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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 162

[CMS-0024-IFC]

RIN 0938-AQ11

Administrative Simplification: Adoption of Standards for Health Care Electronic Funds Transfers (EFTs) and Remittance Advice

AGENCY: Office of the Secretary, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements parts of section 1104 of the Affordable Care Act which requires the adoption of a standard for electronic funds transfers (EFT). It defines EFT and explains how the adopted standards support and facilitate health care EFT transmissions.

DATES: Effective Date: These regulations are effective on [OFR—insert the date of publication in the **Federal Register**]. The incorporation by reference of the publications listed in this interim final rule with comment period is approved by the Director of the Office of the **Federal Register** [OFR—insert date of publication in the **Federal Register**].

Compliance Date: The compliance date for this regulation is January 1, 2014.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below on or before [OFR—insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS–0024-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-0024-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-0024-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

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, call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously 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:

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. Statutory and Regulatory Background

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 (EDI), the complete statutory background, and the regulatory history, see the August 22, 2008 (73 FR 49742) proposed rule entitled "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards".

1. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

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 (DHHS) (hereinafter referred to as the Secretary) to adopt standards for certain transactions to enable health information to be exchanged more efficiently and to achieve greater uniformity in the transmission of health information.

In the August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule entitled "Health Insurance Reform: Standards for Electronic Transactions" (hereinafter referred to as the Transactions and Code Sets final rule). That rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for electronic health care transactions developed by standard setting organizations (SSOs) and medical code sets to be used in those transactions. We adopted Accredited Standards Committee (ASC) X12 Version 4010 standards and the National Council for Prescription Drug Programs (NCPDP) Telecommunication Version 5.1 standard, which are specified at 45 CFR part 162, subparts K through R. Section 1172(a) of the Act states that "[a]ny standard adopted under [HIPAA] shall apply, in whole or in part, to . . . (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a [HIPAA transaction]." These entities are referred to as covered entities.

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 Telecommunication Standard Implementation Guide Version D.0 (hereinafter referred to as Version D.0) and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (hereinafter referred to as Version 1.2) for the electronic health care transactions originally adopted in the Transactions and Code Sets final rule. Covered entities are required to comply with Version 5010 and Version D.0 on January 1, 2012.

Table 1 summarizes the full set of transaction standards adopted in the Transactions and Code Sets final rule and as modified in the Modifications final rule. The table uses abbreviations of the standards and the names by which the transactions are commonly referred as a point of reference for the reader. The official nomenclature and titles of the standards and transactions related to the provisions of this interim final rule with comment period are provided later in the narrative of this preamble.

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 and Version 1.2	Health care claims – Retail pharmacy drugs (telecommunication and batch standards).
ASC X12 837 P, NCPDP D.0 and Version 1.2 (batch)	Health care claims – Retail pharmacy supplies and professional services.
NCPDP D.0 and Version 1.2 (batch)	Coordination of Benefits – Retail pharmacy drugs.
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 and Version 1.2 (batch)	Eligibility for a health plan (request and response) – Retail pharmacy drugs.
ASC X12 276/277	Health care claim status (request and response).

Standard	Transaction
ASC X12 834	Enrollment and disenrollment in a health plan.
ASC X12 835	Health care payment and remittance advice.
ASC X12 820	Health plan premium payment.
ASC X12 278	Referral certification and authorization (request and response).
NCPDP D.0 and Version 1.2 (batch)	Referral certification and authorization (request and response) – Retail pharmacy drugs.
NCPDP 3.0	Medicaid pharmacy subrogation (batch standard).

In the July 8, 2011 **Federal Register** (76 FR 40458), we published an interim final rule with comment period, "Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions" (hereinafter referred to as the Eligibility and Claim Status Operating Rules IFC). That rule adopted operating rules for two HIPAA transactions: (1) eligibility for a health plan; and (2) health care claim status. The Eligibility and Claim Status Operating Rules IFC also defined operating rules and described their relationship to standards.

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. 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 which remains an obstacle to achieving greater health care industry administrative simplification.

Section 1173(a) of the Act requires the Secretary to adopt standards for a number of financial and administrative transactions, as well as data elements for those transactions, to enable health information to be exchanged electronically. Section 1172(b) of the Act requires that a standard adopted under HIPAA "be consistent with the objective of reducing the administrative costs of providing and paying for health care."

Under section 1172(c)(2)(B) of the Act, if no standard setting organization (SSO) has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt, then the Secretary may adopt a standard relying upon recommendations of the National Committee on Vital and Health Statistics (NCVHS), in consultation with the organizations referred to in section 1172(c)(3)(B) of the Act, and appropriate Federal and State agencies and private organizations.

2. Electronic Funds Transfers (EFT) and the Affordable Care Act

Section 1104(b)(2)(A) of the Patient Protection and Affordable Care Act (Pub. L. 111-148) (hereinafter referred to as the Affordable Care Act) amended section 1173(a)(2) of the Act by adding the electronic funds transfers (hereinafter referred to as EFT) transaction to the list of electronic health care transactions for which the Secretary must adopt a standard under HIPAA. Section 1104(c)(2) of the Affordable Care Act requires the Secretary to promulgate a final rule to establish an EFT standard, and authorizes the Secretary to do so by an interim final rule. That section further requires the standard to be adopted by January 1, 2012, in a manner ensuring that it is effective by January 1, 2014.

Sections 1104(b)(2)(B) and 10109(a)(1)(B) of the Affordable Care Act also amended section 1173 of the Act by adding sections 1173(a)(4) and (5), respectively, to provide for new financial and administrative transactions requirements. Section 1173(a)(4) guides us in adopting standards in this interim final rule with comment period and associated operating rules (which we will adopt in future rulemaking) for the EFT transaction, particularly the following requirements: First, such standards and associated operating rules must "be comprehensive, requiring minimal augmentation by paper or other communications;" second, the standards and associated operating rules must "describe all data elements (including reason and remark codes)

in unambiguous terms [and] 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);" and third, the Secretary must "seek to reduce the number and complexity of forms (including paper and electronic) and data entry required by patients and providers."

B. Electronic Funds Transfers (EFT): General Background

While industry and consumers use the term EFT in a number of different ways, the definition of EFT in section 31001(x) of the Debt Collection Improvement Act of 1996 (Pub. L. 104-134) is particularly useful in this general background discussion because it includes a broad spectrum of transmission vehicles and terms that are relevant to our discussion of EFT in this interim final rule with comment period. The Debt Collection Improvement Act defines an EFT as "any transfer of funds, other than a transaction originated by cash, check, or similar paper instrument that is initiated through an electronic terminal, telephone, computer, or magnetic tape, for the purpose of ordering, instructing, or authorizing a financial institution to debit or credit an account. The term includes Automated Clearing House (ACH) transfers, Fedwire transfers, transfers made at automatic teller machines (ATMs), and point-of-sale terminals."

Because we are adopting standards in this interim final rule with comment period that apply only to transmissions of data over the ACH Network, we focus our discussion on EFT that are transmitted over the ACH Network.

1. The Automated Clearing House (ACH) Network

The ACH Network is the "pipeline" through which many EFT travel; it is a processing and delivery system for EFT that uses nationwide telecommunications networks. Consumers use

the ACH Network when, for example, they have paychecks directly deposited in their accounts, or pay bills electronically by having funds withdrawn automatically from their accounts.

In the majority of cases, when an EFT is used by a health plan to pay health care claims, it is transmitted through the ACH Network. However, payments and debits through the ACH Network represent only one category of EFT; some EFT, including some health care claim payments, can be made outside of the ACH Network. One example of an EFT made outside of the ACH Network is a transfer of funds made through the Federal Reserve Wire Network, hereinafter referred to as Fedwire. This is akin in the consumer universe to a wire transfer of funds made via Western Union, for example, except that the Fedwire is an electronic transfer system developed and maintained by the Federal Reserve System. Fedwire transfers on behalf of bank customers include funds used in the purchase or sale of government securities, deposits, and other large, time-sensitive payments.

The ACH initiative began in the early 1970s to explore payment alternatives to paper checks in response to the rapid growth in paper check volume. The establishment of the first ACH Network, Calwestern Automated Clearing House Association in California, led to the formation of similar groups around the country. Agreements were made between these ACH associations and regional Federal Reserve Banks to provide facilities, equipment, and staff to operate regional automatic clearing house networks. The National Automated Clearing House Association (NACHA) was founded in 1974 to centrally coordinate the local ACH associations and to administer, develop, and enforce operating rules and management practices for the ACH Network. In 1978, in a joint effort between NACHA and the Federal Reserve System, regional ACHs were linked electronically, with NACHA serving as the national ACH Network's administrator.

NACHA develops rules, published in NACHA Operating Rules & Guidelines - A Complete Guide to the Rules Governing the ACH Network (hereinafter referred to as the NACHA Operating Rules & Guidelines, available at <https://www.nacha.org>), that govern the ACH Network. The NACHA Operating Rules & Guidelines is an annual publication divided into two sections, the NACHA Operating Rules and the NACHA Operating Guidelines. The NACHA Operating Rules describes NACHA's legal framework for the ACH Network and provides NACHA's specifications for electronic transmissions conducted through the ACH Network. Electronic transmissions conducted through the ACH Network include money transfers, money withdrawals, and non-monetary transactions, and are sent in electronic formats called ACH Files, sometimes referred to as ACH formats, NACHA formats, ACH Entry Classes, or ACH payment applications. In the 2011 NACHA Operating Rules, there are implementation specifications for sixteen different types or "classes" of ACH Files that can be used for business and consumer transactions over the ACH Network.

The NACHA Operating Guidelines provides guidance on implementing the NACHA Operating Rules through narrative, diagrams, illustrations, and examples. The NACHA Operating Guidelines is organized by chapter according to the responsibilities of each of the participants in an ACH transaction and includes an overview of the different classes of ACH Files.

The Federal government is the single largest user of the ACH Network. The Debt Collection Improvement Act requires that all Federal payments made after January 1, 1999, other than payments required under the Internal Revenue Code of 1986, be made by EFT. Subsequent regulations implementing this act allowed for waivers and exceptions. In 31 CFR 210, the United States Department of the Treasury formally adopted the NACHA Operating Rules &

Guidelines for the Federal government's EFT payments made through the ACH Network, including Federal tax collections, tax refund payments, and Social Security and other benefit payments made by direct deposit.

2. The Payment Flow Through the ACH Network

To give context to how EFT are used in the health care industry, we consider here how businesses pay one another by transferring funds and sending related payment information through the ACH Network. We can simplify understanding of the ACH Network payment process by dividing the transaction flow of the EFT into three chronological stages, each of which includes a separate electronic transmission of information (see Illustration A and Table 2).

a. Stage 1 Payment Initiation

In the first stage, the business or entity that is making the payment orders, instructs or authorizes its financial institution to make an EFT payment through the ACH Network on its behalf. This electronic transmission from a business to its financial institution is sometimes referred to as "payment initiation," "payment instructions," "payment authorization," or "originating an entry."

To order, instruct or authorize a financial institution to make an EFT payment through the ACH Network, the business or entity that is making the payment, designated as an "Originator" in the NACHA Operating Rules & Guidelines, must provide its financial institution, called the "Originating Depository Financial Institution" or ODFI, with payment information similar to information that one would find on a paper check. This payment information includes the amount being paid, identification of the payer and payee, bank accounts of the payer and payee, routing information, and the date of the payment.

An Originator may send this payment information formatted in an ACH File in accordance with the NACHA Operating Rules & Guidelines. The Originator may also send the data in a non-ACH File, such as an ASC X12 820, an ASC X12 835, a proprietary file, or a flat file, and the ODFI will format the data into an ACH File as a service to the Originator (Table 2). Regardless of the format that an Originator uses to transmit payment information to the ODFI, we hereinafter refer to the transmission in this stage in the ACH payment flow as the Stage 1 Payment Initiation.

b. Stage 2: Transfer of Funds

In this stage, a number of separate interactions take place, but the end result is that funds from one account are moved to another account. First, the payment information that was sent from the Originator to the ODFI in the Stage 1 Payment Initiation travels from the ODFI to one or both of two ACH Operators: the Federal Reserve, run by the Federal government, or The Clearing House, a private company. These ACH Operators then conduct the actual funds transfer. They sort and batch ACH Network transactions and, on the payment date, debit the ODFI and credit the financial institution of the business that is being paid. The financial institution of the business that is being paid is called the "Receiving Depository Financial Institution" or RDFI. The final step in this stage is that the RDFI credits the account of the business or entity that is being paid, called the Receiver.

In Stage 2, the actual transfer of funds or "settlement," is governed by the NACHA Operating Rules & Guidelines, as well as Federal statutes and regulations. In contrast to the Stage 1 Payment Initiation which allows for a variety of non-ACH File options, the ODFI must transmit the payment and payment information through the ACH Network using an ACH File.

We hereinafter refer to the transmission in this stage of the EFT transaction as the Stage 2 Transfer of Funds.

c. Stage 3: Deposit Notification

In this final stage, the RDFI transmits information to the Receiver that indicates that the payment has been deposited in the Receiver's account. The RDFI can do this proactively by notifying the Receiver at the time the funds are deposited, or the RDFI can simply post the payment to the Receiver's account and it will appear on the Receiver's account summary. The NACHA Operating Rules & Guidelines does not require an RDFI to notify a Receiver that the RDFI has received the ACH File at the time of receipt, unless the RDFI has an agreement with the Receiver that contains a request to do so either automatically when a Receiver receives any deposit via EFT, or episodically if the Receiver specifically requests such notification on a case-by-case basis for any given EFT deposit.

