility and other systems offline periodically in order to perform system maintenance, which means that some systems will not be available for eligibility inquiries and responses on certain nights and weekends. The rule requires that systems be available to process eligibility inquiries no less than 86 percent of the time per calendar week for real and batch modes, and requires health plans to publish regularly scheduled downtime. It ensures that systems are up and running in a consistent manner and that trading partners, including providers, are aware of any downtime so they can plan accordingly.

The Phase II CORE 250: Claim Status Rule (updated for Version 5010) encourages and increases the use of the health care claim status transaction by providing for batch and real-time response times, system availability, the use of a companion guide template, and support for the CORE ''safe harbor'' connectivity requirement. These elements included in the CORE 250 rule follow the same requirements as and build upon the same requirements as for the eligibility for a health plan transaction infrastructure rules included in Phase I CORE 152, Phase I CORE 155, Phase I CORE 156 and Phase I CORE 157 rules we are adopting in this interim final rule with comment period. This means that Phase II CORE 250 rule (updated for Version 5010) requires each health plan to: follow the companion guide format requirement as provided in CORE 152, which is the CORE Version 5010 Master Companion Guide Template; support the CORE ''safe harbor'' connectivity requirements; support a maximum response time of 20 seconds from the time of submission of a Version 5010 276 for real time and for batch mode response to a provider's inquiry submitted by 9 p.m. Eastern time of a business day, the response must be returned by 7 a.m. Eastern time the following business day; ensure system availability of no less than 86 percent per calendar week for both real time and batch modes; and follow the companion guide format requirement as provided in CORE 152, which is the CORE v5010 Master Companion Guide Template.

The CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule (updated for Version 5010). Health plans and health care providers must be able to uniquely identify patients in order to ascertain patient eligibility. Although the Version 5010 270/271 standards specify data elements and data element attributes that may be used to identify an individual, the standards do not address the use of punctuation and special characters. Therefore, the way health plans identify individuals does not always match the way providers identify individuals, which results in the rejection or denial of eligibility transactions. The CAQH CORE 258 rule addresses certain aspects of individual identification that enhance the real time processing of eligibility inquiries and responses.

The Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code

Reporting Rule (updated for Version 5010) provides consistent and specific patient identification information on reasons for patient identification errors on an eligibility for a health plan inquiry. This allows providers to know specifically why they did not receive a match in an eligibility for a health plan inquiry, instead of trying to determine for themselves the reasons for the error and what corrective action is needed. This rule improves the specificity and standardized use of the AAA codes that would give providers better feedback to understand what information is missing or incorrect in order to obtain a valid match. It defines a standard way for health plans to report errors in the eligibility response that cause a health plan not to be able to respond with a Version 5010 271 showing eligibility information for the requested patient or subscriber. The goal is to use a unique error code wherever possible for a given error condition so that the re-use of the same error code is minimized. Where this is not possible, the goal (when re-using an error code) is to return a unique combination of one or more AAA segments along with one or more of the submitted patient identifying data elements such that the provider will be able to determine as precisely as possible what data elements are in error and take the appropriate corrective action.

The Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule (updated for Version 5010) builds on and enhances the Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) by requiring the provision in the eligibility response of the remaining patient deductible amounts for certain service type codes. The use of this rule further reduces the time it takes to track down this information manually or eliminates the time completely after the service has been rendered and decreases the provider's accounts receivable.

The CAQH CORE determined that Phase I CORE rules should focus on improving electronic eligibility and benefits verification, as eligibility is the first transaction in the claims process. Thus, if eligibility and benefits are accurately known to health care providers, all the associated electronic transactions that follow will be more effective and efficient. The Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) primarily outlined a set of requirements for health plans to return base (not remaining or accumulated) patient financial responsibility related to the deductible, co-pay and co-insurance for a set of 12 services in the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271), and for vendors, clearinghouses and providers to transmit and use that financial data. The Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule (updated for Version 5010) extends and enhances the CORE Phase I Version 5010 271 transaction by requiring the provision of remaining deductible amounts for both the Phase I required 12 service type codes and an additional set of 39 other service type codes.

The Phase II CORE 270: Connectivity Rule (updated for Version 5010), which applies to both the eligibility for a health plan and health care claim status transactions, builds on CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) by requiring additional connectivity specifications which further facilitate interoperability. This rule addresses the message envelope metadata (that information which defines the context for interpretation of the rest of the data in the message, for example, response codes, request methods, *etc.*) and the message envelope, (a fixed number of fields that show source, destination, tag, and communicator) and the submitter authentication requirements for both batch and real time transactions, and communications-level errors.

This rule improves utilization of electronic transactions by enabling more entities to interoperate with other entities, including reducing the implementation barrier for small entities (for example, small providers). It also extends the Phase I CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) and establishes a safe harbor by further specifying the connectivity that all covered entities must demonstrate and implement.

Tables 3 and 4 summarize each of the CAQH CORE Phase I and Phase II Version 5010 operating rules, which we are adopting in this interim final rule with comment period, as reflected in 45 CFR 162.920, 162.1203, and 162.1403.

TABLE 3—THE CAQH CORE PHASE I OPERATING RULES

[Updated for version 5010]

Rule	High level requirements
Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, Version 1.1.0, March 2011 and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.	*Goal:* Standardize template/common structure of companion guides for more efficient reference. *Requirements:* Standard template/structure for companion guides.
Phase I CORE 153: Eligibility and Benefits Connectivity Rule, Version 1.1.0, March 2011.	*Goal:* Provide a ''safe harbor'' that application vendors, providers, and health plans can be assured will be supported by any trading partner including providers, to facilitate connectivity standardization and interoperability across the exchange of health information. *Requirements:* Supports data exchange over the public Internet (HTTP/S).
Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, Version 1.1.0, March 2011.	*Goal:* Enable more robust and consistent exchange of eligibility information. *Requirements:* Specifies what is to be included in the 271 eligibility for a health plan response to a 270 eligibility for a health plan inquiry.
Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, Version 1.1.0, March 2011.	*Goal:* Streamline and improve flow of transactions. *Requirements:* Response time is 20 seconds or less for real time, next day for batch.
Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, Version 1.1.0, March 2011.	
Phase I CORE 157: Eligibility and Benefits System Availability Rule, Version 1.1.0, March 2011.	*Goal:* Streamline and improve flow of transactions. *Requirements:* Systems must be available 86 percent per calendar week, and regular downtime must be published.

TABLE 4—THE CAQH CORE PHASE II VERSION 5010

Rule	High level requirements
Phase II CORE 250: Claim Status Rule, Version 2.1.0, March 2011	*Goal:* Promote increased availability and usage of the health care claim status transaction through rules for real-time and batch response times, system availability, and connectivity. *Requirements:* Application of real-time and batch response times, system availability, and connectivity rules for health care claim status transactions, which were derived from the eligibility Phase I infrastructure rules.
Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, Version 2.1.0, March 2011.	*Goal:* Improve patient matching. *Requirements:* Normalize the submitted and stored last name (*e.g.,* remove special characters, suffixes/prefixes) before trying to match.
Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, Version 2.1.0, March 2011.	*Goal:* Provide better information on why a match did not occur in an eligibility for a health plan request. *Requirements:* Return specified AAA codes for each error condition.
Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, Version 2.1.0 , March 2011.	*Goal:* Provide additional financial responsibility/patient liability information in response to an inquiry and support more high volume service type codes. *Requirements:* Includes remaining deductible amount (plus static copay and coinsurance information) in response to an eligibility for a health plan inquiry, along with 39 additional service type codes beyond the service type codes provided in Phase I.
Phase II CORE 270: Connectivity Rule, Version 2.2.0, March 2011	*Goal:* Provide more comprehensive connectivity specifications to further interoperability. *Requirements:* Includes requirements for two message envelope standards submitter authentication (*i.e.,* username/password, digital certificates) and metadata.

In 45 CFR 162.103, we provide that a standard transaction means ''a transaction that complies with an applicable standard adopted under this part.'' In this interim final rule with comment period we are adopting operating rules and requiring that covered entities comply with those operating rules when conducting a transaction for which we have adopted a standard. In order to reflect that requirement in regulation text, in part, we need to modify the definition of standard transaction to be clear that a standard transaction is one that complies with the adopted standard and the adopted associated operating rule. Therefore, we are amending the definition of standard transaction at 45 CFR 162.103. See the ''Additional Requirements'' section for discussion of this change.

In the following sections, we identify and discuss several specific CAQH CORE operating rule requirements that we believe require further explanation. These include acknowledgements, certification, and the use of the CAQH CORE companion guide template. We believe these topics require additional explanation because in this interim final rule with comment period, we are not adopting the operating rules that pertain to acknowledgements or the requirements within the adopted operating rules that pertain to acknowledgements, nor are we adopting the CAQH CORE certification policies. Additionally, we believe we need to be especially clear that we are adopting the CAQH CORE companion guide template to avoid any confusion as to whether the companion guide template is included as part of the companion guide rules under CAQH CORE Phase I and Phase II rules we are adopting.

a. Acknowledgements Operating Rules

Acknowledgements are responses transmitted by EDI that inform submitters whether or not their transaction has been received or if there are problems with the transaction. The use of acknowledgements adds a great deal of value to the underlying transactions for which they are sent by informing the sender that a transaction has been received or has been rejected. Without acknowledgements, it is difficult for the sender to know whether the intended recipient received the transmission, which often results in the sender repeatedly querying the intended receiver as to the status of the transmission.

In the February 2010 report to the NCVHS, the Designated Standards Maintenance Organization (DSMO), which receives and processes requests for adopting new standards or modifying adopted standards recommended that the NCVHS consider acknowledgements for adoption as HIPAA transactions, using the Version 5010 999, 271, 277, and TA1 standards. In the DSMO recommendation, it was noted that acknowledgements help the health care industry better reconcile the status of transmitted EDI transactions, especially when sending claims and remittance transactions. The transaction sender benefits from knowing that the receiving party has successfully received the transaction or has encountered errors that need to be reconciled.

We have received anecdotal reports of wide-spread industry use of acknowledgements on a voluntary basis, and we understand that provisions for acknowledgements are contained in many health plans' companion guides. It is our understanding also that the health care industry has long supported, and even anticipated, the adoption of an acknowledgement transaction standard under HIPAA. The CAQH CORE 150 and 151 rules (updated for Version 5010) specifically pertain to requiring the use of the Version 5010 999, 271, and 277 acknowledgements. Additionally, the use of acknowledgements is referenced throughout many of the other CAQH CORE rules adopted in this interim final rule with comment period, including the CORE v5010 Master Companion Guide Template.

Section 1173(a)(4)(A)(iii) of the Act, as added by section 1104(b) of the Affordable Care Act, provides that standards and associated operating rules shall ''provide for timely acknowledgement, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals).'' This new provision is an indication of Congress' recognition of the important role acknowledgements play in EDI.

Although we are not requiring compliance with any of the CAQH CORE rule requirements regarding acknowledgements, we are addressing the important role acknowledgements play in EDI by strongly encouraging the industry to implement the acknowledgements requirements in the CAQH CORE rules we are adopting herein. We reflect the exclusion of the requirement to use acknowledgments in regulation text at § 162.1203 and § 162.1403.

Until such time as the Secretary adopts a standard for acknowledgments, we support the industry's ongoing voluntary use of acknowledgements and encourage even more widespread use. We welcome industry and stakeholder comments on this topic.

b. CAQH CORE Operating Rules Certification

Currently, the CAQH CORE administers a voluntary certification process, for a fee. Once the entity passes the certification requirements, the CAQH CORE assigns the status of ''CORE-certified Entity'' and requires those entities to adhere to the CAQH CORE policies. The CAQH CORE operating rules are free and available for voluntary use today, and any trading partner, including providers, can opt to use them, they would simply not be able to claim that they were ''CORE certified entities.''

Throughout the CAQH CORE rules we are adopting, there are also many references to CORE certification. For example, the rules reference CORE-certified entity, CORE-authorized testing vendor, CORE-certified participant, and the like. In many places, the rules describe what is required for the successful completion of the approved CORE test suite, CORE testing requirements, *etc.* In this interim final rule with comment period, we are not requiring covered entities to obtain the CAQH CORE certification or to adhere to the CAQH certification policies for Phase I and Phase II operating rules. We want to be clear that we are not requiring compliance with any aspect of CORE certification.

We note that section 1173(h)(1)(A) of the Act (as added by section 1104(b)(2) of the Affordable Care Act) requires that health plans certify to the Secretary no later than December 31, 2013 that they are in compliance with any applicable HIPAA standards and associated operating rules for the eligibility for a health plan, health care claim status, and health care payment and remittance advice transactions. Until we develop a certification process in accordance with section 1173(h) of the Act specifying health plan compliance requirements, health plans and all other covered entities are not required to certify compliance with the CAQH CORE Version 5010 operating rules we are adopting. We reflect the exclusion of CORE certification in regulation text at § 162.1203 and § 162.1403.

c. Use of the CAQH CORE Companion Guide Template

During the July 2010 NCVHS hearing, the NCVHS also heard testimony concerning the continued use of companion guides when operating rules are adopted. The NCVHS indicated that it does not wish to encourage the perpetual use of companion guides, which subvert the goals of administrative simplification; however, it acknowledged that companion guides may continue to be necessary for proprietary information, transmission instructions, and other limited business purposes, and will likely never be totally replaced by operating rules or updated versions of the standards.

The NCVHS recommended that the Secretary require that any companion guides deemed necessary by health plans not conflict with the HIPAA standards, implementation specifications and operating rules, and that they follow a standard format and content agreed upon by industry consensus across all sectors. The NCVHS stated that companion guides should be limited to providing basic trading partner, including providers, facts, such as contact information, Web sites, service phone numbers, and other necessary information for conducting business, *etc.*

With input from health plans, system vendors, provider representatives and healthcare/HIPAA industry experts, the CAQH CORE has developed a companion guide template as part of their Phase I and Phase II operating rules (updated for Version 5010) that organizes information into several simple sections and gives health plans the flexibility to tailor the document to meet their particular needs. The CORE 152: Eligibility and Benefit Real Time Companion Guide Rule states that the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271) transactions must follow the format/flow as defined in the CORE v5010 Master Companion Guide Template. The CORE 250: Claim Status Rule (updated for Version 5010) includes a requirement that entities using the ASC X12N/005010X212 Health Care Claim Status Request and Response (276/277) transactions must follow the format/flow as defined in the Phase I CORE 152, which is the CORE v5010 Master Companion Guide Template. The CAQH CORE companion guide template can be found on the CAQH CORE Web site at *http://www.caqh.org/pdf/CLEAN5010/MasterCompGuidTemp-Version 5010.pdf.*

We are requiring that covered entities that use or plan to use companion guides comply with the CORE 152 and CORE 250 rules requirement to use the CORE v5010 Master Companion Guide Template for the eligibility for a health plan and health care claim status transactions.

d. Updates to Standards and Operating Rules

Section 1173(i) of the Act provides for the establishment of a review committee for the purposes of reviewing and amending the adopted standards and operating rules. It calls for a hearing of this review committee no later than April 2014 and not less than biennially thereafter as well as a report outlining recommendations for updating and improving the standards and operating rules. Per the statute, this review committee can include the NCVHS, or any appropriate committee as determined by the Secretary.