The notification data can be transmitted to the Receiver in any format the RDFI and Receiver agree upon (Table 2). We hereinafter refer to the transmission in this stage of the EFT transaction as the Stage 3 Deposit Notification.

3. Addenda Records

Two types of ACH Files can be used for domestic business-to-business payments in the Stage 2 Transfer of Funds: The Corporate Credit or Debit Entry (CCD), sometimes referred to as the Cash Concentration/Disbursement format, and the Corporate Trade Exchange Entry (CTX) (Table 2, Column 2). The difference between the two is that the CCD is capable of including an "Addenda Record" that holds up to 80 characters of remittance or additional payment information supplied by an Originator, while the CTX has multiple Addenda Records

that together can hold nearly 800,000 characters of remittance or additional payment information supplied by an Originator.

An Originator has the option of conveying remittance or additional payment information in the Addenda Records of the CCD or the CTX so that payment and remittance or additional payment information can move together electronically through the ACH Network. This remittance or additional payment information can be any data that the Originator thinks the Receiver may need to know, such as a tracking or invoice number, as long as the data relates to the associated EFT payment and the data stays within formatting limitations described in the NACHA Operating Rules & Guidelines.

In the Stage 1 Payment Initiation, the remittance or additional payment information can be transmitted to the ODFI by the Originator in the same file and in the same formats that can be used to transmit the payment information; that is, in a flat file, an X12 file (using an ASC X12 835 or 820 standard), a proprietary file (most often proprietary to the financial institution), or an ACH File (CCD or CTX), for which implementation and standards are developed and maintained by NACHA (see Table 2). Because it is "enveloped" in an ACH File, ideally the remittance or additional payment information in the Addenda Record is transmitted from the Originator to the ODFI in the Stage 1 Payment Initiation, through the ACH Network to the RDFI in the Stage 2 Transfer of Funds, then finally to the Receiver in the Stage 3 Deposit Notification.

Before the ODFI enters the ACH File into the ACH Network to initiate the Stage 2 Transfer of Funds, NACHA Operating Rules & Guidelines requires that the data in the Addenda Record of an ACH File be formatted according to any ASC X12 transaction set (the data envelope that consists of a header, detail and summary areas) or ASC X12 data segment (a grouping of data elements which may be mandatory, optional or relational), or in a

NACHA-endorsed banking convention. The Originator may format the Addenda Record according to ASC X12 requirements and transmit it as part of the Stage 1 Payment Initiation, or the Originator may send the ODFI unformatted data in the Stage 1 Payment Initiation and the ODFI will format the data into an ASC X12 format as a service to the Originator. The ODFI then transmits the data in either the CCD or the CTX through the ACH Network to the RDFI as a Stage 2 Funds Transfer.

When a CCD includes an Addenda Record, it is referred to as a "CCD plus Addenda Record" or "CCD+." Hereinafter, we refer to the CCD with Addenda Record as the CCD+Addenda. We refer to the CTX with Addenda Records simply as the CTX.

For the Stage 3 Deposit Notification, the NACHA Operating Rules & Guidelines requires that, upon request of the Receiver, an RDFI provide the Receiver all payment-related information contained within the Addenda Records transmitted with a CCD or CTX. If so requested, the data contained in the Addenda Record(s) are provided by the RDFI to the Receiver in a format agreed to by the Receiver and the RDFI (See Table 2).

ILLUSTRATION A: STAGES IN A BUSINESS-TO-BUSINESS PAYMENT MADE THROUGH THE ACH NETWORK

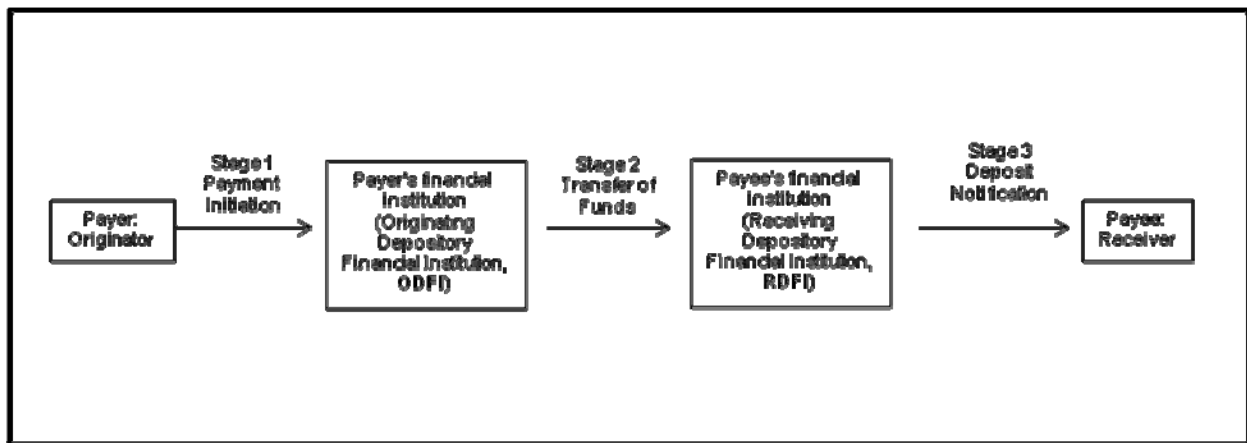


TABLE 2. EFT FORMATS FOR BUSINESS-TO-BUSINESS PAYMENTS THROUGH THE ACH NETWORK

Transmission Stage	Electronic Format Used in Transmission
<p><u>Stage 1 Payment Initiation</u> Payment Information transmission from Originator to ODFI</p>	<ul style="list-style-type: none"> • Non-ACH file such as a proprietary file, a flat file, an ASC X12 835 or 820 format, or • ACH File (CCD or CTX). <p>Remittance or additional payment information for <i>Addenda Record(s)</i> can be transmitted in any of the formats listed in the two bullets above.</p>
<p><u>Stage 2 Transfer of Funds</u> Payment Information transmission from ODFI to RDFI</p>	<ul style="list-style-type: none"> • Standard required by NACHA: ACH File (CCD or CTX). <p><i>Addenda Record(s)</i> must be in ANSI ASC X12 transaction set or data segment format or NACHA-endorsed banking convention.</p>
<p><u>Stage 3 Deposit Notification</u> Payment Information transmission from RDFI to Receiver</p>	<ul style="list-style-type: none"> • Format to be agreed upon by Receiver and RDFI (but RDFI is not obligated to proactively provide payment information unless requested by the Receiver).

4. Advantages and Disadvantages of EFT

According to the 2010 AFP Electronic Payments: Report of Survey Results, produced by the Association for Financial Professionals (AFP) and underwritten by J.P. Morgan,¹ businesses that use EFT cite three main benefits:

- Cost savings: Savings derive from cost avoidance of printing checks, purchasing and stuffing envelopes, and manually depositing checks;

¹ http://www.afponline.org/pub/res/topics/topics_pay.htm

- Fraud control: The above-cited AFP survey found that 90 percent of organizations that experienced payment fraud in 2008 were victims of paper check fraud, while only 7 percent of organizations that experienced payment fraud were victims of EFT fraud; and
- Improved cash flow and cash forecasting: Forty percent of the AFP's 500 survey respondents reported improved cash forecasting as a result of EFT payments.

In terms of disadvantages, some businesses find it expensive or inefficient to overlay the ACH Network payment process onto existing technology, business systems, and processes originally designed to process paper checks. For instance, for many businesses, the payment system and process is separate from the accounts payable/receivable system and electronic data interchange (EDI) systems, and the business cannot send or receive automated remittance information together with electronic payments without significant investment and organizational change.²

C. Payment of Health Care Claims via EFT

To understand the context in which an EFT is used to pay for health care claims, it is necessary to look at the closely-related transmission of health care remittance advice.

A health plan rarely pays a provider the exact amount a provider bills the health plan for health care claims. A health plan adjusts the claim charges based on contract agreements, secondary payers, benefit coverage, expected co-pays and co-insurance, and so on. These adjustments are described in the remittance advice. The health care remittance advice is somewhat analogous to an employee's salary paystub which describes the amount the employee is being paid, the hours worked, and an explanation of any adjustments or deductions that are being made to an employee's salary payment.

² 2010 AFP Electronic Payments: Report of Survey Results

The remittance advice has traditionally been in paper form, sent by mail to the provider. However, the use of electronic remittance advice (ERA) is growing.

The Transactions and Code Sets final rule adopted a definition for the health care payment and remittance advice transaction. The definition, found in 45 CFR 162.1601, includes descriptions for both health care payment and ERA.

The transmission described in §162.1601(a), hereinafter referred to as the transmission of "health care payment/processing information," is primarily a financial transmission. The transmission described in §162.1601(b) is the ERA--an explanation of the health care payment or an explanation of why there is no payment for the claim. The ERA includes detailed identifiable health information.

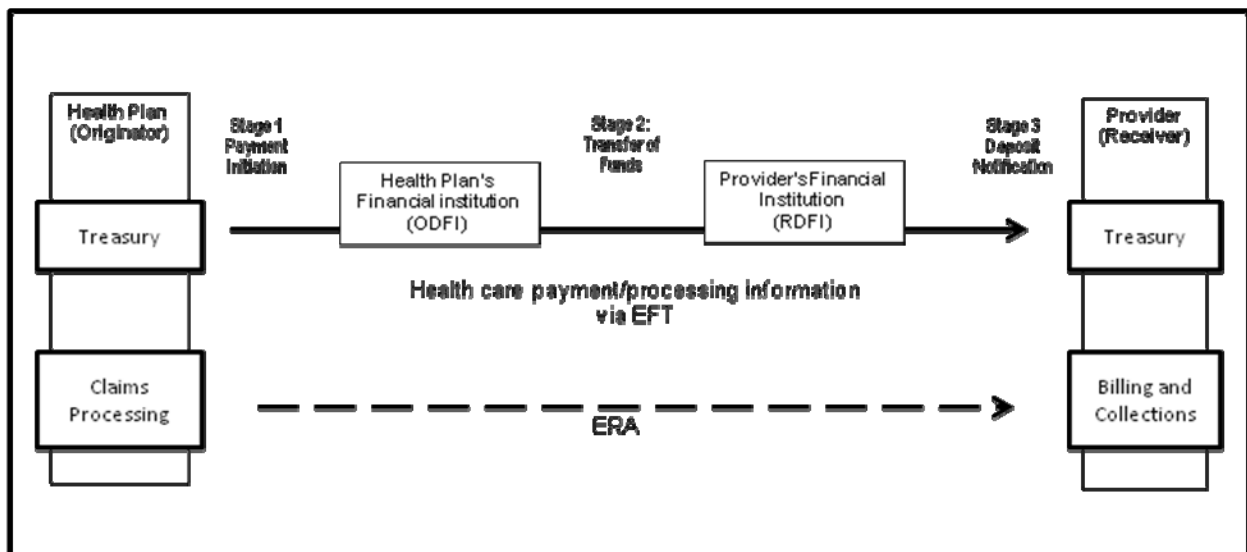
With few exceptions, the ERA and the health care payment/processing information are sent in different electronic formats through different networks, contain different data that have different business uses, and are often received by the health care provider at different times.

The health care payment/processing information is transmitted via EFT from the health plan's treasury system. It is then processed by financial institutions, and ultimately entered into the health care provider's treasury system. Currently, the health care payment/processing information is generally transmitted in a CCD through the ACH Network, though there are instances when other forms of EFT such as Fedwire are used. The path of the health care payment/processing information through the ACH Network from health plan to provider is represented in Illustration B by the solid arrow.

In contrast, the ERA is traditionally sent from the health plan's claims processing system and processed through the provider's billing and collection system. The path of the ERA from health plan to provider is represented in Illustration B by the dashed arrow.

When both the health care payment/processing information and the ERA to which it corresponds arrive at the health care provider (often at different times), the two transmissions must be reassociated or matched back together by the provider; that is, the provider must associate the ERA with the payment that it describes. This process is referred to as "reassociation." Ideally, reassociation of the ERA with the health care payment/processing information is automated through the provider's practice management system. In practice, time-consuming manual reassociation by administrative staff is often required.

ILLUSTRATION B: PATH OF ERA AND EFT IN HEALTHCARE CONTEXT



It is technically possible for the health care payment/processing information and ERA to be combined and sent via EFT through the ACH Network using the CTX. Given the amount of data the CTX can hold in its Addenda Records, all of the ERA can be "enveloped" in a single ACH File and transmitted through the ACH Network. This allows both the health care payment/processing information and ERA to be transmitted as a "package" through the same

network and to be received in the same "package" by the health care provider. Theoretically, the provider can avoid the step of reassociating the ERA with the health care payment/processing information because the ERA and health care payment/processing information are transmitted together via EFT.

However, to our knowledge, the CTX is infrequently, if ever, used by health plans for the transmission of both ERA and health care payment/processing information to pay for health care claims. It appears that there are at least two reasons why the CTX is not used: First, most health plans and health care providers are probably not technically capable of processing the CTX at this time. As noted in this section, the transmission of health care payment/processing information and the ERA are historically sent by health plans and received by health care providers from two different systems through two different processes (Illustration B). It would entail a change in systems and workflow to integrate the two systems and processes, both for the health plans that send these two transmissions and for the health care providers that receive them.

Second, ERA contains protected health information (PHI), as defined at 45 CFR 160.103, and some in the financial industry are reluctant to be subject to HIPAA's privacy and security requirements with respect to such information. On the other side, providers and payers are reluctant to send PHI through the ACH network without assurances that the PHI is adequately protected under HIPAA.

The Transactions and Code Sets final rule adopted the ASC X12 835 TR3 (hereinafter referred to as the X12 835 TR3) as the standard for the health care payment and remittance advice transaction. As noted, the health care payment and remittance advice transaction includes two transmissions, the transmission of health care payment/processing information, and ERA. The X12 835 TR3 includes comprehensive implementation specifications for the ERA, but has

less comprehensive "data use" instructions for transmitting health care payment/processing information. For example:

- According to the X12 835 TR3, health care payment/processing information may be sent through the mail by paper check or via EFT. If transmitted via EFT, the health care payment/processing information can be transmitted by wire or through the ACH Network.

- The X12 835 TR3 does not require a single standard format for Stage 1 Payment Initiation. According to the X12 835 TR3, proprietary, ACH, or ASC X12 data formats can be used in the Stage 1 Payment Initiation (X12 835 TR3, Table 1.1, <http://www.x12.org>).

D. The National Committee on Vital and Health Statistics (NCVHS): December 2010 Hearings on EFT

The NCVHS was established by Congress to serve as an advisory body to the Secretary on health data, statistics, and national health information policy, and has been assigned a significant role in the Secretary's adoption of standards, code sets, and operating rules under HIPAA.

On December 3, 2010, the NCVHS Subcommittee on Standards held a hearing entitled "Administrative Simplification under the Patient Protection and Affordable Care Act Standards and Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA)" (for agenda and testimony, see <http://www.ncvhs.hhs.gov>). The NCVHS engaged in a comprehensive review of potential standards and operating rules for the EFT transaction, as well as a review of standard setting organizations and operating rule authoring entities, for purposes of making a recommendation to the Secretary as to whether such standards and operating rules should be adopted. The NCVHS hearing consisted of a full day of public testimony with participation by stakeholders representing a cross section of the health care industry, including

health plans, health care provider organizations, health care clearinghouses, retail pharmacy industry representatives, standards developers, professional associations, representatives of Federal and State health plans, the Workgroup for Electronic Data Interchange (WEDI), the banking industry, and potential standard setting organizations (also known as standards development organizations or SDOs) for EFT standards and authoring entities for operating rules. These entities included the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE); the Accredited Standards Committee (ASC) X12; the National Automated Clearing House Association (NACHA); and the National Council for Prescription Drug Programs (NCPDP).

The testimony, both written and verbal, described many aspects and issues of the health care payment and remittance advice transaction. Testifiers described the advantages to using EFT to pay health care claims, similar to the advantages that are outlined in section I.B.4. of this interim final rule with comment period. Chief among these advantages was the savings in time and money for health plans and health care providers that EFT affords. Testifiers presented a number of case studies to illustrate these benefits. Testifiers also presented a number of obstacles to greater EFT use in health care. We refer the reader to the testimonies posted to the NCVHS website at <http://www.ncvhs.hhs.gov> for a more comprehensive discussion of the issues.

We summarize here a number of major obstacles for health care providers to adopt EFT, as identified by NCVHS testifiers and subsequent research, including: the administratively difficult enrollment process to accept EFT for health care claim payments; the time lag between receipt of the health care payment/processing information and the arrival of the ERA to the provider; and the problems regarding reassociation of the ERA with the EFT.

1. Enrollment

Health care providers must undertake a labor- and paper-intensive enrollment process in order to receive health care claim payments via EFT through the ACH Network from each of the health plans whom they bill. Each health plan has a different enrollment process. The health care provider must access the enrollment form and the form's instructions, which is sometimes difficult to find on a health plan's web site. Each health plan requires a different form to be filled out that is unique to that health plan. In the majority of cases, these forms are 3 to 18 pages that must be filled out manually, and each health plan requires different information (in some cases, a voided check or bank note) and signature requirements on the form. The health care provider must also discuss the options in accepting EFT and the arrangement for deposit notification with its financial institution. The health plans' enrollment forms must be resubmitted when a health care provider changes bank accounts or financial institutions, as is reportedly done regularly, or when there is a change in a provider's staff such that an authorizing signature on the EFT enrollment form must be changed. Finally, the avenues of submission of the enrollment forms differ from health plan to health plan: Some health plans may require a telephone call to an account representative in order to complete enrollment, while others may require the forms to be emailed, faxed, or mailed.

If a health care provider submits claims to twenty or more health plans, then the enrollment and maintenance of the enrollment data for EFT payments with the health plans reportedly becomes onerous for the provider. If a health care provider decides to pursue EFT at all, it is likely the provider will enroll only with those health plans that process significant numbers of the provider's claims to make the EFT worth the provider's time and effort to enroll.

2. Synchronization of EFT with ERA

According to testimony, another barrier for health care providers to the use of EFT for health care claim payments is that the ERA arrives at a different time than the associated health care payment/processing information that is transmitted via EFT. This is because, as described in section I.C. of this interim final rule with comment period, with few exceptions, the ERA is transmitted separately from the health care payment/processing information, and the two transmissions often arrive on different days or even different weeks. Consequently, if the ERA arrives first, it will describe a deposit that will be made in a health care provider's account sometime in the future, so the provider cannot process the ERA until the health care payment/processing information is transmitted. Or, if the transmission of payment/processing information arrives first, multiple deposits may be made into the health care provider's account without the provider having the corresponding ERA that describes the claims for which the payments are being made. Both of these circumstances create a situation where the accounts receivable process for the provider requires costly manual intervention and oversight.

3. Reassociation and the Transmission of the Trace Number Segment (TRN)

Another barrier for health care providers to the use of EFT for health care claim payments is the difficulty in matching the health care payment/processing information with its associated ERA so that providers can post payments properly in their accounting systems. Because the two transmissions usually travel separately, the ERA must ultimately be reassociated with the health care payment/processing information transmitted via EFT when the two separate transmissions are received by the health care provider.

The trace number segment, hereinafter referred to as the TRN Segment, is a type of tracking code for ERA and the health care payment/processing information transmitted via EFT. The TRN Segment's implementation specifications are included in the X12 835 TR3. Ideally,

the TRN Segment within a specific ERA is duplicated in the health care payment/processing information transmitted via EFT. Specifically, the TRN Segment should be duplicated in the Addenda Record of the CCD+Addenda. After the health care payment/processing information is transmitted with the TRN Segment to a health care provider, the provider's practice management system can use the TRN Segment to automatically reassociate the health care payment/processing information with its corresponding ERA and post the payment in the provider's accounts receivable system.

At the December 2010 NCVHS hearing, industry testifiers noted that a duplicate of the TRN Segment in the ERA is not always conveyed to the health care provider within the Addenda Record of the CCD+Addenda as a part of normal business operations. Therefore, automatic reassociation becomes difficult if not impossible for the health care provider receiving the transaction. Testifiers gave a number of reasons why the TRN Segment is not conveyed to the health care provider, as follows:

- In the Stage 1 Payment Initiation, a health plan may not include an Addenda Record with the CCD or may not authorize its financial institution to include an Addenda Record with the CCD.
- A health plan may include an Addenda Record with the CCD, or instruct its financial institution to include an Addenda Record with the CCD, but may not transmit the proper data elements, may fail to place the data elements in the order specified in the X12 835 TR3, or may include its own proprietary trace number that is different from the TRN Segment included in the associated ERA.

- A health plan may leave out a particular data element, such as the Originating Company Identifier (TRN03), which is part of the TRN Segment specified in the X12 835 TR3, or use a different data element than that used in the associated ERA.

- A health plan may include a TRN Segment in its Stage 1 Payment Initiation but the format that the health plan uses to transmit this data does not make it clear to the financial institution where the TRN Segment must be placed in the CCD+Addenda. The financial institution then puts the TRN Segment in the wrong field or removes it altogether.

- Per NACHA Operating Rules & Guidelines, financial institutions must put their own ACH "trace number," which is different from the TRN Segment, in a CCD in a field outside of the Addenda Record, and there may be confusion among the parties between the financial institution's trace number and the TRN Segment in the Addenda Record that needs to match its associated ERA.

- The TRN Segment is included in the Addenda Record of the CCD+Addenda that a health plan's financial institution transmits through the ACH Network to a health care provider's financial institution, but the provider's financial institution may not communicate the TRN Segment to the provider through the Stage 3 Deposit Notification. This is because, according to the NACHA Operating Rules & Guidelines, the Receiver must proactively request that the information in the Addenda Record be transmitted (NACHA Guidelines, Section III, Chapter 24). Also, a financial institution may translate the data (the TRN Segment) contained in the Addenda Record of the CCD+Addenda into its own proprietary format to transmit to the health care provider. When it is reformatted, the TRN Segment may be altered such that it is no longer matches the TRN Segment in the ERA or cannot be automatically reassociated by the provider's practice management system.

In summary, the obstacles to having a TRN Segment in the CCD+Addenda delivered to the health care provider may be categorized as to their occurrence in two stages of the EFT transmission. First, in the Stage 1 Payment Initiation transmission between the health plan and the health plan's financial institution, the TRN Segment may be entered in the wrong field, contain sequence errors, or be left out or removed. Second, the TRN Segment may travel successfully through the ACH Network in the Addenda Record of the CCD+Addenda but, in the Stage 3 Deposit Notification, the health care provider may not receive the TRN Segment from the financial institution in a format that allows for automated reassociation by the health care provider's practice management system.

E. The NCVHS Recommendation to the Secretary

On February 17, 2011, following the December 2010 NCVHS Subcommittee on Standards hearing, the NCVHS sent a letter to the Secretary with its recommendations for, among other things, adoption of a "health care EFT" standard (<http://www.ncvhs.hhs.gov>). From that letter, we reference the specific recommendations of the NCVHS for the identification and adoption of a standard to be used for payment of health care claims via EFT:

- 1.1 Define health care EFT transaction as the electronic message used by health plans to order, instruct or authorize a depository financial institution (DFI) to electronically transfer funds through the ACH network from one account to another.
- 1.2 Define health care EFT standard as the format and content required for health plans to perform an EFT transaction.
- 1.3 Adopt as the standard format for the health care EFT standard the NACHA CCD+ format, in conformance with the NACHA Operating Rules.
- 1.4 Identify NACHA as the standards development organization for maintenance of the health care EFT standard.
- 1.5 Adopt as the implementation specification for the content for the addenda in the CCD+ the content requirements specified in the X12 835 TR3 REPORT (ASC X12/005010X221) particular to the CCD+.
- 1.6 Consider the implications of the fact that, as the result of the adoption of the healthcare EFT standard, some banks may become de facto healthcare clearinghouses as defined by HIPAA.

We agree with the spirit and intent of the NCVHS' recommendations to the Secretary as relayed in the February 17, 2011 letter. In this interim final rule with comment period, we are adopting standards that reflect the NCVHS' recommendations, with some minor departures. In section II. of this interim final rule with comment period, we explain the reasons for the differences between the standards we are adopting and the NCVHS' recommendations for a standard for payment of health care claims via EFT.

II. Provisions of the Interim Final Rule with Comment Period

A. The Health Care Electronic Funds Transfers (EFT) and Remittance Advice Transaction

As previously described in section I.C. of this interim final rule with comment period, the health care payment and remittance advice transaction is defined at 45 CFR 162.1601 as either or both of two different types of information transmissions. We refer to the first transmission type, in §162.1601(a), as the health care payment/processing information, and the second type of transmission, in §162.1601(b), as the ERA.

As we have discussed, an EFT is an electronic transmission of payment/processing information. For example, in the CCD+Addenda file format, the EFT includes information about the transfer of funds such as the amount being paid, the name and identification of the payer and payee, bank accounts of the payer and payee, routing numbers, and the date of the payment. Using health care claims payments as an example, the CCD+Addenda may also include payment processing information such as a duplicate of the TRN Segment that is in the associated ERA. So, the EFT transaction is described already by part of the definition of a health care payment and remittance advice transaction at §162.1601(a) — it is the transmission of health care payment, information about the transfer of funds, and payment processing information.

We considered creating a new subpart in 45 CFR that would define the EFT transaction separately from the transmission of ERA. However, we believe that dividing the health care payment and remittance advice transaction into two separate transactions, one that defines and adopts standards for the use of EFT to transmit payment/processing information for health care claims, and another that defines and adopts standards for ERA, could create the perception that the two are potentially unrelated transactions. Thus, we believe it is important that the transmission of health care payment/processing information, as described in §162.1601(a) and the transmission of health care remittance advice as described in §162.1601(b) be addressed as a set. In accordance with our decision to link the payment of health care claims via EFT and the ERA transactions by defining them and identifying the standards for them in the same regulatory provisions, we are changing the title of the health care payment and remittance advice transaction to the "health care electronic funds transfers (EFT) and remittance advice" transaction in §162.1601 and §162.1602. For the remainder of this interim final rule with comment period, we refer to the transmission of health care payment/processing information as described in §162.1601(a) as the "health care EFT."