Additionally, section 1173(a)(5) of the Act provides for the solicitation of input from the NCVHS and the Health Information Technology Standards Committee, as well as the standards setting organizations and stakeholders as determined appropriate by the Secretary for the purposes of describing ''(i) whether there could be greater uniformity in financial and administrative activities and items, as determined appropriate by the Secretary; and (ii) whether such activities should be considered financial and administrative transactions * * * for which the adoption of standards and operating rules would improve the operation of the health care system and reduce administrative costs.''

Finally, we note that this interim final rule with comment period does not specify the timing or the process for updating operating rules. The timing and process for updating these, as well as future operating rules will be forthcoming.

e. Additional Information

The current definition of standard at 45 CFR 160.103 is written so broadly that it could include operating rules as we are defining that term at § 162.103. However, as we have determined that operating rules are separate and distinct from standards, and that standards do not encompass operating rules, we believe it is necessary to revise the definition of standard to specifically

exclude operating rules. Therefore, we have amended the definition of standard at § 160.103 to exclude operating rules.

Currently, 45 CFR 162.103 provides that a standard transaction means ''a transaction that complies with an applicable standard adopted under this part.'' In this interim final rule with comment period we are adopting operating rules and requiring covered entities to comply with those operating rules when conducting a transaction for which we have adopted a standard. We believe it is necessary to revise the definition of a standard transaction in order to be clear that a standard transaction is one that uses the adopted standard as well as the adopted operating rule for that transaction. Therefore, we are amending the definition of a standard transaction at 45 CFR 162.103 to mean ''a transaction that complies with an applicable standard and associated operating rules adopted under this part.''

Section 1173(a)(4)(A)(iv) of the Act provides that the standards and associated operating rules must ''describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).'' We interpret this provision to mean that covered entities may not require additional data conditions of their trading partners, including providers, outside of those already included in the adopted standards and associated operating rules, except where it is necessary to implement State or Federal law, or to protect against fraud and abuse. Our regulations at 45 CFR 162.915 already place restrictions on covered entities with regard to what they may require of their trading partners including providers, concerning standards. Currently, under § 162.915(a), covered entities may not enter into a trading partner agreement that would change the definition, data condition, or use of a data element or segment in a standard. We do not need to do anything to incorporate the statutory requirement of section 1173(a)(4)(iv) of the Act into our regulations with regard to standards; however we believe it is appropriate to revise § 162.915(a) to expand the restriction to include operating rules. Therefore, we are amending § 162.915(a) to include operating rules. The law permits limited circumstances under which covered entities may require additional data conditions where necessary to implement State or Federal law, or to protect against fraud and abuse. Therefore, we are also amending § 162.915(a) to reflect that narrow exception.

f. Conclusion

Based on our analysis of the CAQH CORE operating rules and the recommendations of the NCVHS, and for the reasons provided in the previous discussions, we are adopting the CAQH CORE operating rules (updated for Version 5010), including the companion guide template, for the non-retail pharmacy eligibility for a health plan and health care claim status transactions, as reflected at 45 CFR 162.920, 162.1203, and 162.1403. We are not requiring compliance with any of the requirements of the operating rules that pertain to the use of acknowledgements and CAQH CORE certification.

2. NCPDP Telecommunication Standard Implementation Guide Version D.0 Operating Rules for Retail Pharmacy Transactions

In its testimony before the NCVHS, the NCPDP stated that the NCPDP Version D.0 standard represents retail pharmacy industry consensus on clarification of transactions, data elements, data values, and situations of usage. Additionally, the NCPDP testified at the July 2010 NCVHS hearing that it also publishes a free NCPDP Version D.0 Editorial document, which is updated quarterly, and contains frequently asked questions, examples, and further clarifications, as well as addresses Medicare Part D prescription drug program needs that the industry brings forward. As business requirements change, as clarifications are needed, and as questions are asked, the NCPDP has indicated that, where possible, the information in the NCPDP Version D.0 Editorial will be incorporated into future versions of the NCPDP Version D.0 standard to further support ongoing retail pharmacy business needs.

The NCPDP formally requested that the NCVHS recommend to the Secretary that the NCPDP Version D.0 standard be adopted as the operating rule for use with the retail pharmacy eligibility for a health plan transaction, and the NCVHS included this recommendation in its September 30, 2010 letter to the Secretary.

The pharmacy industry has long been utilizing NCPDP standards to conduct electronic transactions. These standards provide for real-time claims adjudication, eligibility and benefit verification, real-time ordering by the physician, and sharing of medication history. We believe that the NCPDP Version D.0 standard itself provides enough detail and clarity to operationalize the standards to the point where no gaps exist that operating rules would need to fill, so that no further infrastructure or data content rules need to be adopted at this time. Additionally, we believe that the NCPDP Version D.0 standard already fulfills the purposes and principles of sections 1173(a)(4)(A) and (B) of the Act so that the adoption of operating rules to supplement or enhance the standard is not appropriate at this time.

III. Effective and Compliance Dates

Section 1173(g)(4)(B)(i) of the Act states that ''[t]he set of operating rules for eligibility for a health plan and health claim status transactions shall be adopted not later than July 1, 2011, in a manner ensuring that such operating rules are effective not later than January 1, 2013.'' In each of our previous HIPAA rules, the date on which the rule was effective was the date on which the rule was considered to be established or adopted, or, in other words, the date on which adoption took effect and the CFR was accordingly amended. Typically, the effective date of a rule is 30 or 60 days after publication in the **Federal Register**. Under certain circumstances the delay in the effective date can be waived, in which case the effective date of the rule may be the date of filing for public inspection or the date of publication in the **Federal Register**.

The effective date of standards, implementation specifications, modifications, or operating rules that are adopted in a rule, however, is different than the effective date of the rule. The effective date of standards, implementation specifications, modifications, or operating rules is the date on which covered entities must be in compliance with the standards, implementation specifications, modifications, or operating rules. Here, the Act requires that the operating rules be effective not later than January 1, 2013. This means that covered entities must be in compliance with the operating rules by January 1, 2013. If we receive comments that compel us to change any of the policies we are finalizing in this interim final rule with comment period, we will seek to finalize any such changes by January 1, 2012, to allow sufficient time for industry preparation for compliance.

IV. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), we are required to publish a notice of proposed rulemaking in the **Federal**

Register. In addition, the APA mandates a 30-day delay in the effective date. Sections 553(b) and (d) of the APA provide for an exception from these APA requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where the agency finds good cause to do so and includes a statement of support.

Subsection (C) of section 1173(g)(4) of the Act is titled ''Expedited Rulemaking'' and provides that ''[t]he Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the [NCVHS] pursuant to paragraph (3). The Secretary shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.'' It is clear to us the statute intends that the ordinary notice and comment rulemaking procedures of the APA do not apply here. We are statutorily *required* to proceed with an interim final rule with comment period, which means we are compelled by the statute to dispense with normal APA notice and comment procedures. In light of the statutory requirement for us to publish an IFC for the adoption of these operating rules, we conclude that it is unnecessary for us to undertake ordinary notice and comment procedures and therefore, for good cause, we waive them. In accordance with the requirements of section 1173(g)(4)(C) of the Act, we are providing a 60-day public comment period.

We also find good cause for waiving the 30-day delay in the effective date of this interim final rule with comment period. The 30-day delay is intended to give affected parties time to adjust their behavior and make preparations before a final rule takes effect. Sometimes a waiver of the 30-day delay in the effective date of a rule directly impacts the entities required to comply with the rule by minimizing or even eliminating the time during which they can prepare to comply with the rule. That is not the case here. In this case, covered entities are not required to comply with the adopted operating rules until January 1, 2013, nearly one-and-one-half years after the publication of this interim final rule with comment period; a waiver of the 30-day delay in the effective date of the rule does not change that fact. A waiver is in fact inconsequential here to covered entities—their statutorily-prescribed date of compliance remains January 1, 2013. Because we believe the 30-day delay is unnecessary, we find good cause to waive it.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information is 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 Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our 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.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements (ICRs): Specifications: Companion Guides Template.

In current practice, companion guides are developed by individual health plans and require providers to adhere to different transaction implementation rules for each health plan. Health plans have created these companion guides to describe the specifics of how they implement the HIPAA transactions and how they will work with their trading partners. Health plans' companion guides vary not only in format and structure, but also in size, being anywhere from a few to 60 pages or more. Such variances can be confusing to trading partners and providers who must implement them along with the standard implementation guides, and who must refer to different companion guides for different health plans. As previously stated, there are currently more than 1,200 such companion guides in use today.

Use of the CORE 152: Eligibility and Benefit Real Time Companion Guide Rule and the CORE 250: Claim Status Rule, two of the operating rules adopted in this interim final rule with comment period provide a standard template/common structure that health plans must use that is more efficient for providers to reference, given the multiple industry companion guides they must consult today.

The increasing use of health care EDI standards and transactions has raised the issue of the applicability of the PRA. The OMB has determined that this regulatory requirement (which mandates that the private sector disclose information and do so in a particular format) constitutes an agency-sponsored third-party disclosure as defined under the PRA.

The burden associated with the requirements of this interim final rule with comment period, which is subject to the PRA, is the initial onetime burden on health plans to use a standardized template for companion guides. The burden associated with the routine or ongoing maintenance of the information reported in the standard template format for companion guides is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

Based on the assumption that the burden associated with systems modifications that need to be made to implement the standard template for companion guides may overlap with the systems modifications needed to implement other HIPAA standards, and the fact that the standard template for companion guides will replace the use of multiple companion guides, resulting in an overall reduction of burden for providers, commenters should take into consideration when drafting comments that: (1) One or more of these current companion guides may not be used; (2) companion guide modifications may be performed in an aggregate manner during the course of routine business; and/or (3) systems modifications may be made by contractors such as practice management vendors, in a single effort for a multitude of affected entities.

Health plans that issue companion guides do so, in part, to direct providers on how to implement the ASC X12 and, in the case of the NCPDP standards, they issue payer sheets specific to their requirements and often times provide other plan-specific information, such as contact information, address, *etc.* It is expected that even with the advent of operating rules, companion guides will never be completely eliminated, but the companion guides themselves may be greatly reduced in size and complexity as a result of the use of operating rules. The companion guide templates serve the purpose of providing a uniform structure for health plans to use when preparing companion guides. The use of these templates by health plans currently issuing companion guides is considered to be a one-time action and is considered a permanent standard

template for a health plan companion guide.

The information collection burden associated with this interim final rule with comment period is for the costs for adapting a health plan companion guide(s) to the CORE v5010 Master Companion Guide Template, 005010, 1.2, March 2011 as required by the CAQH CORE operating rules for the eligibility for a health plan and health care claim status standard transactions. This is a one-time burden on health plans that will commence no later than January 1, 2013, the date by which HIPAA covered entities must be using the adopted operating rules for eligibility for a health plan and health care claim status transactions.

Common practice in the industry is for companion guides to be published as electronic documents and updated periodically in the routine course of business. Companion guides are posted to and made available on health plan Web sites trading partners, including providers, to access; therefore, printing and shipping costs are not considered. As the transition to the template is a one-time requirement, we do not estimate any ongoing labor costs associated with the use of this template beyond the initial first year conversion. We have estimated the one-time conversion to the template will cost industry $3,028,000. Our calculations were determined as follows:

The current length of health plan companion guides related to the eligibility for a health plan and health care claim status transactions, is anecdotally estimated at anywhere from just a few, to 60 or more pages. We estimate it will take a health plan staff person, most likely a technical writer, from 1 to 4 hours per page to reformat companion guides into the standard template for companion guides. This burden would involve re-entering of information, reconfiguration of the sequence in which information appears, addition of information, and other word processing and related tasks. It also would require specific technical knowledge, such as expertise in the Version 5010 standard transactions. We estimate that a technical writer, at an estimated hourly salary rate of $31.55, would make these revisions. Using the high estimate obtained in testimony to the NCHVS by the American Medical Association of 1,200 companion guides currently in use, we calculate an estimated average of 40 pages, (48,000 responses) at an average rate of 2 hours per page (1,200 guides × 40 pages × 2 hours per page × hourly rate of $31.55), for a one-time burden of $3,028,800 across the industry for health plans that issue companion guides to adopt the standard template for health plan companion guides. As existing word processing capabilities would be used for this task, we do not anticipate any software, hardware or other specialized equipment to be purchased and/or maintained for this specific purpose.

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 interim 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–0032–IFC; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov*.

VI. Response to Comments

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

VII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this interim final rule with comment as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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)).

We have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this interim final rule with comment period. 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 to not only engage public 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 (RIA) must be prepared for major rules with economically significant effects ($100 million in 1995 dollars or more in any 1 year). 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. Accordingly, the rule has been reviewed by the Office of Management and Budget. We anticipate that the adoption of these operating rules would result in benefits that outweigh the costs to providers and health plans.

Our Regulatory Impact Analysis also meets the various requirements of the Unfunded Mandates Reform Act of 1995 (URMA). Section 202 of the URMA requires that agencies assess the anticipated costs and benefits before issuing any rule whose mandate requires spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector. That threshold level is currently approximately $136 million. Based on our analysis, we anticipate that the private sector would incur costs exceeding $136 million per year in the first 2 years following publication of the rule.

In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives that are referenced in the RIA section of this rule, HHS has concluded that the provisions in this rule are the most cost-effective alternative for implementing HHS' statutory obligation of administrative simplification.

B. Current State, Need for Mandated Operating Rules and General Impact of Implementation

Based on the current environment, there is a need for operating rules. When a patient calls to set up an appointment with a provider, or comes into the office or hospital for an appointment, a staff member will often verify the patient's eligibility, coverage, and cost-sharing requirements. However, not all

providers will verify the eligibility of their patients, and even for providers' offices that do, often just a subset of patients are verified. Some providers, however, do not conduct eligibility verification at all, and a claim is submitted to the health plan without an eligibility inquiry.

Eligibility verification is done in a variety of ways including the following:

- Accessing patient ''eligibility'' information via a health plan's secure Web site.
- Telephone.
- The ASC X12 270 eligibility for a health plan inquiry. This is an electronic data interchange (EDI).

After an actual claim has been submitted to a health plan, the need sometimes arises for a provider to follow-up on the claim regarding where it is in the payment process. This is called a claim status inquiry and, again, this inquiry is conducted via Web site, telephone, or through EDI.

Currently, many providers do not use EDI at all as a means to conduct these two transactions and, of those that do, do not necessarily conduct them through EDI for every patient. Rather, most providers that use EDI transactions to verify a patient's eligibility or claim status also use telephone or other means.

In a larger context, most providers use EDI, but only for some transactions. For instance, according to the Healthcare Efficiency Index and the Oregon Study, over 75 percent of health care claims are now submitted by providers through EDI.

Because of the infinite number of variations of a specific provider's use of EDI, it is very difficult to determine the following: (1) the number of providers who use the eligibility for a health plan or the claim status transactions (or any other specific transaction) via EDI; and (2) the percent of eligibility for a health plan or claim status transactions that the average provider makes through EDI. However, studies have estimated the total number of electronic transactions conducted by all providers, even at the level of a specific transaction, and we will use such estimates to arrive at our saving assumptions.

We assume that most providers have the technological capacity to perform EDI (or have hired a trading partner with that capacity). We base this assumption on— (1) the high percentage of claim submissions that are conducted through EDI; (2) responses to the Oregon study from providers indicating that 96 percent of hospitals and 93 percent of ambulatory clinics (that is, physicians offices) are ready or would be ready for EDI transactions within 2 years; and (3) the impact analysis in the Modifications proposed rule (73 FR 49757 through 49790) that, through industry interviews, stated ''we do not believe that the number of providers who have no electronic capability is very high.''