Next, the transaction at §162.1601(a) is defined as a transmission "from a health plan to a health care provider's financial institution." This interim final rule with comment period amends §162.1601(a) to revise the recipient of the transmission of a health care EFT to be "a health care provider" instead of "a health care provider's financial institution." We are making this change in the definition for the purpose of clarifying that the ultimate recipient of the health care EFT is not the financial institution, but the provider who requires the health care claim payment/processing information and in whose account the funds are deposited.

While the definition of the transaction at §162.1601(a) is amended to reflect all stages of the transmission of a health care EFT from health plan to health care provider, we are not adopting standards in this interim final rule with comment period for every stage of the health care EFT transmission.

B. Definition of Stage 1 Payment Initiation

We are adding the definition of Stage 1 Payment Initiation to §162.103. The Stage 1 Payment Initiation "means a health plan's order, instruction, or authorization to its financial institution to make a health care claims payment using an electronic funds transfer (EFT) through the ACH Network." We have described the Stage 1 Payment Initiation broadly in section I.B.2. of this preamble, and define it specific to health care claim payments in regulation text. The definition clarifies that the health plan is the sender of the Stage 1 Payment Initiation, and the health plan's financial institution is the recipient of the Stage 1 Payment Initiation.

As we discuss later in this interim final rule with comment period, the standards we are adopting in this interim final rule with comment period are only for Stage 1 Payment Initiation of the health care EFT. We are not adopting standards for Stages 2 and 3 of the health care EFT.

C. Adoption of Standard for Stage 1 Payment Initiation: The NACHA Corporate Credit or Deposit Entry with Addenda Record (CCD+Addenda)

We are adopting the NACHA Corporate Credit or Deposit Entry with Addenda Record (CCD+Addenda) implementation specifications, as contained in the 2011 NACHA Operating Rules & Guidelines, as the standard for Stage 1 Payment Initiation. We are adopting only the specific chapter and appendices of the NACHA Operating Rules that include implementation specifications for the CCD+Addenda, and we are adopting this standard only for the Stage 1 Payment Initiation of the health care EFT (Table 3).

D. Adoption of Standard for the Data Content of the Addenda Record of the CCD+Addenda:

The ASC X12 835 TRN Segment

In its February 17, 2011 letter, the NCVHS recommended that the Secretary "adopt as the implementation specification for the content for the addenda in the CCD+, the content requirements specified in the X12 835 TR3 REPORT (ASCX12/005010X221) particular to the CCD+." In §162.1602, we are adopting the X12 835 TR3 TRN Segment as the standard for the data content of the Addenda Record of the CCD.

The CCD Addenda Record can hold up to 80 characters. The NACHA Operating Rules & Guidelines requires that the data in the Addenda Record be formatted according to any ASC X12 transaction set or data segment, or in a NACHA endorsed banking convention. In order to standardize the data content of the CCD+, in §162.1602, we are requiring health plans to input the X12 835 TRN Segment into the Addenda Record of the CCD+Addenda; specifically, the X12 835 TRN Segment must be placed in Field 3 of the Addenda Entry Record ("7 Record") of a CCD. The TRN Segment implementation specifications are described in the X12 835 TR3: "Section 2.4: Segment Detail, TRN Reassociation Trace Number." The TRN Segment includes, consecutively, the Trace Type Code (TRN01), the Reference Identification (TRN02), the Originating Company Identifier (TRN03), and, if situationally required, the Reference Identification (TRN04).

In order to most efficiently and effectively achieve reassociation, the TRN Segment in the Addenda Record of the CCD+Addenda should be the same as the TRN Segment that is included in the associated ERA that describes the payment. However, this is not a requirement under this interim final rule with comment period. We believe that the details of any such requirement are best addressed through operating rules for the health care EFT and remittance advice transaction.

In summary, we are adopting two standards for the health care EFT: the CCD+Addenda implementation specifications in the 2011 NACHA Operating Rules & Guidance for the Stage 1 Payment Initiation, and the TRN Segment implementation specifications in the X12 835 TR3 for the data content of the Addenda Record of the CCD+Addenda. Hereinafter, when we refer to the "health care EFT standards," we are referring to these two standards. The two standards of the health care EFT, together with the current standard for the ERA, the X12 835 TR3, are the three standards for the health care electronic funds transfers (EFT) and remittance advice transaction.

Table 3 summarizes these standards and the transmissions to which they apply.

TABLE 3. THE HEALTH CARE ELECTRONIC FUNDS TRANSFERS (EFT) AND REMITTANCE ADVICE TRANSACTION FROM HEALTH PLAN TO HEALTH CARE PROVIDER

Transmission	Data in the Transmission	Participants and Direction of Transmission	Electronic Format and Implementation Specifications
Stage 1 Payment Initiation (A health plan's order, instruction or authorization to its financial institution to make a health care claims payment using electronic funds transfer through the ACH Network.)	Information about the transfer of funds and payment processing information	From the health plan (Originator) to the health plan's financial institution (ODFI)	<ul style="list-style-type: none"> • CCD+Addenda as contained in <u>2011 NACHA Operating Rules & Guidelines</u> * • For the Addenda Record ("7"), field 3: X12 835 TR3 TRN Segment implementation specification*
Stage 2 Transfer of Funds	Payment, information about the transfer of funds, and payment processing information	From the health plan's financial institution (ODFI) to the provider's financial institution (RDFI)	Standard required by NACHA (non-HIPAA): ACH File (CCD)

Transmission	Data in the Transmission	Participants and Direction of Transmission	Electronic Format and Implementation Specifications
Stage 3 Deposit Notification	Information about the transfer of funds and payment processing information	From the provider's financial institution (RDFI) to the provider (Receiver)	Format to be agreed upon by the provider and its financial institution
Remittance Advice	Explanation of benefits and/or remittance advice	From the health plan to the provider	X12 835 TR3

* Beginning January 1, 2014.

The goal of the adoption of these standards is to ensure that the TRN Segment is inputted into the CCD+Addenda and is received without error by the health care provider. We believe this can be best achieved by requiring that a single electronic file format, the CCD+Addenda, be used by all health plans that transmit health care EFT to their financial institutions and by requiring that consistent data elements be ordered according to clear implementation specifications found in the X12 835 TR3 and the 2011 NACHA Operating Rules & Guidelines. By using the same standard in the Stage 1 Payment Initiation as is used by financial institutions in the Stage 2 Transfer of Funds (CCD+Addenda), there will be one less step in formatting/translating of the data in the overall transmission and, therefore, a decrease in the risk that an error will be made in that translation. Consistent format and data elements in the file format used by health plans for Stage 1 Payment Initiation of an EFT will make it more likely that the TRN Segment is received by the health care provider and that it will match the TRN Segment sent with the associated ERA.

Section 1173(g)(4)(B)(ii)(I) of the Act requires that the set of operating rules for EFT and health care payment and remittance advice transactions "allow for automated reconciliation of the electronic payment with the remittance advice." We believe the adoption of these standards,

eventually in coordination with complementary operating rules, will allow for automated reassociation of health care EFT with ERA, which will ultimately create considerable time savings for health care providers' accounts receivable processes. We believe that the time savings that will be realized from the use of these standards will increase provider migration from paper checks to EFT for health care claim payments. As well, the savings to health plans in transmitting EFT in place of the time and material cost of sending paper checks will be realized as more health care providers migrate to EFT.

To implement the health care EFT standards, a health plan must comply with two different standards developed and maintained by two different organizations, ASC X12 and NACHA. One of the differences is that the nomenclature used by the two organizations is different as to how their respective electronic formats and data content are organized and labeled (files, records, loops, segments, fields, etc.) In order to achieve successful reassociation of a health care EFT with the associated ERA, the data elements common to both transmissions must be correctly harmonized between the CCD+Addenda and the X12 835 TR3. We anticipate that operating rules for the health care electronic funds transfers (EFT) and remittance advice transaction will create further business rules and guidelines that promote consistent application of these data elements across both standards and will better enable reassociation.

E. X12 835 TR3 Remains the Standard for All Transmissions of ERA

In our new text in §162.1602, we are clarifying that the X12 835 TR3, which is the standard originally adopted for ERA in the Transactions and Codes Sets final rule, remains the standard for ERA transmissions (as defined in §162.1601(b)), including when an ERA accompanies, is transmitted with, or is contained (enveloped) within a health care EFT. For example, the X12 835 TR3 must be used for ERA that travels through the ACH Network, the

Federal Reserve Wire Network, a payment card network, or any system through which an EFT may travel. The new text in §162.1602(d)(2) clarifies this by stating that the X12 835 TR3 must be used "[f]or transmissions described in §162.1601(a), including when transmissions as described in §162.1601(a) and (b) are contained within the same transmission."

F. Other Factors in the Reassociation of the EFT with the ERA

A number of implementation specifications in the X12 835 TR3 and in the 2011 NACHA Operating Rules & Guidelines are pertinent to successful reassociation and are worth re-emphasizing here:

- According to the X12 835 TR3, the total amount of payment transmitted in the health care EFT must equal the total amount of payment indicated on an associated ERA. If a health plan does not comply with this implementation specification, then reassociation will be difficult.
- The 2011 NACHA Operating Rules & Guidelines requires that all financial institutions that participate in the ACH Network must accept CCD+Addenda. Nearly all financial institutions participate in the ACH Network, so nearly all financial institutions accept the CCD+Addenda.
- The 2011 NACHA Operating Rules & Guidelines requires that a Receiver (a health care provider) must request a deposit notification from its RDFI in order to receive payment information. In the context of health care EFT made through the ACH Network, health care providers should work with their banks or financial institutions to ensure that the data in the Addenda Record of the CCD+Addenda (the TRN Segment) is transmitted to them in a format that allows for automated reassociation of the health care EFT with the associated ERA.

G. Additional Considerations

1. The NACHA Standard

We are adopting the CCD+Addenda implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines as one of the standards for the health care EFT Stage 1 Payment Initiation. The implementation specifications for the CCD+Addenda in the NACHA Operating Rules & Guidelines are not the "operating rules" for the health care EFT as that term is used under HIPAA. Rather, as per this interim final rule with comment period, the implementation specifications in the NACHA Operating Rules & Guidelines are one of the *standards* for the health care EFT. The inclusion of "Operating Rules" in the title of the document that includes the implementation specifications should not be confused with the Affordable Care Act's definition and requirement for the adoption of "operating rules" for the transactions as described in section 1104 (b) of the Affordable Care Act. The operating rules in the NACHA Operating Rules & Guidelines are not synonymous with those specified in the Affordable Care Act. The NACHA Operating Rules are implementation specifications regarding financial transactions that were developed and adopted by ACH participants more than three decades before the Affordable Care Act amended HIPAA to mandate the adoption of operating rules for each of the transactions listed in the Act.

2. The Secretary's Authority to Adopt a Non-ANSI Accredited Standard

The NCVHS, in its February 17, 2011 letter to the Secretary, recommended NACHA as the standards development organization for the development and maintenance of the CCD+Addenda, and in this interim final rule with comment period, we are adopting a NACHA ACH File format. However, NACHA is not a standard setting organization (SSO), as the term is defined by HIPAA, because NACHA is not accredited by the American National Standards Institute (ANSI). As previously discussed in this interim final rule with comment period, under

section 1172(c)(2)(B) of the Act, if no SSO has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under HIPAA, then the Secretary may adopt a standard, relying upon recommendations of the NCVHS, and after consultation with the National Uniform Billing Committee (NUBC), National Uniform Claim Committee (NUCC), WEDI, and American Dental Association (ADA), and appropriate federal and State agencies and private organizations. These consultations have taken place through various communication avenues such as the NCVHS hearings, letters and other public meetings.

3. Clarification Regarding Application of Standards to EFT Stages 2 and 3

We note that the definition of the health care electronic funds transfers (EFT) and remittance advice transaction at §162.1601, as newly defined in this interim final rule with comment period, includes all three of the ACH payment stages, as discussed in section I.B.2. of this interim final rule with comment period and illustrated in Table 2. However, the standards adopted herein are required to be used only for the electronic file that a health plan transmits in conducting the health care EFT Stage 1 Payment Initiation (see Table 2 and Illustrations A and B).

The health care EFT standards adopted herein are not required to be used for the Stage 2 Transfer of Funds from the health plan's financial institution (ODFI) to the health care provider's financial institution (RDFI). The health care EFT standards meet the NACHA ACH standards used in Stage 2 Transfer of Funds: The Stage 1 Payment Initiation transmitted according to the health care EFT standards adopted herein (CCD+Addenda) will indicate to the ODFI that the health care EFT remain in the form of the CCD+Addenda for Stage 2 Transfer of Funds.

We are also not requiring that the standards adopted herein be used for the Stage 3 Deposit Notification transmission from the health care provider's financial institution (RDFI) to

the health care provider. The format by which the deposit notification is rendered from the RDFI to the provider remains, at this time, dependent on the business agreement between the provider and the provider's financial institution.

4. The Corporate Trade Exchange Entry (CTX)

Our amendments to §162.1602(d)(1) clarify that the health care EFT standards adopted in this interim final rule with comment period are not required to be used when health care EFT, as described in §162.1601(a), and ERA, as described in §162.1601(b), are transmitted together in the same transmission.

This interim final rule with comment period does not prohibit the voluntary use of EFT formats in which an EFT and ERA travel together in a single transmission using, for example, the CTX ACH File. Some in the financial sector and in the health care industry see the single transmission of EFT and ERA together as a promising approach for seamlessly automating reassociation, and it is hoped that industry initiatives to use and/or test formats that combine the transmission of health care EFT and ERA into one transmission will continue.