There are a number of studies that have illustrated the benefits and savings in conducting EDI in contrast to manual or paper-based transactions. We have noted a number of them in the Impact Analysis Resources section in this interim final rule with comment period. The basic idea is that systems can conduct these transactions faster, less expensive, and more accurate than human intervention. Specific to our purpose, it is faster, less expensive, and more accurate than human intervention for a provider's system to communicate with a health plan's system to verify the eligibility of a patient or check the status of a claim.

So, why do not the majority of providers who have EDI capacity: (1) Use EDI to conduct the eligibility for a health plan or the claim status transaction; or (2) verify all their patients' eligibility through EDI instead of just a few? In the Oregon Survey, the most robust study with regard to a provider environment, 87 percent of hospitals and 60 percent of physician clinics said that the barrier to using the electronic eligibility for a health plan transaction is that health plans ''do not provide enough information in response to this type of inquiry.'' This was the most frequently selected response among the providers surveyed. In addition, 16 percent of hospitals and 20 percent of physician clinics stated that the barrier was that health plans ''do not provide fast enough responses.''

The June 22, 2009 AMA document entitled ''Standardization of the Claims Process: Administrative Simplification White Paper'' (hereinafter referred to as the 2009 AMA White Paper) describes the importance of a robust response in the eligibility for a health plan transaction: ''Receiving an explicit answer can quickly assist in patient scheduling, billing the appropriate payer with financial responsibility for the service, communicating the patient's financial responsibility and reducing the number of denied claims which the physician practice must manually handle.'' (*http://www.ama-assn.org/ama1/pub/upload/mm/368/admin-simp-wp.pdf*)

The picture that emerges is that providers conduct the electronic eligibility for a health plan transaction only with health plans that return robust eligibility information and return the response quickly. If a provider's staff will get more and faster eligibility information out of a specific health plan by picking up the phone or looking up the patient online, then the manual transaction will be used instead of the electronic transaction.

In terms of the claim status inquiry, we know that the average providers' office telephones the health plan in order to check on claim status. The ''Health Care Administration Expense Analysis'', produced by the State of Washington Office of the Insurance Commissioner, found that 37 percent of the telephone calls from providers to the State's largest insurer were claim status inquiries (costing the plan $4 million a year on staffing costs to answer only claim status calls) (Health Care Administration Expense Analysis: Blue Ribbon Commission Recommendation #6, Final Report, 11–16–2007, *http://www.insurance.wa.gov/consumers/documents/BRC_Efficiencies_Report.pdf*.) Other studies indicate that less than 40 percent of all claim status inquires are conducted electronically. Although we do not have direct data that informs the reasons why providers use the telephone instead of EDI for claim status inquiries, we can assume that the same dynamic as the eligibility verification is at play: If the electronic transaction is slower and produces less information, than a manual process will be used instead.

Operating rules address this need for more and faster information. As noted in the provision section, this interim final rule with comment period is adopting specific operating rules with requirements regarding response times and robust responses about a patient's eligibility from health plans.

A number of extensive surveys, both private and governmental, have reinforced the causal link between requiring health plans to return fast, robust responses to the eligibility for a health plan electronic request and an increased use in the transaction itself. In its Blue Ribbon report, the state of Washington reported that less than 9 percent of eligibility verification requests are conducted electronically in the state, while the state of Utah reported closer to 50 percent usage. The report credited Utah's adoption rate with the State having an ''enhanced transaction'' in place for the eligibility verification in which providers are told exactly the benefits a particular patient has. The report concluded that ''improving the enhanced message [of the eligibility for a health plan response]* * * will greatly improve this area of administration.''

The Oregon Survey explicitly expressed the causal link between

''standardizing the standard'' and greater use of EDI by concluding from its research that ''the healthcare industry is unlikely to take major strides toward automated processes until there is greater standardization of the methods for conducting the transactions electronically.''

The 2009 AMA White Paper also speaks to providers' need for robust health plan responses to the eligibility for a health plan transactions and how such a response would affect providers: ''Such information would also be extraordinarily valuable to physicians to ensure accurate and timely payment, and this value would encourage wide-spread utilization of the standard transactions by physicians and increased physician automation. The AMA strongly supports the efforts of the Council on Affordable Quality Healthcare Committee on Operating Rules for Information Exchange [CAQH CORE] to not only expand the value of the eligibility standard transaction but also continue its efforts of adding value to electronic remittance advice and other standard transactions * * *''

The IBM study demonstrates that electronic eligibility for health plan transactions would increase with use of operating rules. The study illustrates that providers' use of the eligibility for a health plan transaction increases on two levels after operating rules are adopted. First, more patients as a whole are having their eligibility verified, either electronically or otherwise. Second, there is an increased use of the electronic transaction. The participating health care entities in the study reported increases in use of the eligibility for a health plan electronic transaction at the average rate of 33 percent in the first year after adopting CORE Phase I rules—a rate that participants of the study credited to operating rules. Additionally, the IBM study showed that providers saw on average 20 percent increase of patients verified prior to a visit, significantly reducing practice administrative and financial burden at the point of care.

On a more general level, in both the Transactions and Code Sets final rule and the update to the standards in the Modifications final rule, the savings analysis has been based on the increased use of electronic transactions due to the implementation of standards (in the Transactions and Code Sets final rule) and increased use of electronic transactions due to improved standards (in the Modifications final rule). The cost benefit of both these rules rested on the causal relationship between improved standards and the predicted increased use of EDI (and the cost savings that use of EDI brought with it). The impact analysis for this interim final rule with comment period rests on the same causality, except that we are more specific in how operating rules cause increased use of electronic transactions.

As an example, the need for more robust and faster response to the eligibility for a health plan transaction has been realized by states seeking to reduce the administrative costs of health care in general. In the ''Health Care Administration Expense Analysis,'' required by Colorado state law and developed under the state's Commissioner of Insurance, recommendations included requiring all health plans and providers to use CAQH CORE Phase I and II data content and infrastructure rules for the eligibility for a health plan and the claim status transactions ''as a means of streamlining and standardizing administrative interoperability between plans and providers.'' (Senate Bill 08–135 Work Group to Develop Standardized Electronic Identification System for Health Insurance: Final Report and Recommendations. September 3, 2009; *http://caqh.org/Host/CORE/SB135_COreport.pdf*)

As well, Minnesota has a set of companion guides for the HIPAA standard transactions. These companion guides are analogous to the operating rules developed by the CAQH CORE in that they are intended to standardize ''administrative processes when implementation of the processes will reduce administrative costs.'' We have already mentioned initiatives and reports by Oregon and Washington that seek to achieve similar savings. (*http://www.health.state.mn.us/auc/mn270271guide.pdf*).

It is evident that both state governments and private industry recognize the cost advantage to operating rules and similar ''enhanced transaction'' business rules to accompany the HIPAA standard transactions, in this case with regard to the eligibility for a health plan transaction. However, both state governments and private industry recognized the need for the adoption of operating rules on the Federal level because of the clear advantages to a faster adoption by all covered entities that a Federal mandate would engender. As illustrated by the numerous State and private initiatives, there is the danger that, without Federally mandated operating rules, different sets of ''operating rules'' will emerge, on a State by State or health plan by health plan basis. In such a case, both plans and providers would have to continue to customize their EDI transactions depending on the operating rules required under a particular state or contract.

As well, some health care entities may be slow to adopt and implement any ''operating rules'' voluntarily for fear that the Federal government, or a particular State government, will adopt ''operating rules'' that require a new set of implementation requirements with associated costs.

Finally, most providers now have to conduct transactions such as the eligibility for a health plan and the claim status transaction through two different processes, electronic and manual and paper-based, depending on the health plan that covers the patient or processes the claim. As long as some health plans continue to conduct standard transactions that are not fast or robust enough for providers' needs, providers may continue to conclude that manually processing all such transactions is easier and more economical.

C. Regulatory Flexibility Analysis: Impact on Small Entities

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the 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 health care sector, a small entity is one with between $7 million to $34.5 million in annual revenues or is a nonprofit organization. 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). (Accessed 2–1–11).

For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We attempted to estimate the number of small entities and provided a general discussion of the effects of this interim final rule with comment period, and where we had difficulty, or were unable to find information, we solicited industry comment. We discuss the impact of the rule on small entities in section VII.K. of this interim final rule with comment period.

As well, section 1102(b) of the RFA requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the

RFA. For purposes of section 1102(b) of the RFA, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. (See the discussion at section VII.K. of this interim final rule with comment period for our discussion of the expected impact on small rural hospitals.)

D. Alternatives Considered

In deciding to adopt operating rules for the eligibility for a health plan and the health care claim status transactions, we considered a number of alternatives, on which we solicit public and industry comments.

1. Do Not Adopt Operating Rules for Non-Retail Pharmacy Industry

We considered this option, but determined that this would only be appropriate if operating rules for use in the health care industry were not available, or available and already in use on a voluntary basis. Per the aforementioned NVCHS hearings, public testimony and analysis, the NCVHS deemed that two authoring entities who came forward and applied to be candidates as authoring entities were qualified under the stipulations for the adoption of operating rules in the Affordable Care Act to act as authoring entities, namely the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE) and the National Council for Prescription Drug Programs (NCPDP). The CAQH CORE offered operating rules that, with some exceptions, have been determined to be feasible for use with the eligibility for a health plan transaction, and the health care claim status transaction under HIPAA, as specified in the Affordable Care Act. The NCPDP also offered operating rules, which are already in use in all retail pharmacies by virtue of the pharmacies' use of the NCPDP Telecommunications standard Version 5.1, and which will be updated on January 1, 2012, when the update to this standard, NCPDP Telecommunications standard Version D.0, goes into effect. Additionally, not adopting any operating rules for the eligibility for a health plan transaction and health care claim status transaction, as required by the Affordable Care Act, would violate the Act's statutory requirements under section 1104(c) ''Promulgation of Rules'', which requires the Secretary to adopt operating rules for the two aforementioned electronic health care transactions by no later than July 1, 2011 with a compliance date of January 1, 2013.

2. Adopt Another Authoring Entity's Operating Rules

As previously discussed in section II.B. of this interim final rule with comment period, section 1104(b)(3) of the Affordable Care Act amends section 1173(g)(3)(a) of the Act by charging the NCVHS with advising the Secretary as to whether a nonprofit entity meets the statutory requirements for developing the operating rules to be adopted by the Secretary, and outlines the entity's specific qualification requirements. Of those organizations testifying at the NCVHS hearing, two organizations formally requested to be considered authoring entities for operating rules, namely the CAQH CORE and the NCPDP.

In its testimony before the NCVHS, the ASC X12, the standards development organization responsible for the development of the Version 5010 standards for electronic health care transactions, expressed its support for the NCPDP being named as an operating rule authoring entity not only for the pharmacy industry, but for the entire health care industry (transcript of the July 20, 2010 NCVHS Subcommittee on Standards hearing at *http://www.ncvhs.hhs.gov*). The ASC X12's support was based upon their belief that—

- The NCPDP's ANSI-approved organization status supports consensus building and open participation;
- The infrastructure for the NCPDP is able to handle the development of operating rules in the associated workgroup task group without any modifications to procedures or processes;
- The NCPDP members are frequent users of the ASC X12 standards and thus the NCPDP is familiar with them; and
- The pharmacy industry's growing experience with real-time eligibility, real-time claim status, and real-time submission of claims beyond pharmacy.

Based on the ASC X12 testimony, the NCPDP stated that it would consider playing a larger role if the NCVHS deemed that there should only be one authoring entity, and would take on the role of more than just the NCPDP standards, as appropriate.

However, with respect to the requirements for the operating rules themselves, neither the NCPDP nor the CAQH CORE met all of the requirements for operating rules for both health care segments. As noted earlier, the July 2010 NCVHS hearings were followed by a request from the NCVHS to each candidate to respond to a detailed questionnaire about the statutory requirements. The questionnaire solicited specific documentation to validate the testimony. Based on review of the CAQH CORE and the NCPDP submissions to this questionnaire the NCVHS determined, and we have concurred, that neither organization can unilaterally provide operating rules to support both retail pharmacy and non-retail pharmacy health care segments. The NCPDP naturally focuses on the NCPDP retail pharmacy standards, while the CAQH CORE has focused on the ASC X12 administrative health care transactions. While both entities have similar policies related to securing a consensus view of health care stakeholders and ensuring that rules are consistent with (and do not conflict with) other existing standards, neither organization has rules in place for both health care segments. While addressing the retail pharmacy industry's needs relative to operating rules, the NCPDP did not present to the NCVHS for their consideration any existing NCPDP operating rules to accommodate the ASC X12 standards. The CAQH CORE has phases of operating rules that accommodate the ASC X12 standard for electronic health care transactions, but are not specific to retail pharmacy transactions.

3. Wait for Resolution of All Outstanding Technical and Administrative Issues Before Adopting the Operating Rules Developed by the Authoring Entities

Both the CAQH CORE and the NCPDP demonstrated to the NCVHS that their operating rules were based upon broad public and stakeholder input. However, as previously discussed in section II. of this interim final rule with comment period, there are certain exceptions that exist with regard to our adoption of the CAQH CORE operating rules in their entirety. Upon analysis, we declined to adopt the CAQH CORE operating rules for the ASC X12 999 acknowledgement transaction, and the references to being ''CORE certified'' contained in the CAQH CORE Operating Rules as we have already described in section II.F. of this interim final rule with comment period. If we had opted to wait until the resolution of the administrative issues affecting the adoption of the entire CAQH CORE operating rules, it would seriously delay the health care industry's ability to begin to achieve the benefits of administrative simplification.

Additionally, as described in section III of this interim final rule with comment period, we have declined to adopt the NCPDP business rules and guidelines as embedded in its NCPDP

Telecommunication Standard Version D.0, as they do not qualify as operating rules as defined in section II.A. of this interim final rule with comment period. The NCPDP business rules and guidelines are embedded within the NCPDP Telecommunications Standard Version D.0, and while technically not operating rules as defined by this interim final rule with comment period, they function as such nonetheless in that they provide robust business rules and guidelines for use in retail pharmacy transactions. The pharmacy industry is already preparing to use the NCPDP Version D.0 standard in their day-to-day pharmacy transactions as required by the January 16, 2009 final rule (74 FR 3296) adopting the NCPDP Telecommunication Standard Version D.0 for use in retail pharmacy transactions, effective January 1, 2012. The NCPDP Telecommunications Standard Version D.0 already provides a full and robust array of tools for the retail pharmacy industry to realize the potential benefits of administrative simplification.

E. Impact Analysis Resources

We have considered a number of different cost benefit studies that have been conducted by industry and independent entities in recent years. The background and conclusions on these studies and surveys will illuminate how we calculated our assumptions and how we applied them to this impact analysis. In this section, we briefly describe these studies, as well as an explanation of all of the following:

- The depth and completeness of the analysis and supporting evidence for the conclusions.
- Data sources and a presentation of the data limitations.
- The perceived objectivity of the analysis as demonstrated by the discussion of data sources and the rigor of the analysis.
- Our ability to explain and justify the findings and conclusions presented in the study.

We then present assumptions and an impact analysis for each of the covered entity types, referencing the data and conclusions of the various studies. The following is a description of the studies and reports referenced for this impact analysis.

1. The Milliman Study

Electronic Transaction Savings Opportunities for Physician Practices, hereinafter referred to as the Milliman study, was published by Milliman in January 2006 (*http://transact.emdeon.com/documents/milliman_study.pdf*). Milliman is an international consulting and actuarial firm serving health care payers, service providers and consumer organizations. The Milliman study was commissioned by the Emdeon Corporation, a nationwide clearinghouse that provides a wide variety of information exchange services that connects payers, providers and patients in the U.S. health care system. The study's main objective focused on how much providers could save by implementing electronic transactions. The Milliman study's calculations are based on examining labor time and costs required to perform both manual and electronic transactions. These labor costs include employee benefits, payroll taxes, and general and administrative overhead. Notably, the study compensated for related fees for transactions and set-up costs for electronic transactions.

The Milliman study's methodology was basically mathematical, using factors established through payrolls and average administrative costs, as opposed to research based on surveys or interviews with providers. Milliman's calculations were based on a model of a provider's administrative processes developed with assumptions about the operating environment of the typical solo physician practice. Ultimately, Milliman tested its results ''by observing administrative procedures in actual physician practices and medical groups.''

The study reflected other industry research that found that, while manual processes are very similar among physicians, ''there is much greater variance among practices * * * in the use of technology and the associated costs for electronic transactions.'' In some cases, providers are fully automated. In the majority, however, there is a mix of electronic and manual processes, as well as processes that require a wide range of levels of human intervention.

Milliman found that a single-physician practice could save as much as $42,000 a year by moving processes from manual to electronic. This estimate is based on a physician office that moves from all manual transactions to fully electronic for six standard transactions. For our impact analysis, this savings could not be used as a factor to project savings for all physicians ($42,000 × the number of physicians), as other studies have demonstrated that most providers are already using some of the electronic transactions.

Milliman's approach was to look at provider costs and benefits, and we opine that it appears to be objective in its assumptions. The Milliman study will be useful in our impact analysis as it provides labor and administrative overhead costs.

The Milliman study was published in 2006. In its calculations, it accounted for inflation and other factors that may have changed since its source data were gathered and the study was finally published. However, its final conclusions are somewhat dated, and we will consider this in our assumptions.

2. The AHIP Survey (2006)

America's Health Insurance Plans' (AHIP) Center for Policy and Research conducted a survey of its members to examine the issue of claims processing and turnaround times for claim payments. The survey is summarized in the document entitled ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006'' at *http://www.ahipresearch.org/pdfs/PromptPayFinalDraft.pdf*.

AHIP is a national association representing nearly 1,300 companies providing health insurance coverage to more than 200 million Americans. The study is a follow-up to a survey done in 2002. We took data from the AHIP study to develop assumptions about savings calculations for health plans.

3. The McKinsey Analysis

Overhauling the U.S. Healthcare Payment System conducted by McKinsey & Company, hereinafter referred to as the McKinsey analysis, was published in *The McKinsey Quarterly* on June 2007 (*http://www.mckinseyquarterly.com/Overhauling_the_US_health_care_payment_system_2012*). McKinsey & Company is an international management consulting firm advising companies on strategic, organizational, technology, and operational issues. The McKinsey analysis relies on a number of different resources in order to calculate the cost of non-electronic transactions compared with the cost of electronic transactions. As in the Milliman study, the McKinsey analysis makes the case for the move from paper to electronic transactions. Their analysis used sources including Faulkner & Gray Health Data Directory; Health Data Management; HIPAA Survey—Claims and Payment Practices; Milliman; National Health Expenditures, Centers for Medicare & Medicaid Services (CMS); U.S. Department of Health and Human Services (HHS); and McKinsey's own analysis. For its analysis' cost per transaction, it appears McKinsey relied mostly on the Milliman study.

As noted, the McKinsey analysis brings together secondary sources to make its assumptions, so it is not based on any primary research or surveys. However, the McKinsey analysis does summarize these secondary sources into quantitative ranges that are useful to our impact analysis. For instance, based on secondary sources, the McKinsey analysis gives a range of 1.4 to 3.5 billion total eligibility verifications annually, both electronic and non-electronic, across the health care industry. While this is a broad range, it is useful in estimating the low and high estimates for our calculations.

The McKinsey analysis suggests that making the flow of dollars in the health care industry more efficient through electronic means will trim the administrative costs that are spent on the payment system, which its analysis calculates as 15 percent of every healthcare dollar.

The McKinsey analysis was objective in its approach, especially with regard to its data on eligibility for a health plan transactions because it was focused on claim-centered transactions. Its emphasis was mostly on the deficiencies and possibilities regarding payment flow between payers and providers, with commentary on the involvement of financial institutions. Its recommendations did not include mention of operating rules or the eligibility for a health plan transaction, so we find its data neutral with regard to the purpose of this impact analysis. The McKinsey analysis, presented in June 2007, is used by other related industry studies, and, because we could not identify studies or analyses that argued against its conclusions, we presume that it reflects industry assumptions.

4. The Healthcare Efficiency Report

The National Progress Report on Healthcare Efficiency, hereinafter referred to as the Healthcare Efficiency Report, is the first annual report from the U.S. Healthcare Efficiency Index (USHEI), (*http://www.ushealthcareindex.com*). an industry forum for monitoring business efficiency in healthcare USHEI's advisory council consists of representatives from hospitals, clearinghouses, health care consultants, health plans and other entities (*http://www.ushealthcareindex.com/advisorycouncil.php*). The USHEI was launched in 2008 to raise awareness of the cost savings associated with the adoption of electronic transactions in health care. The USHEI National Progress Report takes the Milliman, McKinsey, and other studies and applies them to a tool that measures current status of electronic transaction usage (in percentages of transactions) and projects possible cost savings if those percentages are increased.

The Healthcare Efficiency Report analyzed the eligibility for a health plan transaction as a part of its Phase 1, which relied on the Milliman study and the McKinsey report for most of its data. Nevertheless, the Healthcare Efficiency Report consolidates the secondary sources in an original and illustrative manner, and appears to be an accepted yardstick for administrative simplification in the health care industry.

The Healthcare Efficiency Report repeats an important point presented by Milliman and which we considered in our analysis: Even among providers that use electronic means to conduct some of their transactions, there is a broad range of how much they utilize standard transactions, which standard electronic transactions they use, and which transactions are still conducted manually.

5. The Oregon Provider and Payer Survey

Like the Milliman, McKinsey, and the Healthcare Efficiency Report, the Oregon Provider and Payer Survey, hereinafter referred to as the Oregon Survey, (*http://www.oregon.gov/OHPPR/HEALTHREFORM/AdminSimplification/Docs/FinalReport_AdminSimp_6.3.10.pdf*) sought to estimate the possible cost savings that would be realized if there was a continual shift from nonelectronic to electronic transactions among healthcare entities in Oregon. The survey was conducted by the Oregon Health Authority, Office for Oregon Health Policy and Research, which conducts impartial, non-partisan policy analysis, research, and evaluation, and provides technical assistance to support health reform planning and implementation in Oregon. The Office serves in an advisory capacity to Oregon Health Policy Board, the Oregon Health Authority, the Governor, and the Legislature. The survey asked payers, providers, and clearinghouses a number of qualitative questions in terms of how administrative simplification can best be realized.

The study was comprehensive, and used both secondary sources and a survey in which responses were gathered from 55 percent of the State's hospitals and 225 of the State's ''ambulatory clinics.'' Of those 225 ambulatory clinics, 69 percent were clinics with less than 9 clinicians, and 23 percent were clinics with only 1 clinician. In our impact analysis on providers, the category of ''physicians'' corresponds to the Oregon Survey's category of ''ambulatory clinics.''

Of all the studies cited in this impact analysis, the Oregon Survey had the most recent and statistically valid data with regard to provider use of electronic transactions and gave the clearest picture of how providers verify eligibility. The study received quantitative and qualitative data from a large number and range of providers. Oregon itself is a mix or rural and urban communities. However, we recognize that there are regional differences in the health care industry and the fact that only Oregon health care entities were surveyed.

6. The IBM Study

In 2009, the CAQH CORE contracted with IBM's Global Business Services, the world's largest business and technology services provider with the aim towards helping companies manage their IT operations and resources, to conduct a study (hereinafter referred to as the IBM study) (*http://www.caqh.org/COREIBMstudy.php*) to assess the costs and benefits to health plans, provider groups, and vendors of adopting the CAQH CORE Phase I rules, which include the operating rules for the electronic eligibility for a health plan transaction, as adopted under this interim final rule with comment period. According to the IBM study, industry-wide adoption of the CAQH CORE Phase I rules could potentially yield $3 billion in savings in 3 years.

The IBM study consisted of interviews during which participants answered a set of questions geared towards assessing the costs and savings of adopting the CAQH CORE operating rules. Participants in the study included six national and regional health plans, five clearinghouses and vendors, and six providers. The health plans together represented 33 million commercial members, 1.2 million providers, 22 million eligibility verifications per month, and 30 million claims per month. The providers included hospitals, physician groups, and a surgery center.

The IBM study did not track the costs and benefits of adopting the operating rules for the health care claim status transactions. It did attempt to track the costs and benefits of the infrastructure elements of the operating rules (connectivity, response time, system availability, acknowledgements, and companion guides) but health plan study participants were not able to fully account for the costs related to implementation, citing that they may

have allocated some costs to IT overhead.,

Highlights of the IBM study closely parallel the three key objectives outlined above that necessitate the adoption of operating rules:

• Providers rapidly took advantage of the new capabilities that the operating rules provided; for example, real-time transactions (page 20 of IBM study report).

• The average return on investment (ROI) for health plans surveyed in the study was less than a year. Average initial and on-going cost of implementing the operating rules for an individual health plan was $592,000. The average savings, due mostly to moving away from telephone to electronic transaction over the same time period, was nearly $2.7 million for an individual health plan (page 23 of the IBM study report). The ratio of verifications to claims was up from .63 to .73 after the operating rules were adopted (page 20 of IBM study report).

7. The 2009 Health Affairs Survey

In 2009, Health Affairs published survey results in an article entitled ''What Does It Cost Physician Practices to Interact With Health Insurance Plans,'' authored by Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, and Wendy Levinson (Health Affairs, 28, no. 4(2009):w533–w543, published online May 14, 2009; 10:1377hlthaff.28.4. 2533). The survey collected data from physicians from those identified as working in solo or two-physician practices, and physicians from those working in practices of three or more. Selection was stratified by specialty type—primary care (including family physicians, general internists, and general pediatricians), medical specialists, and surgical specialists, for a total of 895 physician practices. The survey asked about the physicians' offices' interactions with health plans by the physicians themselves and by staff at the administrative level, including the nursing staff, clerical staff, senior administrators, and lawyers and accountants.

The survey was able to calculate the mean time and cost that a physician's office spent interacting with health plans according to the size of the practice and according to the level at which the interaction took place, that is, whether the interaction was with the physicians themselves, the nursing staff, the administrative staff, or with the accountants, *etc.*

Among other conclusions, the study demonstrated that a single physician spent a mean average of 3 hours a week interacting with plans, while nursing and clerical staff spent much larger amounts of time.

We find the conclusions of the survey to be valid based on the large sampling of physicians' offices that were used. We will be applying some of the results of the survey to our calculation of savings for providers.

8. The Project SwipeIt (MGMA) Study

In 2009, the Medical Group Management Association (MGMA) launched an industry wide effort calling on health insurers, vendors, and healthcare providers to adopt standardized, machine-readable patient ID cards by Jan. 1, 2010. In support of the effort, the MGMA developed costs estimates of implementing a machine-readable patient ID card. Ultimately, the project's aim is for administrative simplification. The Project SwipeIt study demonstrated the quantifiable benefits to administrative simplification. Therefore, some of Project SwipeIt study's estimates, especially the base assumptions used in the savings calculations can be applied to our impact analysis of the implementation of operating rules.

Through their study, the MGMA estimated that it costs $25 to resubmit a denied claim. Additionally they found that 50 percent of the time claims are being denied because of incorrect patient information. We believe this could also be alleviated through the implementation of operating rules since eligibility information, including patient information, will be returned prior to or at the point of care.

The MGMA cites many resources that were used to gather their data for their analysis. We find that the data used in the MGMA study are relevant to our analysis and therefore we will use some of this data in our calculations of provider savings.

We invite public and industry stakeholder comments on our assumptions.

F. Impacted Entities

All HIPAA covered entities would be affected by this interim final rule with comment period, as well as software vendors and any other business associates providing transaction related services, such as billing support and third party administrators (TPAs). 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. We note that health care providers may choose not to conduct transactions electronically. Therefore, they would be required to use these operating rules only for HIPAA transactions that they conduct electronically. However, one of the objectives of operating rules is to not only decrease manual transactions by entities that currently conduct some health care transactions electronically, but to make electronic transactions, specifically the eligibility for a health plan and health care claim status transactions attractive to those entities that do not currently use the HIPAA standards in EDI transactions to verify eligibility or claim status. (See the Transactions and Code Sets rule (65 FR 50361) for a more detailed discussion of affected entities under the HIPAA.)

As mentioned previously in this interim final rule with comment period, the barrier to adoption of the HIPAA standards is due to their flexibility and ''situationality'' that allows health plans to implement them in very different ways. It allows plans to send back information that is inconsistent from plan to plan. By making these optional or situational elements mandatory, more entities, especially providers, will have more consistent data across health plans, making it easier to determine what information they will be receiving in a transaction, thus increasing the use of electronic transactions.

We recognize that a few health plans have already embraced the use of the CAQH CORE operating rules and have, in a published report on the utility of operating rules in the health care industry, noted substantive return on investment (ROI) derived from reduced costs associated with avoidance of manual (both paper and staff time) response to provider inquiries. This raises the question of why all health plans would not voluntarily adopt the use of operating rules (or standards, for that matter) given the benefits. We opine that there are a number of barriers, including a tendency by providers to simply accept the status quo, for example, whatever information currently is provided to them by a health plan; a health plan's lack of experience with, and knowledge of, the role that operating rules play in making a standard work more efficiently, given that the use of operating rules is not yet widespread throughout the health care industry; and the expense to a health plan of systems and other business transitions without a regulatory mandate for adoption. Despite projected savings, health plan system managers would be hard pressed to obtain from their managements the upfront funds, staff and/or contractors, and corporate commitment needed for such a

transition without a regulatory requirement. Absent specifications as codified in regulation, health plans could be confused as to which operating rule version to use, and/or any exceptions to the use of operating rules that may or may not be effective, which would adversely affect enforcement of the HIPAA transaction and code sets. In our impact analysis, we analyze the impact of moving from non-electronic to electronic transactions among all entities, whether they currently use some electronic transactions or not. We assume that most providers and health plans use some electronic transactions and very few if any use none. Through the use of operating rules, we assume that all entities will increase their use of electronic transactions. The total savings and return on investment for each category of covered entity will not include the costs associated with setting up the basic infrastructure to send and receive standard health care transactions. Those costs are accounted for in the May 7, 1998 (63 FR 25300) proposed rule entitled, ''Health Care Reform: Standards for Electronic Transactions''. The costs included in this impact analysis include only those that are necessary to implement the operating rules as adopted for the two HIPAA transactions stipulated in this interim final rule with comment period.

Based on industry surveys and research referenced herein, we do not believe there are many entities that are not capable of conducting electronic transactions. As stated previously, according to the Oregon Survey, 96 percent of hospitals and 93 percent of ambulatory clinics (physicians) in that state indicated that they were ready, or could be ready within 2 years, to implement a system for electronic information exchange. Although the study only reflects Oregon providers, we believe the study's findings demonstrate that there will be very few covered entities that will not have the ability to conduct electronic health care transactions by the time the operating rules are required to be implemented.