While this interim final rule with comment period does not adopt a specific standard for transmitting the ERA together with a health care EFT in a single transmission, compliance with the X12 835 TR3 is required for transmitting the ERA regardless of how the ERA is transmitted. As well, the X12 835 TR3 provides some implementation specifications for transmittal of the CTX, and nothing in this interim final rule with comment period alters or amends the implementation specifications related to transmitting the CTX within that standard. It is possible that a standard or standards for transmitting the ERA together with the health care EFT in a single transmission could be adopted in future regulations.

5. EFT Conducted Outside the ACH Network

The health care EFT standards adopted in this interim final rule with comment period do not apply to health care claim payments made via EFT outside of the ACH Network. Health plans are not required to send health care EFT through the ACH Network. They may decide, for instance, to transmit a health care EFT via Fedwire or via a payment card network . This interim final rule with comment period neither prohibits nor adopts any standards for health care EFT (as defined in §162.1601(a)) transmitted outside of the ACH Network. When health plans do, however, send health care EFT through the ACH Network, they must do so using the health care EFT standards adopted herein.

We emphasize that the new regulation text at §162.1602 specifies that the X12 835 TR3 continues to be the standard whenever the ERA (as defined in §162.1601(b)) is transmitted, including when an ERA is transmitted together with a health care EFT either through the ACH Network or outside of the ACH Network.

6. International Payments

The CCD+Addenda standard adopted in this interim final rule with comment period cannot be used for Stage 1 Payment Initiation health care EFT made to or from countries outside of the United States. The NACHA Operating Rules & Guidelines requires that all international payment transactions transmitted via the ACH Network use the IAT ACH File. According to NACHA Operating Rules & Guidelines (Section V, Chapter 43), "IAT transactions include specific data elements defined within the Bank Secrecy Act's (BSA) 'Travel Rule' so that all parties to the transaction have the information necessary to comply with U.S. law, which includes the programs administered by the Office of Foreign Assets Control (OFAC)." Because

the Stage 2 Transfer of Funds must be in the IAT ACH File, the Stage 1 Payment cannot be in the CCD+Addenda.

H. Applicability

1. Covered Entities: Health Plans, Health Care Clearinghouses, and Health Care Providers

The health care EFT standards adopted in this interim final rule with comment period apply to transactions that originate with health plans. We note that some health care providers choose not to conduct transactions electronically. In practice, health plans will only have to use the health care EFT standards adopted herein if the provider wants to receive health care claim payments via EFT through the ACH Network.

If an entity sends payment/processing information to another entity for the purpose of having that receiving entity format the information so that it is compliant with the EFT standards in order to transmit it to the ODFI, then that receiving entity would meet the definition of a health care clearinghouse under HIPAA. The receiving entity would be required to use the health care EFT standards adopted in this interim final rule with comment period.

2. Financial Institutions

The February 17, 2011, NCVHS recommendations on the EFT standard included a recommendation for the Secretary to "consider the implications of the fact that, as the result of the adoption of the health care EFT standard, some banks may become de facto health care clearinghouses as defined by HIPAA."

In Stage 1 Payment Initiation, some health plans currently transmit a flat file, an ASC X12 formatted file, or a proprietary formatted file containing payment/processing information to their financial institutions. The financial institutions then translate the data into the CCD format to transmit it through the ACH Network. In this interim final rule with comment period, we have

adopted standards that apply to the Stage 1 Payment Initiation. Therefore, were financial institutions to continue to provide this service after the effective date of the health care EFT standards adopted herein, such financial institutions would be accepting information from health plans in a nonstandard format and translating it into the standard format consistent with the activities of a health care clearinghouse as defined at §160.103.

Under section 1179 of the Act, the HIPAA Administrative Simplification standards do not apply to entities to the extent they are engaged in the activities of a financial institution. Section 1179 of the Act provides as follows:

To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check or electronic funds transfer.

Section 1179(1) of the Act expressly refers to the use or disclosure of "information . . . for processing . . . a payment for . . . health care, where such payment is made by any means, including . . . electronic funds transfer" as an activity of a financial institution. Financial institutions that process or facilitate the processing of health information from a nonstandard format or containing nonstandard data content into health care EFT standards are engaging in "activities of a financial institution" as set forth in section 1179 of the Act in performing the processes inherent in the health care EFT standards adopted herein and will continue to be considered doing so after their effective date. Therefore, we have determined that, upon the effective date of these health care EFT standards, when financial institutions receive

payment/processing information for these transactions and translate it into the CCD+Addenda format, they will not be required to comply with the health care EFT standards adopted herein.

The health care EFT standards adopted herein are the only HIPAA transaction standards adopted to date that do not contain individually identifiable health information (though, like all HIPAA transactions, they contain health information as defined by HIPAA at §160.103). The information that is required or optional in the health care EFT standards adopted herein is payment/processing information that is necessary for a financial institution to process an EFT through the ACH Network. In fact, the inclusion of protected health information in a Stage 1 Payment Initiation would be inconsistent with the adopted health care EFT standards. As we stated in the preamble to the December 28, 2000, HIPAA Privacy final rule (65 FR 82615):

"...the ASC X12N 835 we adopted as the 'Health Care Payment and Remittance Advice' standard in the Transactions Rule has two parts. They are the electronic funds transfer (EFT) and the electronic remittance advice (ERA). The EFT part is optional and is the mechanism that payors use to electronically instruct one financial institution to move money from one account to another at the same or at another financial institution. The EFT includes information about the payor, the payee, the amount, the payment method, and a reassociation trace number. Since the EFT is used to initiate the transfer of funds between the accounts of two organizations, typically a payor to a provider, it includes no individually identifiable health information, not even the names of the patients whose claims are being paid."

Thus, even absent section 1179 of the Act, the HIPAA Privacy and Security rules would not apply to the transmission of the health care EFT standards adopted herein.

In summary, we anticipate that after the adoption of the health care EFT standards, some financial institutions will continue to translate nonstandard payment/processing information received from health plans into the CCD format. With the adoption of the health care EFT standards, these financial institutions will, by virtue of performing these activities, become de facto health care clearinghouses as defined by HIPAA. To the extent, however, those entities

engage in activities of a financial institution, as defined in section 1101 of the Right to Financial Privacy Act of 1978, (Pub. L. 95-630; effective March 10, 1979), they will be exempt from having to comply with these HIPAA standards with respect to those activities.

The health care EFT standards adopted herein apply to health plans, and health plans are ultimately responsible for ensuring compliance with the standards regardless of whether a health plan puts the data into standard format itself or uses a financial institution to do so. This means that, with regard to the health care EFT standards adopted herein, upon their effective date, if a health plan has an arrangement with a financial institution for the financial institution to format the health plan's nonstandard payment/processing information into the standard CCD+Addenda format for a Stage 1 Payment Initiation and, for whatever reason, the bank does so in a way that is noncompliant with the standards, where the financial institution is the agent of the health plan, the health plan may be responsible for the noncompliance. We expect that some health plans will need to educate their financial institutions about the health care EFT standards adopted herein in order to ensure compliance.

I. Effective and Compliance Dates

Section 1104(c)(2) of the Affordable Care Act states that "[t]he Secretary shall promulgate a final rule to establish a standard for electronic funds transfers (as described in section 1173(a)(2)(J) of the [Act], as added by subsection [1104](b)(2)(A) [of the Affordable Care Act]." The Secretary may do so on an interim final basis and shall adopt such standard not later than January 1, 2012, in a manner ensuring that such standard is effective not later than January 1, 2014." 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 standard for electronic funds transfers be effective not later than January 1, 2014. This means that covered entities must be in compliance with the standards by January 1, 2014. 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 to allow sufficient time for industry preparation for compliance.

III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), we are required to publish a notice of proposed rulemaking (NPRM) in the **Federal Register**. Section 553(b) of the APA provides for an exception from this APA requirement. Section 553(b)(B) of the APA authorizes an agency to waive normal rulemaking requirements if the Department for good cause finds 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 waive the 30-day delay in effective date where the agency finds good cause to do so and includes a statement of support.

Section 1104 of the Affordable Care Act amended section 1173 of the Act to require the Secretary to adopt standards and a set of operating rules for certain electronic health care transactions under HIPAA. Section 1104(c)(2) of the Affordable Care Act requires the Secretary to "promulgate a final rule to establish a standard for electronic funds transfers. . . . The Secretary shall adopt such standard not later than January 1, 2012, in a manner ensuring that such standard is effective not later than January 1, 2014." Given the statutory requirement to promulgate a final rule by January 1, 2012, there is a highly compressed window of time before the statutory adoption date of the EFT standards. We believe Congress may have had this in mind when it expressly authorized the adoption of the EFT standard by an interim final rule. For the reasons detailed below, we have concluded that there is good cause to waive normal rulemaking notice and comment procedures, as they are impracticable. We believe the rationale provided here supports our exercise of the option provided by Congress to promulgate the final rule on an interim final basis.

Section 1172(f) of the Act requires the Secretary to "rely on the recommendations of the National Committee on Vital and Health Statistics... and [to] consult with appropriate Federal and State agencies and private organizations" before adopting a standard under HIPAA. Furthermore, the Secretary is required to consult four organizations named in section 1172(c)(3)(B) of the Act before adopting a standard that has not been developed, adopted or modified by a standard setting organization, which is the case with one of the EFT standards adopted herein.

Upon passage of the Affordable Care Act in March 2010, the NCVHS immediately scheduled hearings in order to gather industry and government input on the new transaction standards and operating rules mandated by the Affordable Care Act. The order in which the

hearings were scheduled was established by the NCVHS based on the statutory effective dates of the new standards and operating rules. Thus, a hearing on operating rules for the eligibility for a health plan and health care claim status transactions was scheduled for July 20, 2010, as those operating rules were required to be adopted by July 1, 2011. Between July and December of 2010, the NCVHS solicited testifiers for a hearing on EFT standard and operating rules for EFT and ERA, and the NCVHS held a hearing on December 3, 2010.

Based on the December 3, 2010 NCVHS hearing, the NCVHS issued a letter to the Secretary on February 17, 2011 detailing its recommendations for EFT standards. As per the consultation requirements in the Act, we could not proceed with developing a rule for the EFT standard until we received and considered the NCVHS recommendation as well as consulted with appropriate Federal and State agencies and private organizations. Given that the Affordable Care Acts mandates that the EFT standard be adopted by January 1, 2012, the agency had only until November 30, 2011 to consult with the required agencies and organizations and to publish a final rule on the standard – approximately 8 months from the week the Secretary received the NCVHS recommendations.

The December 3, 2010 NCVHS hearing on an EFT standard and operating rules triggered a wave of discussions within industry on the use of EFT in the health care industry. An ASC X12 workgroup began work on an "ASC X12 Type 2 Technical Report" entitled Health Care Claim Payment/Advice Reference Model. The Workgroup for Electronic Data Interchange (WEDI) initiated the EFT Sub Work Group that began drafting an educational document for health care entities called Creating and Implementing an EFT Process for Payers and Providers. A number of representatives from various federal government agencies began meeting on the use of EFT in medical payments from government agencies under the auspices of the Department of

Treasury. After March 2011, CAQH CORE began a number of meetings with industry on operating rules for EFT and ERA.

It was crucial for us to participate in these meetings, conduct in-depth research on the payment systems of the health care industry, and continue industry discussions on the EFT transaction. All of these actions were particularly critical because the health care EFT standards are the first standards to be adopted under HIPAA in which the standards and business practices of the financial industry would be considered and a new standards development organization would be part of the process. Not only did this require extensive discussion with the financial industry, it also required the Department to participate in meetings coordinated between the financial industry, representatives of covered entities, and government agencies. These meetings and discussion included issues such as the NCVHS recommendation (in comparison to other options), the relationship between the EFT transaction and the ERA transmission in the health care payment and remittance advice standard transaction, and the implications to the health care and financial industries of an EFT standard in terms of privacy and security issues.

The development of the provisions of this interim final rule with comment period required a thorough understanding of EFT as a tool of the financial industry and how it intersects and works within the health care industry. Based on these discussions from March to July 2011, we developed and drafted the provisions for the health care EFT standards. As detailed in the preamble, the health care EFT standards are a unique combination of a standard from the financial industry and a standard from the health care industry. Without these discussions and research over the past several months, it would not have been feasible to adopt standards for health care EFT that met both industry needs and fulfilled the intentions of HIPAA administrative simplification.

After the research and drafting phase of the rule was completed in July 2011, we were left with four months to publish the rule to meet the statutory deadline of January 1, 2012. Given the minimum practical time it takes to promulgate a rule, we determined there was insufficient time to publish both a proposed and final rule before November 30, 2011.

We also note that the operating rules for EFT and ERA cannot be adopted until a standard for the EFT is adopted. Any delay in adopting the EFT standard would delay adoption of EFT and ERA operating rules, which are required by section 1173(g)(4)(B)(ii)(II) of the Act to be adopted by July 1, 2012, and which must be effective by January 1, 2014. Most importantly, the operating rules benefit industry in significant ways for the processing of claims payments; any delay in the adoption of EFT and ERA operating rules delays industry opportunity for efficiency and cost savings.

Therefore, we conclude that there is good cause to waive normal rulemaking requirements as they are impracticable, and we avail ourselves of the interim final rule option provided by Congress in the Affordable Care Act.