The segments of the health care industry that will be affected by the implementation of operating rules include the following:

- Providers: Physicians and Hospitals
- Health Plans
- Clearinghouses and Vendors

Please note that we have not included an impact to pharmacies because this interim final rule with comment period adopts only operating rules for the eligibility for a health plan (270/271) and the health care claim status (276/277) transactions which are not used by the retail pharmacy industry for drugs and medications. Therefore, we assume no impact to pharmacies of this interim final rule with comment period.

Table 5 outlines the number of entities in the health care industry that we use in our analysis along with the sources of those numbers. We have not apportioned the data to reflect any particular sub-segment of the industry, other than ''physicians'' and ''hospitals'' in general terms. In this impact analysis, the number of providers impacted is not a factor in our calculation of the benefits of the adoption of these operating rules. (The number if providers are a factor in our calculation of providers costs.) Rather, benefits for providers are based on the total number of all health care claims throughout the health care system, including non-hospital institutions. We invite public comment on our assumptions and estimates, particularly as they related to non-hospital institutions.

TABLE 5—TYPE AND NUMBER OF AFFECTED ENTITIES

Type	Number	Source
Providers—Offices of Physician Offices (includes offices of mental health specialists).	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 the AMA statistics).
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.*
Providers—All	239,986	Physicians Offices + Hospitals.
Health Plans—Commercial	4,523	The # of health plans was obtained from the 2007 Economic Census Data—Finance and Insurance (sector 52)—NAICS code 5241114 (Direct health and medical insurance carriers). (n=4,523) *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0752A1&-geo_id=01000US&-dataitem=*.*
Health Plans—Government	54	Represents the 51 state Medicaid programs, Medicare, the Veteran's Administration (VA), and Indian Health Service (IHS).
Health Plans—All	4577	Census Data for commercial plans (n=4,523) + Medicaid agencies (N=51) + Medicare, VA and IHS = 4,577 total health plans.
Clearinghouses	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asp.*
Vendors	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asphttp://www.ec-edi.biz/content/en/dir-guest-login.asp.*

Also, although we acknowledge the impact to ERISA (Employee Retirement Income Security Act) plans, we did not include them in our analysis due to the complexity involved with describing downstream costs to these plans, as well as members/beneficiaries of health plans, tax payers, *etc.* While it is understood that the approximately 2.5 million ERISA plans (and, ultimately, their members) may be charged by their third party administrators (TPAs) and health insurance companies to comply with any Federal regulation, ultimately we assume that the 4,577 plans that do business as health plans, or their business associates, are the entities conducting the transactions and that is where the costs will be incurred. We assume that few, if any, of the ERISA plans do their own transactions. Additionally, because not all ERISA plans are required to report, it is difficult to determine the exact number of ERISA plans.

G. Impact Analysis Approach

This impact analysis is framed by the two key objectives that operating rules will achieve by augmenting the eligibility for a health plan and health care claim status transactions:

- Decrease covered entities' use of more costly manual activities, including telephone and paper-based transactions,

by addressing ambiguous requirements of the standards and clarifying when to use or not use certain elements or code values. We assume that the cost and benefits of these operating rules will be directed toward covered entities that currently perform some or no eligibility for a health plan and claim status transactions. For those who currently perform these two standard transactions, we assume that their volumes of electronic transactions will increase due to operating rules.

- Decrease the clerical burdens that are associated with the inconsistent use of these two standard transactions; for example, the instances of denied claims and pended claims that burdens patients, providers, and health plans in terms of time and money.

Our overall calculation for this analysis is as follows:

(X * Y) + C–Z = Annual Return on investment of operating rules implementation

Where—

X = annual increase in number of electronic eligibility for a health plan and health care claim status transactions due to operating rules implementation

Y = savings per transaction conducted electronically

C = savings through decrease in claim denials for providers and pended claims for health plans

Z = cost of operating rules implementation

In order to make this calculation, we need to describe baseline assumptions, transaction increase assumptions, and cost assumptions that correspond to the X, Y, C, and Z factors in the calculation before arriving at costs and benefits.

In section VII.H. of this interim final rule with comment period, we describe the baseline assumptions for each of the two transactions. The baseline assumptions include, first, an estimate on the number of electronic and non-electronic eligibility for a health plan transactions and health care claim status transactions, respectively, that physicians, providers, and health plans will be conducting in 2012, the year before the operating rules take effect. Second, from those estimates, we will estimate the number of eligibility for a health plan transactions and health care claim status transactions that are conducted *electronically* starting in 2012. For the baseline assumption on the number of electronic transactions in 2012, we have developed a range of high and low estimates derived from data gathered from a number of studies. This range of high and low reflects different estimates that are presented by industry studies that have attempted to arrive at a similar baseline. The final baseline assumption is an estimate on the rate of increased use of each of the two transactions due to operating rules adopted herein for 10 years after implementation of the operating rules (X factor in the calculation).

The transaction increase estimate (X factor in the calculation) assumes an annual percentage increase in the use of the eligibility for a health plan and health care claims status electronic transactions due to the implementation of operating rules. In this specific baseline assumption, we will be giving a range of high and low estimates. Although these estimates on the increase in usage due to operating rules are informed by industry studies, specifically the IBM study, they also illustrate the uncertainty inherent in such a predictive estimate. As we have described, there is a causal link between operating rules and increased use of EDI. However, the rate of increased use of the two transactions is dependent on many factors above and beyond operating rules. For instance, visits to physicians' offices and hospital emergency and outpatient departments are experiencing a steady rise, translating into an accompanying rise in health care transactions in general. (The CDC reports that health care visits increased 25 percent from 1997 to 2007: *http://www.cdc.gov/nchs/data/series/sr_13/sr13_169.pdf accessed on June 21*). The range of estimates on the increased use of the two electronic transactions included in our baseline assumptions should be viewed as a reflection of the uncertainties involved.

For our cost assumptions, Z in the calculation is the total cost of implementing the operating rules for both the eligibility for a health plan transaction and the health care claim status transaction. The costs will be analyzed according to each impacted category of health care entity. Many of our estimates in terms of cost are derived from the cost estimates in the Modifications final rule because industry studies we surveyed focused on savings rather than costs. These costs will be presented in a range of high and low estimates to reflect the broad range in readiness for operating rule implementation among covered entities in terms of infrastructure, software, and business process. In section VII.I. of this interim final rule with comment period, we describe our cost assumptions.

For our savings assumptions, Y and C in the calculation, Y is the dollar savings per eligibility of a health plan and health care claim status transaction that is saved when the transactions are conducted electronically as opposed to non-electronically, and C is the dollar saved, or cost avoided, of a decrease in claim denials for providers and a decrease in pended claims for health plans. For the C estimate, we will again provide a high and low range of estimates. Industry studies indicate that more robust eligibility for a health plan transactions will result in a decrease in pended and denied claims (which, in turn, will result in savings). However, we are less certain of the percent of decrease that operating rules will effect, so we have reflected this uncertainty with a range. In section VII.J. of this interim final rule with comment period, we describe our savings assumptions.

Our analysis begins with a description of the baseline and transaction increase assumptions; that is, how we arrived at the numbers of eligibility for a health plan transactions and health care claim status conducted electronically as of 2012, and our assumptions on what percentage of annual increase in the transactions are due to the implementation of operating rules. We will subsequently describe our cost assumptions, savings assumptions, and finally summarize the costs and savings. The costs and savings will also be presented in a range of high and low estimates.

In general, the high and low range approach used in this impact analysis illustrates both the range of probable outcomes, based on state and industry studies, as well as the uncertainty germane to a mandated application of business rules on an industry with highly complex business needs and processes. Within those ranges, however, the summary demonstrates that there is considerable return on investment resulting from the implementation of operating rules. We solicit comments on these assumptions as well as the direct costs of implementing these operating rules adopted under this interim final rule with comment period.

H. Baseline Assumptions

1. Baseline Assumption A

Total number of electronic and nonelectronic eligibility for a health plan and health care claim status transactions conducted by providers.

We estimate that the total number of claims submitted, both electronically and manually, for the year 2012 is 5.6 billion. This estimate is the average of the high and low estimates given in the January 2009 Modifications final rule, *http://edocket.access.gpo.gov/2009/pdf/E9-740.pdf.*

In order to arrive at the number of eligibility verifications conducted in 2012, both electronic and non-electronic, we applied the per claim

ratio as concluded by the Oregon Survey. The Oregon Survey concluded that, for every claim submitted, the low estimate was 0.68 eligibility verifications per claim; the high estimate was 1.12 eligibility verifications per claim submitted. We use the average of these two estimates, 0.9 eligibility verifications per claim submitted. We then assume that of the 5.6 billion claims submitted, 0.9 of those were preceded by an eligibility inquiry to come up with approximately 5 billion eligibility verifications.

In order to arrive at the number of claim status inquiries conducted in 2012, both electronic and non-electronic, we again applied the per claim submitted ratio as concluded by the Oregon Survey. The Oregon Survey concluded that, for every claim submitted, they estimated that 0.14 claim status inquiries were submitted. We looked at other studies that included various numbers for claim status transactions, but we believe the Oregon Survey to be the most valid picture of providers' use of these transactions based on the interviews conducted. Based on our previous assumptions, we estimate that there will be 784 million claim status inquiries conducted in 2012.

To find the total number of eligibility for a health plan transactions and health care claim status transactions that physicians and hospitals conducted individually, we divided the total number of eligibility for a health plan transactions and health care claim status transactions between physicians and hospitals by a factor of 9 to 1; that is, approximately 90 percent of all eligibility for a health plan and health care claim status inquiries, electronic and non-electronic, are conducted by physicians, while 10 percent are conducted by hospitals. We have taken this physician to hospital ratio from the Oregon Survey due to its reliance on direct provider input. The survey indicated that physicians are responsible for 91 percent of all eligibility for a health plan transactions and 89 to 90 percent of health care claim status transactions.

TABLE 6—ESTIMATES ON TOTAL NUMBER OF ELIGIBILITY AND HEALTH CARE CLAIM STATUS INQUIRIES, ELECTRONIC AND NON–ELECTRONIC CONDUCTED ANNUALLY

	Total number of transactions, electronic and non-electronic, conducted per year (in millions)	Number conducted by physicians (90%)	Number conducted by hospitals (10%)
Claim submissions	5,600	N/A	N/A
Eligibility inquiries	5,040	4,536	504
Claim status inquiries	784	705.6	78.4

For the health plan eligibility transaction, we determined that the total number of eligibility for a health plan inquiries conducted electronically by physicians to be between 453.6 million, and 201.6 million for hospitals. The Oregon Survey found that approximately 10 percent of all eligibility for a health plan transactions conducted by physicians are electronic. Other studies appear to contradict Oregon's findings by a considerable margin. For instance, the Healthcare Efficiency Index reports that 40 percent of all eligibility for a health plan transactions are conducted electronically and the McKinsey report estimates 40 to 50 percent. We weighed the Oregon Survey more heavily, and estimated that 10 percent, or 453.6 million, of all eligibility for a health plan transactions conducted by physicians are electronic. (Table 7). For the percentage of hospitals' use of the electronic eligibility for a health plan transaction, we relied on the Oregon Survey's finding that 40 percent, or 201.6 million, of all eligibility for a health plan inquiries conducted by hospitals are electronic. This Oregon estimate appears to be more in line with other industry studies on the use of these transactions. (Table 7).

For the health care claim status electronic transaction, the Oregon Survey found that none of the physicians or hospitals it surveyed uses the health care claim status electronic transaction. Instead, physicians and hospitals use the telephone and, to a lesser extent, a secure Internet Web site provided by the health plan or contractor to check the status of health care claims.

Although, as we have stated before, the Oregon Survey appears to have the most valid methodology, the McKinsey study's conclusion implies that many providers do conduct the health care claim status transaction electronically (30 to 50 percent). The two studies are basically incompatible with respect to conclusions about usage of the electronic health care claim status transaction. As noted, a percentage of the health care claim status checks are conducted through the Internet. It is possible that the numbers of the McKinsey analysis are affected by considering Web-based health care claim status transactions as ''electronic.'' Only the Oregon Survey is clear in its methodology to make a distinction between electronic data interchange of HIPAA transactions and electronic Web-based transactions. Still, the McKinsey analysis has been used by others, for example, the Healthcare Efficiency Report, to demonstrate the frequency of use of HIPAA standard transactions.

We assume that there are some physicians who use the electronic health care claim status and response transaction, but believe that the McKinsey study's high estimate of 30 to 50 percent of health care claim status transactions being electronic is too high given the Oregon Survey finding. We estimate that 10 percent of all health care claim status inquiries, 70.56 million for physicians and 7.84 million for hospitals, will be made electronically in 2012. Again, we weigh the Oregon Survey more heavily. (See Table 7).

In order to determine the number of eligibility for a health plan and health care claim status transactions that health plans respond to electronically, we use the number of eligibility for a health plan inquiries for physicians and hospitals added to the number of health claim status inquiries for physicians and hospitals, based on our assumption that for all inquiries submitted by physicians and hospitals, health plans will submit the same number of responses. We assume that health plans will conduct 655.2 million electronic eligibility responses and 78.4 million claim status responses.

TABLE 7—ESTIMATES ON NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTIONS CONDUCTED BY PROVIDERS AND HEALTH PLANS

For 2012	Number of total eligibility for a health plan and health care claim status inquiries (non-electronic and electronic) conducted (in millions)	Percentage of inquiries that are electronic	Total number of electronic eligibility for a health plan and health care claim status as of 2012 (in millions)
Physicians:			
Eligibility for a Health Plan	4,536	10	453.6
Health Care Claim Status	705.6	10	70.56
Hospitals:			
Eligibility for a Health Plan	504	40	201.6
Health Care Claim Status	78.4	10	7.84
Health Plans:			
Eligibility for a Health Plan	N/A	N/A	655.2
Health Care Claim Status	N/A	N/A	78.4

2. Baseline Assumption B

Transaction Increase Assumptions: Annual increase in use of electronic eligibility for a health plan and health care claims status transactions due to implementation of operating rules.

a. Providers

As stated, there is a direct causal link between the implementation of operating rules and an increase in the use of eligibility for a health plan and health care claim status transactions industry-wide.

In its conclusions, the IBM study estimated the baseline growth of total health care eligibility for a health plan transaction transactions (electronic and non-electronic) to be 10 percent without operating rules over a period of 3 years. It then estimated a 25 percent increase in the use of electronic eligibility for a health plan transaction across the entire industry if operating rules are implemented. For our analysis, we have assumed a more conservative growth rate in the use of the electronic eligibility for a health plan transactions than that of the IBM study both *in general* (that is, not attributed to any particular factor) and *as a result of* the implementation of operating rules.

We have estimated a 15 percent annual growth rate *in general* from 2013 through 2017, and then an 8 percent annual growth for 5 years thereafter. This general growth rate is reflected in Table 8. *In general,* eligibility for a health plan inquiries, electronic and non-electronic, for both physicians and hospitals, are expected to increase annually due to a number of market forces. For one, it is anticipated that population trends will increase the total overall number of patient visits and claims in the United States, especially in regards to baby-boomers who will require more care in the coming years. (*http://www.cdc.gov/nchs/data/databriefs/db41.htm*). It is probable that this increase alone will account for our 15 percent estimated annual growth rate of the use of the eligibility for a health plan transaction. As well, it is probable that providers will adopt EDI out of necessity from the sheer number of health care visits and claims that will experienced. In summary, we have chosen this estimate as our *general* predicted increase because it is a probable increase, even without the mandated implementation of operating rules.