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 standards until January 1, 2014, nearly two 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. That 30-day time period is in fact inconsequential here to

covered entities – their statutorily prescribed date of compliance remains January 1, 2014.

Because we believe the 30-day delay is unnecessary, we find good cause to waive it. We are providing a 60-day comment period.

IV. 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 the information collection requirements (ICRs) regarding third party health care EFT enrollment forms.

The health care EFT standards are the implementation specifications for the electronic format that a health plan is required to use for the Stage 1 Payment Initiation. The standards adopted herein do not affect how a provider's financial institution transmits the TRN segment to the provider. Therefore, the provider is not required to change or amend systems or processes.

There will be no direct systems costs to physician practices and hospitals to implement the health care EFT standards adopted herein.

However, we do assume that, in part due to this regulation, physician practices, and hospitals will increase their usage of EFT, or in some cases will begin accepting EFT for health care claim payments for the first time. As we relay in section V.A.2. of this interim final rule with comment period, in the savings for health plans, the high range of estimated increase in EFT usage attributable to implementation of the health care EFT standards makes up a percentage of the total increase. The rest will be due to an increased number of insured patients, business culture acceptance of EFT, and statutory and other regulatory initiatives.

We have included both physician practices and hospitals in our calculation (Table 4). Data have demonstrated that hospitals have a much higher usage of EDI than physician practices and, by extension, we assume that hospitals have a higher usage of EFT than physician practices. However, there is no valid data on EFT usage among hospitals and so we will include them with physician practices, knowing that cost estimates are likely conservative.

Many physician practices and hospitals already accept EFT for health care claim payments from the health plans that pay them the most (as a percentage of total payments to the provider), pay them most often, or transmit payment/processing information that works most successfully with the particular provider's practice management system.

While some physician practices and hospitals do not accept any payments via EFT, we assume that all physician practices and hospitals, or their trading partners, are technically capable of receiving payment via EFT. This assumption is based on the fact that no infrastructure is necessary because the provider's financial institution is responsible for the necessary technology required to receive a health care EFT through the ACH Network, and there are few, if any,

"financial institutions" that do not participate in the ACH Network. Therefore, we assume no systems costs or infrastructure requirements for providers relative to enrolling for health care EFT.

The burden associated with the requirements of this interim final rule with comment period, which is subject to the PRA, is the completion of the health care EFT enrollment, which is accomplished by filling out and submitting what is generally a 3 to 18-page form, obtaining signatures, and transmitting the completed document.

In order to quantify the average cost per physician practice or hospital, we have outlined the following assumptions in the form of a model physician practice that we will use to project enrollment costs:

- For the model physician practice, the time burden of an EFT enrollment with a single health plan is 2 hours. We base this time burden on the estimated length of time it would take an average consumer to complete and submit a 3- to 18-page form, including obtaining bank account, bank routing, and necessary signatures to allow an employer to Direct Deposit an employee's salary into the employee's account (a common consumer EFT enrollment).
- The majority of the enrollment will be done by billing and posting clerk, at that position's average salary rate of approximately \$17.5 per hour in 2014 based on Bureau of Labor Statistics. We factored labor costs to increase at the rate of 3 percent per year.
- The model physician practice receives the vast majority of its payments from 25 or less plans. From the beginning of 2014 through 2018, we assume that the number of health plans

with whom the model physician practice does business will remain constant because industry trends indicate that the number of health plans will remain constant, or even decrease.³

- The model physician practice will receive 34 percent of its health care claim payments via EFT at the beginning of 2014, and this will increase to 56 percent by the end of 2018 (reflecting our calculation in V.A.2. of this interim final rule with comment period for the whole industry).

- Using these factors, we can calculate that the model physician practice is already enrolled in an EFT program with approximately eight of the 25 health plans with whom it does business (34 percent) at the beginning of 2014.

- We predict that the model physician practice would be expected to add six new EFT enrollments from 2014 through 2018. Any updates to the enrollments would be in conduct of the normal course of business.

TABLE 4. COSTS AND NUMBER OF ENROLLMENTS IN HEALTH CARE EFT BY PHYSICIANS AND HOSPITALS FOR 2014 THROUGH 2018

Time (in hours) per Enrollment Form (Column 1)	Base Hourly Rate (in dollars) for Billing and Posting Clerks* (Column 2)	Number of Physician Practices/Hospitals (Column 3)	Total Number of Increased EFT Enrollments (Column 3 * 6 enrollments) (Column 4)	Total Number of EFT Enrollments Attributable to Health Care EFT Standards at 18% of Total (Column 5)	Number of Annual Enrollments in Health Care EFT Attributable to Adoption of Standards (Column 6)
2	\$17.5	240,727	1,444,362	259,985	52,000

* Department of Labor statistics, based on average hourly salary for billing and posting clerks for NAIC Sector 62, May, 2010 with 3 percent annual increase between 2010 and 2014.

³American Medical Association, "Competition in Health Insurance: A Comprehensive Study of US Markets," 2008 and 2009.

The total increase in the number of health care EFT enrollments from 2014 through 2018 is projected to be 1,444,362 of which approximately 18 percent or 259,985 will be attributable to the implementation of the health care EFT standards. Distributed over 5 years and factoring a 3 percent increase in labor costs for each of the 5 years produces a total burden to industry of nearly \$10 million over 5 years.

TABLE 5. PAPERWORK REDUCTION ACT ESTIMATED ANNUALIZED BURDEN

	Year					Total
	2014	2015	2016	2017	2018	
Cost (Burden Hours for total hospitals & providers) (in millions)	\$1.8	\$1.9	\$1.9	\$2.0	\$2.1	\$9.7

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 with comment period; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-0024-IFC

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

V. Regulatory Impact Analysis

We have examined the impacts of this interim final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104-121), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates

Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13563 also directs agencies 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). We estimate that this rulemaking is "economically significant," 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, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of this interim final rule with comment period, and the rule has been reviewed by the Office of Management and Budget. We anticipate that the adoption of the health care EFT standards would result in benefits that outweigh the costs to health care providers and health plans.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit

organizations, and small government jurisdictions. Small businesses are those with sizes below thresholds established by the Small Business Administration (SBA).

We have determined, and certify, that this rule will not have a significant economic impact on a substantial number of small entities, and that a regulatory flexibility analysis is not required. Our reasoning follows:

Most physician practices, hospitals and other health care providers are small entities, either by nonprofit status or by having revenues of \$7 to \$34.5 million in any one year. However, the only costs to providers are the possible costs of filling out EFT enrollment forms with health plans, detailed in the Collection of Information section herein. Those costs are approximately \$35 per health care provider per year. Numbers of this magnitude do not remotely approach the amounts necessary to be a "significant impact" on an individual provider.

The health insurance industry was examined in depth in the Regulatory Impact Analysis prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866), published on August 3, 2004. In that analysis, it was determined that there were few if any "insurance firms," including health maintenance organizations (HMOs), that fell below the size thresholds for "small" business established by the SBA. Then and even more so now, the market for health insurance is dominated by a relative handful of firms with substantial market shares. We assume that the "insurance firms" are synonymous, for the most part, with health plans that make health care claims payments to health care providers and are, therefore, the entities that will have costs associated with implementing health care EFT standards.

There are, however, a number of HMOs that are small entities by virtue of their nonprofit status even though few if any of them are small by SBA size standards. There are approximately one hundred such HMOs. These HMOs and health plans that are non-profit organizations, like

the other firms affected by this interim final rule, will be required to implement the health care EFT standards for Stage 1 Payment Initiation for health care claims to health care providers. Accordingly, this interim final rule will affect a "substantial number" of small entities. However, we estimate, that the costs of this interim final rule with comment period are, at most, approximately \$12,000 per health plan (regardless of size or non-profit status). Again, numbers of this magnitude do not remotely approach the amounts necessary to be a "significant economic impact" on firms with revenues of tens of millions of dollars (usually hundreds of millions or billions of dollars annually).

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This interim final rule would not affect small rural hospitals, under the same reasoning previously given with regard to health care providers. Therefore, the Secretary has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This interim final rule with comment period does not impose spending costs on State, local or tribal government in the aggregate, or by the private sector, of \$136 million. As is reflected in the RIA, costs on all entities are estimated to be not more than \$20 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule does not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

A. Current State, Need for Mandated EFT Standards, and General Impact of Implementation

1. Billing and Insurance Related (BIR) Costs

Health care spending in the United States makes up an estimated 17 percent of the U.S. Gross Domestic Product (GDP)⁴ and costs over \$8,000 per person annually.⁵ Many factors contribute to the high cost of health care in the United States, but studies point to administrative costs as having a substantial impact on the growth of spending⁶ and an area of costs that could likely be reduced.⁷

A significant portion of administrative costs for physician practices and hospitals are billing and insurance-related (or BIR) costs (See Illustration C). It is estimated that half of administrative costs for physician practices are BIR costs⁸ – or between 10 to 12 percent of a physician practice's annual revenue.⁹ In contrast, the U.S. retail sector spends about 5 percent of annual revenue on accounts receivable.

⁴ <http://stats.oecd.org/index.aspx>

⁵ Keehan, S.P.; Sisko, A.M.; Truffer, C.J.; Poisal, J.A.; Cuckler, G.A.; Madison, A.J.; Lizonitz, J.M.; & Smith, S.D.; "National Health Spending Projections Through 2020: Economic Recovery and Reform drive faster Spending Growth," *Health Affairs* 30,(8): doi:10.1377/hlthaff.2011.0662, 2011.

⁶ "Technological Change and the Growth of Health Care Spending," A CBO Paper, Congressional Budget Office, January 2008, <http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf>

⁷ Morra, D., Nicholson, S., Levinson, W., Gans, D. N., Hammons, T., & Casalino, L. P. "U.S. Physician Practices versus Canadians: Spending Nearly Four Times as Much Money Interacting with Payers," *Health Affairs*: 30(8):1443-1450,2011.

⁸ Kahn, J. G., Kronick, R., Kreger, M., & Gans, D.N., "The cost of health insurance administration in California: Estimates for insurers, physicians, and hospitals," *Health Affairs*: 24(6):1629-1639, 2005.

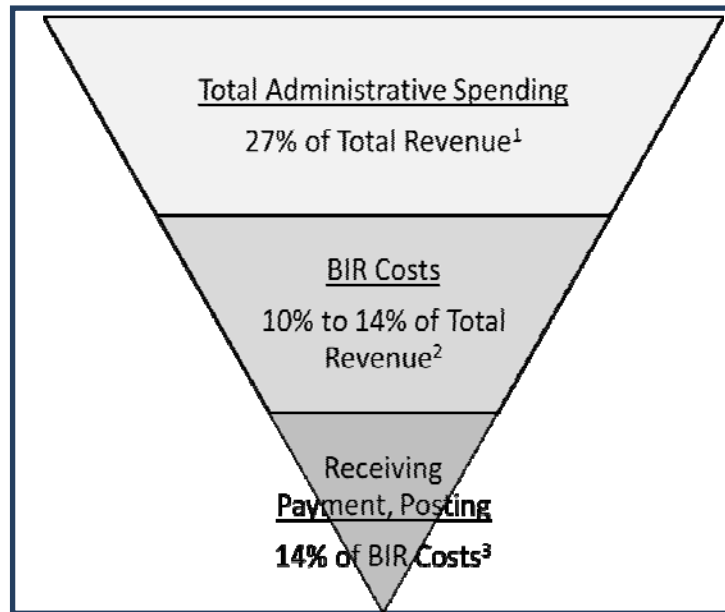
⁹ Sakowski, J.A., Kahn, J.G., Kronick, R.G., Newman, J.M., & Luft, H.S., "Peering into the black box: Billing and insurance activities in a medical group," *Health Affairs*: 28(4):w544-w554, 2009.

Along with estimated increases in all health care administrative costs, we can expect BIR costs to grow as well: In a study by the Washington State Office of the Insurance Commissioner, BIR costs grew between 1997 and 2005 at an average pace of 20 percent per year for hospitals in Washington State and 10 percent per year for physicians.¹⁰ In some cases, the increasing administrative cost of processing claims threatens the survival of small and mid-size physicians' offices.¹¹

¹⁰ "Health Care Administrative Expense Analysis, Blue Ribbon Commission Recommendation #6: Final Report 11/26/07;" Washington State Office of the Insurance Commissioner.

¹¹ Akscin J., Barr T., & Towle E.; "Key Practice Indicators in Office-based oncology practices: 2007 Report on 2006 data. *J Oncol Pract* 3:200-203, 2007, and Mulvey, T.: "The Time has Come for National Insurance Cards," *J. Oncol Pract*, 4:161, 2008.

ILLUSTRATION C. ADMINISTRATIVE COSTS OF PHYSICIAN PRACTICES



¹ Woolhandler, S., Campbell, T., and Himmelstein, D.U., "Costs of health Care Administration in the United States and Canada," *New England Journal of Medicine*, 2003; 349: 768-75

² Kahn, et. al., 2005; Sakowski, et. al., 2009

³ Sakowski, et. al., 2009. BIR costs are allocation of nonclinical full-time-equivalent staff performing BIR activities.