With the implementation of operating rules, the estimate on the increased use of transactions by providers moves from probable to practical. The estimate on the percentage increase due to operating rules is the primary savings driver in our per transaction benefit analysis. Again, we assume a more conservative growth rate *due to operating rules* than the IBM study. In this regard, our analysis of the IBM study follows: Although the IBM study did not control for other factors that may have contributed to an increased use of the eligibility for a health plan transaction, the study was based on interviews which directed respondents to isolate the costs and benefits of operating rules in particular. While it is probable that other factors contributed to the extreme increase in the use of the transaction among the study's participants, the participants themselves believed that both the costs and benefits were a consequence of the operating rules and CAQH CORE certification.

However, because the IBM study analyzed a comparably small number of entities that have adopted operating rules, we are hesitant to accept the study's conclusions as the normative result of implementing operating rules for the eligibility for a health plan transaction. There may be entities that have implemented (or will implement) the operating rules that did not experience the same success as those that were surveyed in the study.

With this in mind, we have given a high and low range of probable increase usage rates due to operating rules. Our low and high estimate of 10 to 12 percent annual for the first 5 years falls far below the IBM study's average rate (25 percent annual increase). We believe these estimates are conservative, but do not believe that we are justified in estimating a more aggressive growth.

We also assume that 5 years after implementation of the operating rules the 10 to 12 percent annual growth *due to operating rules* will decrease to 5 percent a year. We assume this will be due to the fact that by this time the health care industry will have implemented the operating rules thus making the use of the electronic transactions more widespread, resulting in market stabilization and less of an increase in the number of electronic transactions.

We then estimate the annual increase in the number of electronic eligibility for a health plan inquiries from physicians and hospitals respectively due to operating rules. It is calculated by multiplying the range of total number of electronic eligibility for a health plan inquiries by the range of total percent increase in electronic transactions due to operating rules per year.

TABLE 8—ANNUAL INCREASE IN NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS FOR PHYSICIANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Number of electronic eligibility for health plan transactions (in millions). Assumes 15% increases first 5 yrs/8% increase second 5 yrs	Number increase in electronic eligibility for health plan transactions from previous year (in millions) (high = low)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (low) (percent)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (high)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (high)
2012	453.6	0.0	0	0	0.0	0.0
2013	521.6	68.0	10	12	45.4	54.4
2014	599.9	78.2	10	12	52.2	62.6
2015	689.9	90.0	10	12	60.0	72.0
2016	793.3	103.5	10	12	69.0	82.8
2017	912.4	119.0	10	12	79.3	95.2
2018	985.3	73.0	5	5	45.6	45.6
2019	1064.2	78.8	5	5	49.3	49.3
2020	1149.3	85.1	5	5	53.2	53.2
2021	1241.2	91.9	5	5	57.5	57.5
2022	1340.5	99.3	5	5	62.1	62.1
Totals					573.5	634.6

TABLE 9—ANNUAL INCREASE IN NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS FOR HOSPITALS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Number of electronic eligibility for health plan transactions (in millions). Assumes 15% increases first 5 yrs/8% increase second 5 yrs	Number increase in electronic eligibility for health plan transactions from previous year (in millions) (low = high)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (low)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (high)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (high)
2012	201.6	0.0	0			0.0
2013	231.8	30.2	10	12	20.2	24.2
2014	266.6	34.8	10	12	23.2	27.8
2015	306.6	40.0	10	12	26.7	32.0
2016	352.6	46.0	10	12	30.7	36.8
2017	405.5	52.9	10	12	35.3	42.3
2018	437.9	32.4	5	5	20.3	20.3
2019	473.0	35.0	5	5	21.9	21.9
2020	510.8	37.8	5	5	23.6	23.6
2021	551.7	40.9	5	5	25.5	25.5
2022	595.8	44.1	5	5	27.6	27.6
Totals					254.9	282.1

We assume that health care claim status inquiries will increase annually for all providers *in general* at a rate of 20 percent a year for the first 5 years, for many of the same reasons as our estimates on the usage rate of the eligibility for a health plan transaction. We also assume that this rate of increase will slow after 5 years to about 10 percent a year. This general growth rate is reflected in Tables 10 and 11. We expect health care claim status transactions to be adopted at a higher rate than the eligibility for a health plan transaction because there is significantly less use of the transaction now (and so there is more room for growth).

We again have given a range of high and low estimates for the rate of increase that can be attributed to the implementation of operating rules. We have estimated a 12 to 15 percent annual growth in usage attributable to operating rules from 2013 through 2017, and then a 7 percent annual growth in usage for 5 years thereafter.

TABLE 10—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR PHYSICIANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Minimum number of electronic health care claim status transactions (in millions). Assumes 20% increases first 5 yrs/10% increase second 5 yrs	Number increase in electronic health care claim status transactions from previous year (in millions) (high = low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (high)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (high)
2012	70.6	0.0	0	0	0.0	0.0
2013	84.7	14.1	12	15	8.5	10.6
2014	101.6	16.9	12	15	10.2	12.7
2015	121.9	20.3	12	15	12.2	15.2
2016	146.3	24.4	12	15	14.6	18.3
2017	175.6	29.3	12	15	17.6	21.9
2018	193.1	17.6	7	7	12.3	12.3
2019	212.4	19.3	7	7	13.5	13.5
2020	233.7	21.2	7	7	14.9	14.9
2021	257.1	23.4	7	7	16.4	16.4
2022	282.8	25.7	7	7	18.0	18.0
Totals					138.0	153.8

TABLE 11—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR HOSPITALS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Minimum number of electronic health care claim status transactions (in millions). Assumes 20% increases first 5 yrs/10% increase second 5 yrs	Number increase in electronic health care claim status transactions from previous year (in millions) (high = low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (high)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (high)
2012	7.8	0.0	0	0	0.0	0.0
2013	9.4	1.6	12	15	0.9	1.2
2014	11.3	1.9	12	15	1.1	1.4
2015	13.5	2.3	12	15	1.4	1.7
2016	16.3	2.7	12	15	1.6	2.0
2017	19.5	3.3	12	15	2.0	2.4
2018	21.5	2.0	7	7	1.4	1.4
2019	23.6	2.1	7	7	1.5	1.5
2020	26.0	2.4	7	7	1.7	1.7
2021	28.6	2.6	7	7	1.8	1.8
2022	31.4	2.9	7	7	2.0	2.0
Totals					15.3	17.1

b. Health Plans

To find the increase in electronic eligibility for a health plan and health care claims status transactions annually for health plans, we add the total annual increase usage of the two transactions by providers. The sum again gives us a low to high range of increased usage of the two transactions due to operating rules.

We solicit comments on these baseline assumptions.

TABLE 12—ANNUAL INCREASE IN NUMBER OF ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Physician number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions		Hospital number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions		Plan number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions	
	Low	High	Low	High	Low	High
2012	0.0	0.0	0.0	0.0	0.0	0.0
2013	45.4	54.4	20.2	24.2	65.5	78.6
2014	52.2	62.6	23.2	27.8	75.3	90.4
2015	60.0	72.0	26.7	32.0	86.7	104.0
2016	69.0	82.8	30.7	36.8	99.6	119.6
2017	79.3	95.2	35.3	42.3	114.6	137.5
2018	45.6	45.6	20.3	20.3	65.9	65.9
2019	49.3	49.3	21.9	21.9	71.2	71.2
2020	53.2	53.2	23.6	23.6	76.9	76.9
2021	57.5	57.5	25.5	25.5	83.0	83.0
2022	62.1	62.1	27.6	27.6	89.6	89.6
Totals	573.5	634.6	254.9	282.1	828.3	916.7

TABLE 13—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR HEALTH PLANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Physician number increase in electronic health care claim status transactions from previous year due to operating rules in millions		Hospital number increase in electronic health care claim status transactions from previous year due to operating rules in millions		Plan number increase in health care claim status transactions from previous year due to operating rules in millions	
	Low	High	Low	High	Low	High
2012	0.0	0.0	0.0	0.0	0.0	0.0
2013	8.5	10.6	0.9	1.2	9.4	11.8
2014	10.2	12.7	1.1	1.4	11.3	14.1
2015	12.2	15.2	1.4	1.7	13.5	16.9
2016	14.6	18.3	1.6	2.0	16.3	20.3
2017	17.6	21.9	2.0	2.4	19.5	24.4
2018	12.3	12.3	1.4	1.4	13.7	13.7
2019	13.5	13.5	1.5	1.5	15.0	15.0
2020	14.9	14.9	1.7	1.7	16.5	16.5
2021	16.4	16.4	1.8	1.8	18.2	18.2
2022	18.0	18.0	2.0	2.0	20.0	20.0
Totals	138.0	153.8	15.3	17.1	153.4	170.9

I. Cost Assumptions

1. Providers

We assume that physicians and hospitals will incur some start-up costs for implementing operating rules. These include training of staff and changes to internal business processes. Unlike the costs to health plans, we assume that the costs are less likely to be expensive infrastructure updates, because we assume most providers will already have the necessary infrastructure in place to accommodate the operating rules adopted under this interim final rule with comment period. We base this assumption on industry studies that demonstrates that EDI is utilized in over 75 percent of claim submissions. This means that the majority of providers or their business partners are capable of transmitting EDI.

While we assume that there may remain some providers who do not conduct any EDI, the operating rules adopted herein do not apply to providers who prefer paper-based or manual transactions. If such a provider were to move to EDI after learning of the advantages of operating rules, the provider's costs for initial EDI infrastructure can be found in the Transaction and Code Sets final rule, and impacts of the operating rules per se can be found in this interim final rule with comment period. In summary, costs regarding initial EDI infrastructure to transmit HIPAA transactions are not a factor in our estimates. We solicit comments on these assumptions.

We assume the costs of implementing operating rules will mostly be borne by health plans. However, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses, such as upgraded software costs and an increase in per-claim transaction fees based on the increase in volume of transactions. These fees are variable depending on existing infrastructure, number of providers in a practice, geographic areas, *etc.* To account for possible costs to providers, we have assumed that the costs attributed to implementing the Modifications final rule are applicable here. We estimate the cost for providers

to implement operating rules will be 25 percent of the total unadjusted costs estimated by the Modifications rule. We use this estimate based on the fact that most of the costs of implementing operating rules will be realized by health plans due to the more robust information they will be required to send in these transactions. As well, any software updates that providers will need may only apply to the eligibility for a health plan and health care claim status transactions, unlike the Modifications rule, which required software updates that applied to up to seven transactions. (See Table 14.)

We base our estimates on provider costs solely on the Modifications final rule because the types of costs included in that impact analysis are similar to those that would be borne by implementing operating rules: software upgrades; training; and testing of transaction improvements.

We believe that these costs are high considering the fact that the Modifications rule applies to seven different transactions, while the operating rules adopted in this interim final rule with comment period only applies to two. However, we have no evidence or justification for supporting a lower cost.

TABLE 14—PROVIDER COSTS

	Unadjusted total physicians' cost from modifications final rule	Physicians' cost to implement operating rules for eligibility for a health plan and health care claim status transactions (25% of modifications final rule estimates)	Unadjusted total hospital's cost from modifications final rule	Hospitals' cost to implement operating rules for eligibility for a health plan and health care claim status transactions (25% of modifications final rule estimates)	Total cost to providers
5010 Implementation Costs—Low	$370	$93	$792	$198	$291
5010 Implementation Costs—High	740	185	1,584	396	581
5010 Transition Costs—Low	174	44	373	93	137
5010 Transition Costs—High	348	87	746	187	274
Total Costs—Low	544	136	1,165	291	427
Total Costs—High	1,088	272	2,330	583	855

2. Health Plans

As stated earlier, we assume that health plans will bear the majority of costs of adopting operating rules. All of the studies that were considered for this impact analysis provided qualitative descriptions of the possible costs of adoption; however, the IBM study was the only one to attribute specific costs of operating rule adoption for health plans. The IBM study gave a range of costs: $8,000 to $1.7 million total cost of adoption including IT staff services such as programming, software, and hardware across a number of systems; and annual ongoing costs of $0 to $79,000 for IT staff services such as programming, and minor hardware and software upgrades to annually update operating rules.

In contrast, total implementation costs to implement the updated Version 5010 of the HIPAA standards ranged from an average of $1.14 to $2.28 million per health plan, excluding government health plans. We assume that implementing Version 5010 may be comparable to implementing the operating rules adopted herein. However the Modifications rule broadly amends or alters seven HIPAA standard transactions. This interim final rule with comment period adopts operating rules for only two transactions.

To calculate the range of costs for health plans we start with the low and high costs to health plans estimated in the Modifications rule. We increased these costs by 14 percent to account for the 14 percent increase in the number of health plans from the Modifications rule. We estimate the cost for health plans to implement operating rules will be 50 percent of the total costs estimated by the Modifications rule. We estimated a low cost of $2.6 billion and a high $5.1 billion for health plans. We reduced the estimate of health plans costs based upon the Modifications final rule because, unlike the Modifications final rule, operating rules adopted herein only apply to the eligibility for a health plan and health care claim status transactions.

We will assume that the ongoing cost to maintaining operating rules for eligibility for a health plan and health care claim status will continue 2 years after implementation. However, since we do not know what updates will be needed at this time, we cannot determine costs for those updates. Afterwards, we will assume that ongoing costs will decrease to zero. We base this assumption on the IBM study finding that the majority of the ongoing cost was due to IT staff services for programming, and after 2 years we assume that this programming will no longer be necessary.

Note that by using 4,577 as the total number of health plans, we have not adjusted for the number of health plans that have already updated their infrastructure and communications, and have already implemented the operating rules. This includes not only those health plans that have been certified by the CAQH CORE as having implemented portions of Phase I and, perhaps, Phase II, but also health plans that have done so without going through the CAQH CORE certification process. As we have noted, a number of states have statutes that are similar, to the CAQH CORE operating rules with which all health care entities operating in the same state must comply. Therefore, we believe our costs may be overstated. We invite public and interested stakeholder comments on our cost assumptions.

TABLE 15—COST TO HEALTH PLANS OF OPERATING RULE ADOPTION FOR ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTIONS

	Total health plans' cost from modifications final rule (+14% to account for increase in number of plans)	Health plans' cost to implement operating rules for eligibility for a health plan and claim status transactions (50% of adjusted modifications final rule estimates)
5010 Implementation Costs—Low	$3,483	$1,742
5010 Implementation Costs—High	6,968	3,484
5010 Transition Costs—Low	1,640	820
5010 Transition Costs—High	3,279	1,639
Total Costs—Low	5,123	2,562
Total Costs—High	10,246	5,123

3. Vendors and Clearinghouses

None of the studies considered for this impact analysis were able to quantify the costs and savings, or the return on investment of adopting operating rules for vendors or clearinghouses. As previously mentioned, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses, such as upgraded software costs and an increase in per-claim transaction fees based on the increase in volume of transactions.

Because of this we believe that costs to vendors will be the same as the costs expected by providers since vendors pass along their costs to their provider clients in the form of increased fees, which are included as the costs to providers of implementing these operating rules. Additionally, we believe that costs to clearinghouses for routing of additional electronic transactions, which we assume will be due to implementation of the operating rules, are included in the costs expected by health plans. We invite interested stakeholder comments regarding these costs and assumptions for vendors and clearinghouses.