BIR tasks include patient billing, insurance verification, responding to patients' cost questions, contracting with health plans, health care provider credentialing, processing payer requests for additional information, authorizations (procedures, referrals), payment for services provided outside the group, coding support, entering charges, claims review and edits, filing claims, creating and mailing patient statements, data entry and payment processing managements, collecting payments and posting to patient accounts, depositing checks and payments, account reconciliation, discrepancy research, follow-up, and write-offs, posting

refunds, follow-up on denials, underpaid, nonresponsive claims, filing for shared risk-pool payments, and filing for contractual payments.¹²

BIR tasks are costly, in part, because physician practice staff must often manually customize transactions depending on the separate requirements of multiple health plans, insurance companies, clearinghouses, and third party administrators with whom the physician practice contracts. Because of the manual nature of BIR tasks, the majority of BIR costs are associated with staffing costs. Hospitals, physician offices and other health care providers employ more billing and posting clerks than any other industry, according to the U.S. Bureau of Labor Statistics.¹³ These costs include not just the labor costs of employing staff, but also the opportunity cost of providers whose time would otherwise be spent caring for patients. A 2009 study found that the average physician spent three hours a week interacting with health plans – nearly three weeks a year – while physicians' nursing and clerical staff spent much more time.¹⁴ Above and beyond the financial costs of manual BIR tasks, interruptions in the work of physician practices to deal with BIR tasks may interfere with patient care.

Simply put, there are qualitative and quantitative savings to be gained by automating many BIR tasks. For example, 14 percent of administrative staff time on BIR tasks in a physician practice is spent simply receiving payments and posting the payments to accounts receivable.¹⁵ Automated electronic payment and posting, such as what is possible through use of EFT, would decrease this percentage.

¹² Casalino, L.P., Nicholson, S., Gans, D.N., Hammons, T., Morra, D., Karrison, T., & Levinson, W., "What does it cost physician practices to interact with health insurance plans?" *Health Affairs*, 28(4) (2009):w533-w543.

¹³ <http://data.bls.gov/cgi-bin/print.pl/oes/current/oes433021.htm>

¹⁴ Casalino, et. al., 2009.

¹⁵ Sakowski et al., 2009

The August 2000 Transaction and Code Sets final rule was intended, among other things, to reflect the Congress' intent in the 1996 HIPAA statute to decrease health care administrative costs for some of the electronic health care transactions that include BIR tasks. Standards for electronic transactions for claim submission, payment, and remittance advice were adopted in the Transaction and Code Sets final rule with the goal of making these transactions more consistent, and therefore less costly, for health care providers.

A standard for EFT was not adopted at that time because section 1173(a)(2)(E) of the Act stipulates the transaction for which the Secretary is required to adopt a standard as the "health care payment and remittance advice," with no explicit reference to EFT. At that time, we adopted the ASC X12 TR3 835 to support primarily the ERA.

In general, the savings and benefits related to use of EFT for business-to-business transactions is well established (see section I.B.4. of this interim final rule with comment period) and demonstrates that a physician practice that accepts EFT payments for health claim payments could expect to decrease its BIR costs. Yet adoption and use of EFT by physician practices and hospitals has been slow when compared to U.S. consumer and other industry EFT use, and seemingly obvious BIR savings go unrealized in the health care industry.

We have noted the reasons given by industry as to why there has not been greater adoption of EFT for health care claim payments among health care providers in Section I.D. The obstacles to greater adoption and use of EFT, and thus the possibility of staff time savings conducting BIR tasks throughout the health care industry, could be lessened by the adoption of health care EFT standards.

This interim final rule with comment period aims to solve a collective action problem that currently leads to underutilization of EFT. Without health care EFT standards, the costs of

adopting EFT by a particular physician often exceed the benefits. By creating EFT standards, this rule will result in benefits exceeding costs for most physicians.

2. Current and Projected EFT Usage

For an estimated current usage of EFT for health care claim payments, we considered numerous health care and other industry studies. All these studies vary, but all report that EFT is generally used for less than 40 percent of health care claim payments.

According to the "2010 AFP Electronic Payments: Report of Survey Results," produced by the Association for Financial Professionals and underwritten by J.P. Morgan,¹⁶ the typical U.S. business makes 43 percent of its business-to-business payments by EFT. There was general agreement among industry representatives who testified at the December 2010 NCVHS hearing that the usage of the EFT in the health care industry was considerably less than other industries (that is, less than 43 percent). The National Progress Report on Healthcare Efficiency, 2010, reports that only ten percent of all health care claim payments are conducted electronically.¹⁷ The National Progress Report calculated this based on data supplied by Emdeon, a national health care clearinghouse that sponsors the report. PNC Bank testified at the December 3, 2010 NCVHS hearing that 30 percent of health care claim payments it initiated on behalf of health industry clients in September 2010 were EFT payments.¹⁸ Seventy percent of Medicare payment to health care providers are made via EFT. The Medicare EFT payments to health care providers account for 20 percent of all industry health care claim payments.

Based on this data and research, we estimate the entire health care industry combined, including Medicare, used EFT for approximately 32 percent of all health care claim payments in

¹⁶ http://www.afponline.org/pub/res/topics/topics_pay.html

¹⁷ Produced by the U.S. Healthcare Efficiency Index , <http://www.ushealthcareindex.com>

¹⁸ <http://www.ncvhs.hhs.gov>

2010 (see Table 6), approximately 26 percent less than the 43 percent U.S. business-to-business average as estimated in the J.P. Morgan study and 12 percentage points more than the number of Medicare health care claim payments transmitted via EFT(that is, only 12 percent of all health care claim payments via EFT were made by Medicaid, other government, and private payers.) We estimate that commercial health plans transmit health care claim payments via EFT for approximately 15 percent of their total health care claim payments. This approximates to Emdeon statistics, adjusted to account for the fact that data illustrates that Emdeon statistics are low.

TABLE 6. EFT USAGE FOR MEDICARE, MEDICAID AND OTHER GOVERNMENT HEALTH PLANS, AND COMMERCIAL HEALTH PLANS IN 2010

Health Plan Category	EFT Usage as a Percentage of Payments per Category in 2010
Medicare	70%
Medicaid, CHIP, VHA, and Other Federal, State, and Local Governmental Payers	19%
Commercial Health Plans	15%
Entire Industry	32%*

*Weighted average, based on proportion of payments per category.

We will apply these estimates to our cost/benefit analysis, but will adjust them for 2013 levels, the year before the health care EFT standards will be implemented, to establish a baseline for EFT usage for health care claim payments. Our projected numbers of health care claim payments in 2013 and EFT health care claim payments in 2013 are based on data and projections derived from a number of different sources:

- The Center for Medicare & Medicaid Services (CMS) "National Health Expenditure Data" (http://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp).
- CMS Electronic Data Interchange (EDI) Performance Statistics (<http://www.cms.gov/EDIPerformanceStatistics/>) and CMS CROWD data. Medicare data is the

most precise data we can use for our baseline because it tracks EFT usage among Medicare providers alone. With over 42 million participants, Medicare is the largest single payer of health care in the U.S. and accounts for 20 percent of total health care expenditures.¹⁹ Therefore, we have based many of our estimates and projections on Medicare data.

- "The 2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds"

(<http://www.cms.gov/ReportsTrustFunds/downloads/tr2010.pdf>).

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

- DeNavas-Walt, Carmen, Bernadette D. Proctor, and Jessica C. Smith, U.S. Census Bureau, Current Population Reports, P60-238, "Income, Poverty, and Health Insurance Coverage in the United States: 2009," U.S. Government Printing Office, Washington, DC, 2010.

- Veteran Health Administration Chief Business Office.

A major assumption in our impact analysis is that the percentage of total health care claim payments that are transmitted via EFT will increase by 52 percentage points from 2010 to 2023 across the health care industry (Table 7). Another way of illustrating this increase is that we estimate that the average physician's practice or hospital will begin receiving EFT health care claim payments from a little more than one additional health plan every year between 2013 and 2023. We base this estimated growth on three premises:

First, the number of total health care claim payments are expected to increase considerably, due to the anticipated increase in the number of claims, and usage of EFT is

¹⁹ The Center for Medicare & Medicaid Services (CMS) "National Health Expenditure Data" (http://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp), 2011.

expected to rise with it. Health care claims are expected to increase due to an aging population that will require an increasing number of health care services; for instance, aging baby boomers will double Medicare's enrollment between 2011 and 2031.²⁰ As well, the Affordable Care Act is expected to increase the number of insured adults by 32 million in 2014,²¹ though this anticipated rise in the number of health care claims may be countered somewhat by the Affordable Care Act's initiatives to encourage the bundling of payments.²² Not only will more health care claims mean more payments, but the expected increase in claims will drive health care providers to seek more automated BIR processes in order to handle them all.

Second, it is anticipated that the use of electronic payments is expected to become more widespread and acceptable for U.S. businesses and society at large. ACH payments increased 9.4 percent every year between 2006 and 2009.²³ Business-to-business transactions have increasingly moved to EFT. E-commerce is expected to have a compound average growth rate of 11 percent each year from 2009 to 2014.²⁴ Growth of ACH payments is expected in sectors of the economy that have remained largely untapped by electronic payments; for instance, business-to-consumer transactions and person-to-person EFT transactions.²⁵

Third, statutory and regulatory initiatives at the State and Federal level will drive or attract health care entities to increased usage of EFT. For example, in 2010, Ohio implemented a

²⁰ "The 2011 Medicare Trustees Report: The Baby Boomer Tsunami," presentation by the American Enterprise Institute for public Policy Research, May 2011: <http://www.aei.org/event/100407>

²¹ <http://www.whitehouse.gov/healthreform/relief-for-americans-and-businesses>

²² <http://www.whitehouse.gov/healthreform/timeline>

²³ "The 2010 Federal Reserve Payments Study: Noncash Payment Trends in the United States: 2006-2009," Research Sponsored by the Federal Reserve System, April 2011, http://www.frbservices.org/files/communications/pdf/press/2010_payments_study.pdf

²⁴ Sucharita Mulpuru, P.Hult, "U.S. Online Retail Forecast, 2009 to 2014: Online Retail Hangs Tough for 11% Growth in a Challenging Economy," March, 2010, Forrester Research, http://www.forrester.com/rb/Research/us_online_retail_forecast_2009_to_2014/q/id/56551/t/2

²⁵ Shy, Oz, "Person-to-Person Electronic Funds Transfers: Recent Developments and Policy Issues," Public Policy Discussion Paper No. 10-1, Federal Reserve Bank of Boston, <http://www.bostonfed.org/economic/ppdp/2010/ppdp1001.pdf>

state law requiring that health care plans pay health care claims via EFT if the claims are submitted electronically.²⁶ On the Federal level, regulatory initiatives include EFT requirements for Federal payments issued by the Department of the Treasury, and implementation of provisions in the Affordable Care Act, including the health care EFT standards and the anticipated operating rules on the health care and remittance advice standards.

Table 7 illustrates the predicted increase in adoption by health plan sector, driven by the increased number of health care claims, business acceptance, and regulatory initiatives. Taken as a whole, we estimate EFT usage will increase by 52 percentage points, as a percentage of total payments, across the whole industry, from 32 percent in 2010 (Table 6) to 84 percent in 2023 (Table 7).

TABLE 7. PREDICTED EFT USAGE BY 2023

Health Plan Category	EFT Usage as a Percentage of Payments per Category in 2023
Medicare	98%
Medicaid, VHA, & Other Federal, State, and Local Government Payers	79%
Commercial	79%
Entire Industry	84%*

*Weighted average, based on proportion of payments per sector.

3. Projected Increase in EFT Usage Attributable to Implementation of the Health Care EFT Standards

This impact analysis is based on the assumption that the health care EFT standards will make health care claim payments via EFT more cost effective and will therefore incentivize increased usage of EFT by physician practices and hospitals. We estimate a 6 to 8 percentage

²⁶ <http://www.osma.org/tools-resources/reimbursement-payer-assistance/electronic-funds-transfers-eft>

point annual increase in the use of EFT for health care claim payments (as a percentage of total payments year over year) from 2014 through 2018 attributable to implementation of the health care EFT standards. Thereafter, we estimate a 4- to 6- percentage point increase in the use of EFT for health care claim payments (as a percentage of total payments year over year) from 2019 through 2023 attributable to implementation of the health care EFT standards. We now look more carefully at the basis and dynamics of that assumption.

The numbers illustrated in Table 6 reflect the current total number of EFT transactions transmitted by all health plans and received by all health care providers. On the sending side, health plans find that they only transmit EFT to some of the health care providers with whom they do business, and, even to providers who receive health care claim payments from them via EFT, health plans may still sometimes send health care claim payments via paper checks.

On the receiving end, all health care providers have the capability to receive EFT, just as all consumers with a bank account are able to receive Direct Deposit. However, many health care providers only receive EFT from only a subset of health plans from which they receive health care claim payments. For example, most physician practices and hospitals with Medicare patients receive their health care claim payments via EFT, but many do not receive EFT health care claim payments from the other health plans with which they do business, as the percentages in Table 6 demonstrate.

Although health plans are the entities that send EFT and that will be required to comply with the health care EFT standards, it is the physician practices and hospitals that drive overall adoption and usage of EFT. Most health plans give physician practices and hospitals a choice of payment between paper checks (sometimes accompanied by paper remittance advice) or EFT. Up until now, the numbers demonstrate that, while physician practices and hospitals may choose

to accept EFT from some health plans, they are clearly choosing to continue to receive paper checks from the majority of the health plans with whom they do business.