J. Savings Assumptions

1. Providers

We have analyzed two areas in which providers will find savings or avoid costs upon implementation of the operating rules for eligibility for a health plan and health care claim status transactions. The first area that provides considerable cost savings is the avoidance of claim denials that implementation of the eligibility for a health plan operating rules is estimated to provide. The second area of savings for providers will be the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to EDI.

It is difficult, if not impossible, to estimate the number of eligibility for a health plan and claim status transactions conducted per provider, even as an average. Given the added difficulty of the range of technological capabilities of providers, it would be difficult, if not impossible, to make any assumptions on the cost or benefit on a per provider basis, or to project an estimate of increased EDI use for any one provider.

This impact analysis will not base its cost or benefit to providers on the number of providers or on a per-provider or average provider basis. It would be specious to presume that such numbers reflect any real situation in a provider's office. Rather, we will look at the total number of eligibility for a health plan and claim status transactions that we estimate all providers conduct through a given year, and estimate an increase based on the implementation of operating rules. In the same vein, we will calculate a savings based on an estimate of the total number of denied claims, instead of attempting to calculate an average of denied claims per provider.

In the area of claims denials, we assume that there will be a low to high range of $$560 million to $700 million annual cost savings in the reduction of denied claims once the eligibility for a health plan transaction operating rules are implemented. We base this assumption on a number of studies. We use the total annual number of claims submitted from the Modifications final rule as mentioned above, 5.6 billion, and divide it between physicians and hospitals according to the Oregon Survey's 9 to 1 ratio of physician to hospital transactions. We then take the 5 billion annual claims for physicians and 560 million for hospitals and apply the 5 percent of denied claims as outlined in the MGMA Project Swipe IT study. With this number, we consider the IBM study data that found that the implementation of eligibility for a health plan operating rules resulted in a 10 percent to 12 percent decrease in denied claims. We have consistently created low to high ranges in this impact analysis that uses the results of the IBM study as the ''best case'' or high estimates, and we will do so here as well. We have provided a range of 8 to 10 percent decrease in denied claims due to operating rules.

This results in a total of 22.4 million to 28 million denied claims for providers that could be avoided through eligibility for a health plan operating rules. We then take these numbers and apply them to the cost to providers of processing denied claims, which is $25 per denied claim according to a December 2000 study sponsored by the Medical Group Management Association, *http://www.acpinternist.org/archives/2000/12/claimsdenied.htm*). This results in $560 million to $700 million in annual savings for providers due to implementation of operating rules for the eligibility for a health plan transaction.

X * Y * Z * A = Total annual savings to providers by avoiding denied claims

Where:

X = Total number of claims (Column II)
Y = Percent of claims that are denied (Column III)
Z = Percent of denied claims that will be avoided by implementing eligibility for a health plan operating rules (Column V)
A = Cost for providers to resubmit a single denied claim (Column VII)

TABLE 16—ANNUAL SAVINGS TO PROVIDERS FOR AVOIDING CLAIMS DENIALS AFTER IMPLEMENTATION OF OPERATING RULES FOR ELIGIBILITY FOR A HEALTH PLAN

I	II	III	IV	V	VI	VII	VIII	IX	X	XI
	Total number of claims (in millions)	Percent of claims denied (MGMA 2007) (percent)	Number of claims denied in millions = *(Col II)* × *(Col III)*	Percent of denied claims that will be avoided through eligibility for a health plan operating rules (IBM: 10%–12%) (percent)		Number of denied claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col IV)* × *(Col V/VI)*		Cost to resubmit a denied claim (Larch 2000, ACP–ASIM Observer)	Total annual savings of eligibility for a health plan operating rules through reduction in claims denial in millions (Col VII/VIII) × (Col IX)	
				LOW	HIGH	LOW	HIGH		LOW	HIGH
Physician	5,040	5	252	8	10	20.16	25.2	$25	504	630
Hospital	560	5	28	8	10	2.24	2.8	25	56	70
Totals						22.4	28		560	700

In the area of per transaction savings, we assume that the move from non-electronic to electronic transmission of the eligibility for a health plan transaction will save providers, physicians and hospitals, $2.10 per transaction. This number reflects the difference in labor time and costs required to conduct the electronic transaction compared to the manual transaction. It includes the difference in the cost of labor—employee salary, benefits, and payroll taxes—as well as the difference in general overhead.

We arrived at $2.10 savings per transaction after analyzing a number of the studies already mentioned, including the Health Efficiency Report, the Milliman study, and the IBM study. We decided that the IBM study's estimate of a savings of $2.10 per eligibility for a health plan transaction that moves from non-electronic to electronic was the best starting estimate because, unlike the other studies, the IBM study surveyed entities that actually realized costs savings as a result of the use of operating rules for the electronic eligibility for a health plan transactions. As well, the IBM study gives us the most conservative estimate, as can be seen by comparing it with other studies' conclusions.

We assume that the move from non-electronic to EDI transmission of the health care claim status transaction will save physicians and hospitals $3.33 per transaction. The benefits to physicians in streamlining the health care claim status transaction through operating rules are potentially significant if, as we assume, it leads to less dependence on more time consuming and costly manual means, and increased use of the EDI transaction.

Unlike the eligibility for a health plan transaction analysis, we did not base our savings per health care claim status transaction for providers on the IBM study, as the IBM study did not measure the impact of the operating rules for the health care claim status transaction. Instead, we took our assumptive savings of $3.33 per transaction from the number that is used in all studies we analyzed and which was first illustrated in the Milliman study. We will use this assumption as this is the number on which industry studies appear to agree. However, we note that, as the health care claim status transaction is very seldom used, there is very little data on which to base actual savings.

Note that the low to high estimates on the estimated increase in the transactions based on operating rules are carried through this calculation. We arrived at this range in our calculations described in the baseline assumptions.

TABLE 17—SAVINGS FOR PROVIDERS PER ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIMS STATUS TRANSACTION THAT MOVES FROM NONELECTRONIC TO ELECTRONIC FOR PROVIDERS

Source	Savings for every eligibility for a health plan transaction that moves from non-electronic to electronic	Savings for every health care claim status transaction that moves from non-electronic to electronic
Health Efficiency Report	$2.95	$3.33
Oregon Survey (low estimate)	2.46	3.33
Milliman study	2.44	3.33
IBM study	2.10	NA
Our assumption	2.10	3.33

TABLE 18—PROVIDER (PHYSICIAN AND HOSPITALS) SAVINGS FOR ELIGIBILITY

I	II	III	IV	V	VI
Year	Low number increase in eligibility for a health plan transactions from previous year due to operating rules in millions (from table 12)	High number increase in eligibility for a health plan transactions from previous year due to operating rules in millions (from table 12)	Savings per transaction	Low annual savings in millions	High annual savings in millions
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	65.5	78.6	2.10	137.6	165.1
2014	75.3	90.4	2.10	158.2	189.9
2015	86.7	104.0	2.10	182.0	218.4
2016	99.6	119.6	2.10	209.3	251.1
2017	114.6	137.5	2.10	240.6	288.8
2018	65.9	65.9	2.10	138.4	138.4
2019	71.2	71.2	2.10	149.4	149.4
2020	76.9	76.9	2.10	161.4	161.4
2021	83.0	83.0	2.10	174.3	174.3
2022	89.6	89.6	2.10	188.3	188.3
Total				1,739.5	1,925.0

TABLE 19—PROVIDER (PHYSICIAN AND HOSPITALS) SAVINGS FOR CLAIM STATUS

I	II	III	IV	V	VI
Year	Low number increase in health care claim status transactions from previous year due to operating rules in millions (from table 13)	High number increase in health care claim status transactions from previous year due to operating rules in millions (from table 13)	Savings per transaction	Low annual savings in millions	High annual savings in millions
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	9.4	11.8	3.33	31.3	39.2
2014	11.3	14.1	3.33	37.6	47.0
2015	13.5	16.9	3.33	45.1	56.4
2016	16.3	20.3	3.33	54.1	67.7
2017	19.5	24.4	3.33	65.0	81.2
2018	13.7	13.7	3.33	45.5	45.5
2019	15.0	15.0	3.33	50.0	50.0
2020	16.5	16.5	3.33	55.0	55.0
2021	18.2	18.2	3.33	60.5	60.5
2022	20.0	20.0	3.33	66.6	66.6
Total				510.8	569.0

TABLE 20—PROVIDER SAVINGS SUMMARIZED

Year	Low savings			High savings		
	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)
2013	$168.92	$560	$729	$204.27	$700	$904
2014	195.83	560	756	236.87	700	937
2015	227.08	560	787	274.75	700	975
2016	263.40	560	823	318.78	700	1,019
2017	305.61	560	866	369.98	700	1,070
2018	183.85	560	744	183.85	700	884
2019	199.46	560	759	199.46	700	899
2020	216.42	560	776	216.42	700	916
2021	234.84	560	795	234.84	700	935
2022	254.83	560	815	254.83	700	955

TABLE 20—PROVIDER SAVINGS SUMMARIZED—Continued

Year	Low savings			High savings		
	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)
Cumulative Totals	.....	.....	7,850	.....	.....	9,494

2. Health Plans

We have analyzed two areas in which health plans will find savings or avoid costs upon implementation of the operating rules for eligibility for a health plan and health care claim status transactions. The first area that provides considerable cost savings is a decrease in the number of pended claims that implementation of the eligibility for a health plan operating rules is estimated to provide. Pended claims are claims that necessitate a manual review by the health plan. The second area of savings for health plans will be the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to EDI transmittal.

In the area of pended claims, we base this assumption on a study by the America's Health Insurance Plans in 2006 (AHIP Center for Policy and Research, An Updated Survey of Health Care Claims Receipt and Processing Times (May 2006) at *http://www.ahipresearch.org/pdfs/PromptPayFinalDraft.pdf*).

We start our calculation with the total annual number of claims submitted based on the Modifications final rule as mentioned previously, 5.6 billion. AHIP reported that 14 percent of all claims were pended by health plans, which calculates to 784 million pended claims. The AHIP study broke down the reasons why claims were pended. Four of those categories, including lack of necessary information, no coverage based on date of service, non-covered/non-network benefit or service, and coverage determination, we believe can be avoided by implementing operating rules for the eligibility for a health plan transaction and the increased use of the eligibility for a health plan transactions. These categories comprise 31 percent of all pended claims. We also assume that many pended claims can be avoided with increased use of the claim status transaction and its operating rules. However, we were unable to establish a correlation between use of claim status operating rules and a decrease in pended claims, and have not included any savings attributable to the claim status operating rules.

To reflect the uncertainty of this effect of operating rules on a ''downstream'' process, we estimate that 20 to 25 percent of pended claims could be avoided through use of operating rules. (See Table 21.)

AHIP estimated that $0.85 was the cost to reply electronically to a ''clean'' claim submission, while $2.05 was the cost to claims that ''necessitate manual or other review cost,'' according to the study. The difference is $1.20, which is the per pended claim factor we use for our cost savings analysis. (See Table 21.)

This results in $188 million to $235 million for health plans in annual savings of eligibility for a health plan operating rules through reduction in pended claims.

X * Y * Z * A = Total annual savings to providers by avoiding denied claims

Where:

X = Total number of claims (Column I)

Y = Percent of claims that are pended (Column II)

Z = Percent of pended claims that will be avoided by implementing eligibility for a health plan operating rules (Column IV)

A = Cost for health plans to manually review a pended claim (Column VI)

TABLE 21—ANNUAL SAVINGS TO PLANS FOR AVOIDING PENDED CLAIMS AFTER IMPLEMENTATION OF OPERATING RULES FOR ELIGIBILITY FOR A HEALTH PLAN

I	II	III	IV	V	VI	VII	VIII	IX	X
Total number of claims in millions	Percent of claims pended (AHIP 2006)	Number of claims pended claims in millions = *(Col I)* × *(Col II)*	Percent of pended claims that will be avoided through eligibility for a health plan operating rules (AHIP 2006) Low	Percent of pended claims that will be avoided through eligibility for a health plan operating rules (AHIP 2006) High	Number of pended claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col III* × *(Col IV)* Low	Number of pended claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col III)* × *(Col V)* High	Cost to review a pended claim (AHIP, 2006)	Total annual savings of eligibility for a health plan operating rules through reduction in pended claims in millions *(Col VI)* × *(Col VIII)* Low	Total annual savings of eligibility for a health plan operating rules through reduction in pended claims in millions *(Col VII)* × *(Col VIII)* High
5,600	14%	784	20%	25%	156.8	196	$1.20	$188	$235

The second area of savings for health plans is the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to electronic transmittal. We assume that the average savings for health plans in adopting operating rules for eligibility for a health plan is approximately $3.13 per transaction that moves from non-electronic to electronic, and $3.75 for health care claim status transactions that move from non-electronic to electronic.

To determine these savings, we assumed that the IBM study and the Oregon Survey were the most recent and the most valid with regard to eligibility for a health plan savings, as they are based on detailed surveys with health plans. To arrive at our savings

assumption, therefore, we averaged the two studies. (See Table 22)

For health care claim status transactions, we relied solely on the Oregon Survey, again based on the validity of its results. (See Table 22)

TABLE 22—SAVINGS PER ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTION THAT MOVES FROM NON–ELECTRONIC TO ELECTRONIC FOR HEALTH PLANS

Source	Savings for every eligibility for a health plan transaction that moves from non-electronic to electronic	Savings for every health care claims status transaction that moves from non-electronic to electronic
Oregon Survey	$3.75	$3.75
IBM study	$2.50	NA
Our assumption	$3.13	$3.75

Note that the low to high estimates on the estimated increase in the transactions based on operating rules are carried through this calculation (in Tables 23 and 24). We arrived at this range in our calculations described in the baseline assumptions.

TABLE 23—SAVINGS FOR ELIGIBILITY FOR A HEALTH PLAN OPERATING RULES FOR HEALTH PLANS

I	II	III	IV	V	VI
Year	Number increase in electronic eligibility for a health plan transactions from previous year due to operating rules (in millions) low	Number increase in electronic eligibility for a health plan transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	65.5	78.6	3.13	205.1	246.1
2014	75.3	90.4	3.13	235.8	283.0
2015	86.7	104.0	3.13	271.2	325.5
2016	99.6	119.6	3.13	311.9	374.3
2017	114.6	137.5	3.13	358.7	430.4
2018	65.9	65.9	3.13	206.2	206.2
2019	71.2	71.2	3.13	222.7	222.7
2020	76.9	76.9	3.13	240.6	240.6
2021	83.0	83.0	3.13	259.8	259.8
2022	89.6	89.6	3.13	280.6	280.6
Total				2,592.7	2,869.2

TABLE 24—SAVINGS FOR HEALTH CARE CLAIM STATUS OPERATING RULES FOR HEALTH PLANS

I	II	III	IV	V	VI
Year	Number increase in health care claim status transactions from previous year due to operating rules (in millions) low	Number increase in claim status health care transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	9.4	11.8	3.75	35.3	44.1
2014	11.3	14.1	3.75	42.3	52.9
2015	13.5	16.9	3.75	50.8	63.5
2016	16.3	20.3	3.75	61.0	76.2
2017	19.5	24.4	3.75	73.2	91.4
2018	13.7	13.7	3.75	51.2	51.2
2019	15.0	15.0	3.75	56.3	56.3
2020	16.5	16.5	3.75	62.0	62.0
2021	18.2	18.2	3.75	68.2	68.2
2022	20.0	20.0	3.75	75.0	75.0

TABLE 24—SAVINGS FOR HEALTH CARE CLAIM STATUS OPERATING RULES FOR HEALTH PLANS—Continued

I	II	III	IV	V	VI
Year	Number increase in health care claim status transactions from previous year due to operating rules (in millions) low	Number increase in claim status health care transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
Total				575.2	640.8

TABLE 25—HEALTH PLAN SAVINGS SUMMARIZED

	Low savings			High savings		
	Annual health plan savings due to increased use of electronic transactions	Annual health plan savings due to decrease in claim denials	Total annual savings to health plans (in millions)	Annual health plan savings due to increased use of electronic transactions	Annual health plan savings due to decrease in claim denials	Total annual savings to health plans (in millions)
2013	$240.4	$188	$429	$290.19	$235	$525
2014	278.2	188	466	335.93	235	571
2015	322.0	188	510	388.96	235	624
2016	372.9	188	561	450.48	235	686
2017	431.8	188	620	521.86	235	757
2018	257.5	188	446	257.45	235	493
2019	279.1	188	467	279.07	235	514
2020	302.5	188	491	302.52	235	538
2021	328.0	188	516	327.97	235	563
2022	355.6	188	544	355.57	235	591
Totals			5,049			5,862

3. Vendors and Clearinghouses

None of the studies considered for this analysis were able to quantify the costs and savings, or the return on investment of adopting operating rules for the eligibility for a health plan and health care claim status inquiry and response transactions for vendors and clearinghouses. As noted previously, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses such as upgraded software costs.

We would anticipate that the savings, as well as the costs, to vendors of upgrading provider software will be passed along to their provider clients. Therefore, we assume that the costs and benefits for vendors in implementing the operating rules will be the same as those for providers.

Additionally, since clearinghouses work on behalf of health plans and act as intermediaries between providers and health plan in regards to electronic transactions, we believe that the savings, as well as the costs, to clearinghouses for routing of additional electronic transactions will be the same savings and costs as those expected by health plans. We invite public and interested stakeholder comments on our assumptions.

K. Summary

1. Providers

As previously noted, providers will assume the least cost and see the greatest benefit from the implementation of operating rules as required by this interim final rule with comment period. Within 10 years of implementation of the operating rules for eligibility for a health plan and health care claim status transactions, we estimate that there will be $7.9 billion to $9.5 billion in savings for providers at a cost of up to $855 million.

TABLE 26—SUMMARY OF PROVIDER SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Provider Savings	$7,850	$9,494
Total Provider Costs	427	855

2. Health Plans

We estimate that health plans will see a savings of $5 billion to $5.8 billion within 10 years of the implementation of operating rules (both for eligibility for a health plan and health care claim status transactions). We believe that this is a conservative estimate. The IBM study found an average return on investment of over $2 million per health plan within 1 year of implementation. If multiplied by the number of health plans, this results in over $9 billion savings after the first year. We estimate that costs to health plans will range from $2.6 billion to $5.1 billion over 10 years.

In March 2010, the Congressional Budget Office (CBO) (*http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf*) estimated that the administrative simplification requirements in the Affordable Care Act would produce savings to the Federal budget. In contrast to the CBO analysis, government health plans are not considered separately in our impact analysis and summary estimate, and were instead included along with private health plans. When considering the impact on the Federal government of this interim final rule with comment period, note that the operating rules adopted herein are only one part of the broader administrative simplification mandates outlined in section 1104 of the Affordable Care Act, from which a

greater return on investment (ROI) in total is anticipated. Also, because we are addressing requirements that will impact the entire health care industry, we again reiterate that we choose to make conservative estimates based on the variation within the studies on which to base such estimates.

TABLE 27—SUMMARY OF HEALTH PLAN SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Health Plan Savings	$5,049	$5,862
Health Plan Costs	2,562	5,123

TABLE 28—SUMMARY OF PROVIDER AND HEALTH PLAN SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Provider and Health Plan Savings	$12,899	$15,356
Total Provider and Health Plan Costs	2,989	5,978

L. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the interim final rule with comment 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 healthcare sector, the Small Business Administration (SBA) size standards define a small entity as one with between revenues of $7 million to $34.5 million in any 1 year. 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). (Accessed 2–1–11).

For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of this interim final rule with comment period, and where we had difficulty, or were unable to find information, we solicit industry comment. Because most medical providers are either nonprofit or meet the SBA's size standard for small business, we treat all medical providers as small entities.

1. Number of Small Entities

The following sections discuss which entities across the health care industry, that are impacted by this interim final rule with comment period, are considered small entities as part of this Regulatory Flexibility Analysis.

- Providers—All health care providers are assumed to be small entities. The number of providers utilized in this analysis is taken from the August 21, 2008 HIPAA Electronic Transaction Standards proposed rule, as well as the U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010. The determination to include all health care providers as small entities is modeled after many previous HHS rules which utilized the same assumption.
- Clearinghouses—All clearinghouses were assumed to not be small entities. Three national association Web sites were consulted (EHNAC, HIMSS and the Cooperative Exchange). Additionally, the Health Data Dictionary by Faulkner and Gray which was last published in 2000 determined that the number of clearinghouses that would be considered small entities was negligible. The top 51 clearinghouse entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. It was determined that even based on this data, few of the entities would fall into the small entity category, and as such, we did not count them in this RFA analysis.
- Health Plans—All health plans are assumed to not be small entities. Based on the available public data, the number of plans that meet the SBA size standard of $7 million in annual receipts was unable to be determined; therefore we did not include an analysis of the impact on health plans.
- Software Vendors—Vendors are not considered covered entities under HIPAA; however we assume that all vendors are small entities based on their relation to providers. Based on our analysis in the regulatory impact analysis, we assume that the costs and benefits for software vendors would be the same as those for providers.

We solicit industry comment on our above assumptions.

In total, we estimate that there are approximately 300,000 health care organizations that may be considered small entities either because of their nonprofit status or because of their revenues. On the provider side, practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $7 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*) lists 97 billing companies on its Web site. It notes that these are only ones with Web sites.

The Business Census data shows that there are 4,526 (plus Medicare, VA, and IHS) firms considered as health plans and/or payers responsible for conducting transactions with health care providers (not including State Medicaid Agencies). For purposes of the RFA, we did not identify a subset of small plans, and instead solicit industry comment as to the percentage of plans that would be considered small entities. State Medicaid agencies were also excluded from the analysis as well because States are not considered small entities in any Regulatory Flexibility Analysis. We solicit industry comment on this assumption.

We identified the top 51 clearinghouses/vendors in the Faulkner and Gray health data directory from 2000, the last year this document was produced. Health care clearinghouses provide transaction processing and translation services to both providers and health plans.

The following table outlines the estimated number of small entities utilized in the preparation of the initial regulatory flexibility analysis.

TABLE 29—NUMBER OF IMPACTED SMALL ENTITIES

[In Whole Numbers]

Type	Number	Source
Hospitals (NAICS 622)	6,505	U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010.

TABLE 29—NUMBER OF IMPACTED SMALL ENTITIES—Continued

[In Whole Numbers]

Type	Number	Source
Ambulatory health care services (NAICS code 6211).	547,561	U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010.
Clearinghouses	0	Survey of EHNAC, HIMSS, the Cooperative Exchange, and the Maryland Commission for Healthcare) Assume, all clearinghouse are not small entities.
Health Plans (including Government Health Plans such as Medicare, VA and IHS).	0	Assume all health plans are *not* small entities.
Vendors (NAICS code 5415—Computer design and related services).	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asp*.
Health Plans—Medicaid	0	State Medicaid agencies were excluded from the analysis because States are not considered small entities in any Regulatory Flexibility Analysis.

2. Cost for Small Entities

To determine the impact on health care providers we used Business Census data on the number of establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each NAICS code. Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For other providers, we assumed that the costs to implement the operating rules for eligibility for a health plan and health care claim status transactions would be accounted for at the level of firms rather than at the individual establishments. Therefore, we reported the number of firms for all other providers.

In the following tables, we take the information from the impact analysis and break out the costs for both physicians and hospitals. As stated earlier in the impact analysis, we assume that vendor costs will be the same as those for providers because of our assumption that vendors will pass along their costs in the form of increased fees to their provider clients.

As we are treating all health care providers as small entities for the purpose of the regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for physicians and hospitals. Accordingly we treat all software vendors as small entities based on their relationship to providers and allocate the same costs. Table 30 shows the impact of the implementation costs of operating rules as a percent of the provider revenues. Data on the number of entities for these tables were gathered from the 2007 census (*http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=0&-ds_name=EC0762SSSZ1&-_lang=en*). We used the NAICS code 5415 computer system design and related services for software vendors.

TABLE 30—ANALYSIS OF THE BURDEN OF IMPLEMENTATION OF OPERATING RULES ON SMALL COVERED ENTITIES

NAICS No.	Entities	Total number of entities	Number of small entities	Revenues or receipts ($ in millions)	Small entity receipts of total receipts (percent)	Op rules costs annual ($ in millions)	Implementation cost revenue receipts (percent)
6211	Ambulatory health care services.	547,561	547,561	668,453	100	136–272	0.0002–0.004
622	Hospitals	6,505	6,505	702,960	100	291–583	0.0004–0.0008
5415	Computer system design and related services.	105,710	105,710	297,200	100	136–272	0.0005–0.0009

In Column I we display the NAICS code for class of entity. Column II shows the number of entities that are reported in the Business Census for 2002 and Column III shows the number of small entities that were computed based on the Business Census and Survey of Annual Service. As mentioned previously, we assume that all health care providers are small. Column IV shows revenues that were reported for 2008 in the Survey of Annual Services (*http://www.census.gov/services/sas_data.html*). Column V shows the percent of small entity revenues. Column VI shows the costs to providers for implementation of eligibility for a health plan and health care claim status operating rules. Column VII shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues.

Column VIII presents the percent of the small entity share of implementation costs as a percent of the small entity revenues. We have established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold.

We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities previously listed, which is below the threshold we consider as a significant economic impact. As expressed in the guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus, based on the foregoing analysis, we conclude that some small health care providers may encounter some burdens in the course of implementing the eligibility for a health plan and health care claim status operating rules. However, we are of the opinion that, for most small providers, the costs will not be significant, and for providers who are not HIPAA covered entities and do not conduct electronic health care transactions, there is no cost.

We did not include an analysis of the impact on small health plans here, because we were not able to determine the number of plans that meet the SBA size standard of $7 million in annual receipts.

In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS, and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the number of clearinghouses that would be considered small entities was negligible.

Revenues cited on the Cooperative Exchange Web site (*http://www.cooperativeexchange.org/faq.html*) divided clearinghouses into three revenue categories—small ($10 million); medium ($10 million to $50 million) and large ($50 million or greater). We identified the top 51 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare *etc.,* none of which fit into the category of small entity. As referenced earlier, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. We determined that even based on this data, few of the entities would fall into the small entity category, and we do not count them in this analysis.

Based on the results of this analysis, we are reasonably confident that the rule will not have a significant impact on a substantial number of small entities. Nevertheless, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the operating rules adopted in this interim final rule with comment period.

We solicit industry comment on our above assumptions.

3. Alternatives Considered

As stated in section VII.D. of this interim final rule with comment period, we considered various policy alternatives to adopting operating rules, including not adopting operating rules, adopting another authoring entity's operating rules, or waiting for resolution of all outstanding technical and administrative issues before adopting the operating rules developed by the authoring entities. For reasons cited in section VII.D. of this interim final rule with comment period we have determined that none of these options were viable. Please see section VII.D. of this interim final rule with comment period for a discussion of these options and why we determined they were not viable.

4. Conclusion

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, we could certify that this interim final rule with comment would not have a significant economic impact on a substantial number of small entities.

However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of small entities affected by this interim final rule with comment period. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Based on the analysis above, including that the overall costs to small hospitals is under the $136 million threshold, we do not believe this rule would have a significant impact on small rural hospitals, for the reasons stated above in reference to small entities. Therefore, the Secretary has determined that this interim final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

M. Accounting Statement

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2011 TO FY 2023

[in millions]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, *etc.*
BENEFITS				
Annualized Monetized benefits				
7% Discount	Not estimated	$1,124	$1,347	RIA.
3% Discount	Not estimated	1,153	1,376	RIA.
Qualitative (un-quantified) benefits.	Wider adoption of standards due to consistent use of standards and responses robust in data; increased productivity due to decrease in manual intervention requirements; avoidance of pended claims, claim denials, and other obstacles to expedited billing.			
Benefits generated from plans to providers, and providers to plans.				
COSTS				
Annualized Monetized costs				
7% Discount	Not estimated	$373	$745	RIA.
3% Discount	Not estimated	314	627	RIA.
Qualitative (un-quantified) costs	None	None	None	

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2011 TO FY 2023—Continued

[in millions]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, *etc.*
Providers will pay costs to vendors and clearinghouses. Health plans will pay costs to software vendors, programming and IT staff/contractors, and clearinghouses. Clearinghouses will pay costs to programming and IT staff/contractors and software developers. Government will pay costs to vendors and staff.				
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

45 CFR Part 160

Administrative practice and procedure, Computer technology, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

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 parts 160 and 162 to read as follows:

PART 160—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d–1320d–8, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), 5 U.S.C. 552; secs. 13400 and 13402, Pub. L. 111–5, 123 Stat. 258–263, and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

Subpart A—General Provisions

§ 160.101 [Amended]

■ 2. Amend § 160.101 by removing the phrase ''and section 13410(d) of Public Law 111–5.'' and adding in its place the phrase ''section 13410(d) of Public Law 111–5, and section 1104 of Public Law 111–148.''

■ 3. Amend § 160.103 by adding a paragraph (3) to the definition of ''standard'' to read as follows:

§ 160.103 Definitions.

* * * * *

Standard * * *

(3) With the exception of operating rules as defined at § 162.103.

* * * * *

PART 162—ADMINISTRATIVE REQUIREMENTS

■ 4. The authority citation for part 162 is revised 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

■ 5. Amend § 162.103 as follows:

■ A. Adding the definition of ''operating rules''.

■ B. Revising the definition of ''standard transaction''.

The revision and addition read as follows:

§ 162.103 Definitions.

* * * * *

Operating rules means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

* * * * *

Standard transaction means a transaction that complies with an applicable standard and associated operating rules adopted under this part.

Subpart I—General Provisions for Transactions

■ 6. Amend § 162.915 by revising paragraph (a) to read as follows:

§ 162.915 Trading partner agreements.

* * * * *

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

* * * * *

■ 7. Amend § 162.920 as follows:

■ A. Revising the section heading and introductory text.

■ C. Adding paragraph (c).

The revisions and addition read as follows:

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* The materials are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244.

For more information on the availability on the materials at CMS, call (410) 786–6597. The materials are also available from the sources listed below.

* * * * *

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861–1492; Fax (202) 861- 1454; E-mail *info@CAQH.org*; and Internet at *http://www.caqh.org/benefits.php*.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§ 162.1203 and 162.1403.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

Subpart L—Eligibility for a Health Plan

■ 8. Adding a new § 162.1203 to read as follows:

§ 162.1203 Operating rules for eligibility for a health plan transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction:

(1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in § 162.920).

(2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920).

(9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

Subpart N—Health Care Claim Status

■ 9. Add § 162.1403 to read as follows:

§ 162.1403 Operating rules for health care claim status transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase II operating rules (updated for Version 5010) for the health care claim status transaction:

(1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920).

(2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

Dated: May 26, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 29, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–16834 Filed 6–30–11; 2:00 pm]

BILLING CODE 4120–01–P