In general, physician practices and hospitals choose to receive EFT: (1) from health plans with whom they do the most business in terms of amounts or frequency of payments; and/or (2) from health plans that transmit payment/processing information via EFT that allows the physician practices' and hospitals' practice management systems to reassociate the payment with the ERA with the least amount of manual intervention. In terms of the first criteria, many physician practices and hospitals will not go to the trouble of enrolling with health plans with which they do not conduct much business. For these providers, the burden of enrollment outweighs the health care provider's perceived benefits to accepting EFT. In terms of the second criteria, a health care provider may find that manually reassociating paper checks with remittance advice (paper or electronic) is easier, more efficient, and more familiar than attempting to manually reassociate an EFT with remittance advice.

The reasons why automated reassociation may be more difficult or less efficient than manually reassociating paper checks with remittance advice were described in testimony at the December 3, 2010 NCVHS hearing and fall into two categories (see section I.D. of this interim final rule with comment period for a complete summary): (1) the time difference between the arrival of the EFT and the arrival of the ERA; and (2) the lack of a TRN Segment in the EFT needed for automated reassociation of the ERA with the associated ACH payment. The focus of the health care EFT standards adopted herein is to ameliorate the latter issue.

According to the American Medical Association, "If a payer does not include the accurate TRN Segment, or the bank fails to maintain it without any change, there is no easy way for the physician practice to match the payment with the X12 835.....unless payers are required to

use a tracking number, and complete the fields to determine accurate payment to the highest specificity, the value of the EFT transaction will be limited."²⁷

A number of industry representatives stated their support for the use of the TRN Segment in increasing health care provider usage of EFT at the December 3, 2010 NCVHS hearing: "The need for reconciled transactions is key," a representative of HERAE, a health care payment and data automation company, stated in written testimony, "but without key elements of data being retained through the entire process, a significant quality breakdown occurs that can exasperate the industry and stifle innovation. Such is the case with EFT data elements being transmitted and received for provider use."²⁸

In deciding to receive health care claim payments via EFT from any particular health plan, the health care provider is making a cost/benefit analysis, comparing the cost and benefit of processing paper checks with the costs and benefits of EFT. This is analogous to the payment decision consumers make every day between paper-based transactions and electronic payments when considering how to receive their paychecks, how to pay their bills, and how to manage their accounts. One reason for the current slow adoption rate of EFT among physician practices and hospitals is that the EFT transaction fails to win physicians' and hospitals' cost/benefit analysis. Many physician practices and hospitals conclude that, because of the difficulties in enrollment and reassociation, they will maintain their current processes based on paper checks.

²⁷ "Standardization of Electronic Funds Transfer Transaction and Process White Paper," prepared by the American Medical Association Practice Management Center, December 2010, <http://www.ama-assn.org/ama1/pub/upload/mm/368/electronic-funds-transfer-white-paper.pdf>

²⁸ "Six Years of Marketplace ERA & EFT Learnings & Recommendations Regarding the Rules: Written Testimony to the National Committee on Vital and Health Statistics (NCVHS), the Sub-Committee on the Rules for ERA/EFT per the Patient Protection and Affordable Care Act," by Jim Ribelin, HERAE, LLC., submitted December, 2010,.

The health care EFT standards are intended to make the EFT a more efficient and economic method for receiving health care claim payments. The health care EFT standards require that the payment information needed for automated reassociation (the TRN segment) be sent with the EFT. By mandating use of an ACH File and holding the health plan accountable for including the X12 835 TRN Segment, the health care EFT standards give physician practices and hospitals assurance that intermediaries on the health plan's side (clearinghouses, financial institutions, payment vendors) will not alter or omit payment/processing information required for automated reassociation. In so doing, more of the benefits of EFT to physician practices and hospitals can be realized, and physicians and hospitals will be more likely to conclude that EFT is more cost effective than continued use of paper checks.

For these reasons, we believe that an estimated range of 6 to 8 percent annual increase in the percentage of payments per year that are EFT from 2014 through 2018 and a 4 to 6 percent increase from 2019 through 2023 can be attributed to the implementation of the health care EFT standards.

Table 8 illustrates the percentage of EFT usage by 2023 that is attributable to adoption and implementation of the health care EFT standards. The Table demonstrates that usage of EFT to pay claims by the health care industry would be an estimated 12 to 17 percent less in 2023 were the health care EFT standards not adopted. This projection is derived from the estimated number of payments that will shift from paper checks to EFT because providers recognize the time and cost savings produced by health plans use of the health care EFT standards. However, in order to have a comprehensive picture of the consequences of *not* adopting the health care EFT standards, we would have to consider other factors.

For instance, because operating rules for the health care EFT and remittance advice transaction cannot be adopted before the adoption of health care EFT standards, the increased use of EFT by providers that might be attributable to EFT and ERA operating rules will not occur without adoption of the health care EFT standards. Considering that factor, if the health care EFT standards are not adopted, use of EFT by providers could be less than what is estimated in Table 8, Column 3.

Another factor to consider when attempting to estimate the consequences of *not* adopting the health care EFT standards is the fact that payers realize savings in printing and mailing costs when they use EFT with or without the adoption of health care EFT standards. In contrast, as we have described in this preamble, without the data elements required by the health care EFT standards, the time and cost savings of EFT will not be realized by providers. If health care EFT standards are not adopted, it is possible that state laws and health plans would create laws and requirements that would force providers to accept EFT for health care claim payments, thus allowing savings for the payers but creating a possible burden for providers. The result would be that providers use of EFT might increase, even at the rate illustrated in Table 7, but the considerable time and cost savings possible through use of EFT transmission would not be realized.

TABLE 8: PREDICTED USAGE OF EFT IN 2023 WITH AND WITHOUT THE HEALTH CARE EFT STANDARD

Health Plan Category (Col 1)	EFT Usage as a Percentage of Payments per Category in 2023 assuming Adoption of Health Care EFT Standards (Col 2)	Increase in EFT Usage as a Percentage of Payments if Health Care EFT Standards are <i>not</i> Adopted (Col 3)
Medicare	98%	98%
Medicaid, VHA, & Other Federal, State, and Local Government Payers	79%	56% to 63%
Commercial	79%	56% to 63%
Entire Industry	84% *	67% to 72%

*Weighted average, based on proportion of payments per sector.

It should be noted that the health care payment is only one element of the payment process, and the sending and receiving of health care claim payments is only one part of the total BIR cost. As such, the health care EFT standards work in concert with other regulatory and industry-based initiatives that are intended to decrease overall costs associated with how a health care provider gets paid. For instance, we will be adopting operating rules for the health care EFT and remittance advice transaction by July, 2012, as per the Affordable Care Act, and operating rules will be adopted for four other HIPAA transactions before July 2014. By themselves, none of these initiatives will significantly decrease BIR costs. However, there is industry consensus that BIR costs can be reduced considerably, and the health care EFT standards are an important part of that overall effort.

B. Alternatives Considered

1. Alternative 1: Adopt a standard for Stage 2 Transfer of Funds or Stage 3 Deposit Notification transmissions

The CCD+Addenda is an ACH File that is used between financial institutions, the ODFI and the RDFI, in the Stage 2 Transfer of Funds. As this interim final rule with comment period demonstrates, the CCD+Addenda is also an electronic format that an Originator can use in the Stage 1 Payment Initiation to order, instruct, or authorize the ODFI to send a transaction through the ACH Network. In the December 2010 NCVHS hearing, these two different uses of the CCD+Addenda – to initiate payment and to actually transfer funds through the ACH Network – were not consistently differentiated in testimony. However, the co-chair of the NCVHS Subcommittee on Standards made clear to testifiers what the aim of the health care EFT standard(s) was to be: "We're not trying to standardize [transmissions] between two banks.

That's not our role; not our responsibility. Our responsibility and role is to identify the standard that a health plan will be submitting to a bank, and defining that as the standard, and operating rules that will go along with it. Between the banks there is no role, in many respects, for what we do."²⁹

In this interim final rule with comment period, we did not adopt a standard for the Stage 2 Transfer of Funds for two reasons, and we believe these reasons reflect why the NCVHS did not perceive recommending the adoption of a standard "between two banks" as its "responsibility and role," as follows:

First, as the NCVHS pointed out, Stage 2 Transfer of Funds is a transaction between two financial institutions. As we describe in the Applicability section of this preamble, due to the nature of the contents of the health care EFT (payment/processing information with no PHI), the standards adopted herein would not be applicable to financial institutions.

Second, there is no practical reason to adopt the CCD+Addenda as the standard for the Stage 2 Transfer of Funds. When a health plan's financial institution receives the Stage 1 Payment Initiation in the form of a CCD+Addenda, there is no question that the Stage 2 Transfer of Funds should also be transmitted in CCD+Addenda by the health plan's financial institution. The Stage 1 Payment Initiation transmitted according to the health care EFT standards will indicate to the health plan's financial institution that the health care EFT remain in the form of the CCD+Addenda for Stage 2 Transfer of funds. This is one of the main reasons for adoption of an ACH File as the health care EFT standard for Stage 1 Payment Initiation instead of other possible formats. We intend to reduce the number of places that data translations or reformatting

²⁹ Co-chair Walter Suarez, NCVHS Subcommittee on Standards, Administrative Simplification under the Patient Protection and Affordable Care Act Standards and Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA), December 3, 2010, hour 5:05 in audio recording: http://hhs.granicus.com/MediaPlayer.php?publish_id=11

occur in the transmittal of health care EFT from the health plan to the health care provider. Data can be lost or misplaced every time the payment/processing information is translated or reformatted.

In this interim final rule with comment period, we did not adopt a standard for the Stage 3 Deposit Notification. Although the testimony at the NCVHS December 3, 2010 hearing referred to the loss of the TRN Segment in the translation or reformatting that a health care provider's financial institution undertakes in the Stage 3 Deposit Notification, there was no specific discussion or recommendations from those testifying regarding the adoption of a standard for Stage 3 Deposit Notification.

2. Alternative 2: Adopt the CTX as a Health Care EFT Standard

At the December 3, 2010 NCVHS hearing, stakeholder testimony was given concerning the CTX. The CTX, as previously noted, is an ACH file that could include the health care payment/processing information as well as the entire ERA. According to some testimony at the NCVHS December 3, 2010 hearing, if both the health care EFT (payment/processing information) and the ERA were transmitted together in a single transmission, then reassociation by the health care provider would not be necessary. It would be the electronic version of a paper check sent through the mail together with paper remittance advice, but without the material and time costs associated with paper transactions. In testimony, a representative from the financial industry recommended the CTX and stated that "a significant opportunity will have been lost in this process if the end result is a solution which does not tackle this reassociation challenge."³⁰

³⁰ "How the Payment and Remittance Advice Process Works in Healthcare," presented to National Committee on Vital and Health Statistics at the hearing on "Administrative Simplification under the Patient Protection and Affordable Care Act: Standards and Operating Rules for Electronic Funds Transfer (EFT) and Remittances Advice(RA), Presenter: Stuart Hanson, Fifth Third Bank, December 3, 2010, http://hhs.granicus.com/MediaPlayer.php?publish_id=11

We did not adopt the CTX for three reasons. First, as discussed in section I.C. of this interim final rule with comment period, the health care EFT is processed and transmitted from a different system in a health plan than the system that transmits the ERA. In essence, adoption of the CTX would be a mandate to dramatically change the processes and systems of health plans and health care providers. Second, there is little to no experience with the CTX in the health care industry, and it is therefore difficult to support assumptions that administrative simplification and its estimated benefits can be realized simply by the adoption of an untried electronic format. Third, although there was industry and stakeholder testimony supporting the adoption of the CTX, the great majority of testimony favored adoption of the CCD+Addenda. There was much interest in and support for the CTX, but the testimony, in general, urged further exploration of the use of the CTX before it is considered as a viable standard.

As has been illustrated, EFT is used much less in the health care industry than it is in other industries. Our intent with the health care EFT standards is to attract more physician practices and hospitals to use the EFT for health care claim payments, and achieve some clear savings in a relatively short period of time. However, adoption of the CTX would require an overhaul of most health plans', physician practices', and hospitals' payment/billing and claim adjudication systems, processes, and organizational structures. Given the low use of EFT by physician practices and hospitals, and the assumed cost of an overhaul of systems and processes to accommodate the CTX, it is possible that adoption of the CTX at this time as the health care EFT standard would actually reduce the number of physicians and hospitals willing to use EFT to receive health care claim payments in the short term.

3. Alternative 3: Adopt the X12 835 TR3 as the Health Care EFT Standard for Stage 1 Payment Initiation

This interim final rule with comment period adopts two standards for the health care EFT: the CCD+Addenda as the standard for Stage 1 Payment Initiation and the X12 835 TR3 TRN Segment for the data content of the Addenda Record. ASC X12 is the SDO of the X12 835 TR3; NACHA has authority over the CCD+Addenda.

It is possible for a data segment of X12 835 TR3 to be utilized as a Stage 1 Payment Initiation from a health plan to its financial institution. According to X12 835 TR3: "... the 835 can authorize a payee to have a DFI [(Depository Financial Institution)] take funds from the payer's account and transfer funds to the payee's account. The 835 can authorize a DFI to move funds. In this mode, the 835 is sent to the payer's DFI." (Section 1.10.1.1) Because a data segment of the ASC X12 835 TR3 can be used by a health plan in a Stage 1 Payment Initiation to its financial institution, it was considered a possible candidate for the Stage 1 Payment Initiation health care EFT standard.

Along with the X12 835 TR3, other electronic formats were considered candidates for the standard for the Stage 1 Payment Initiation health care EFT standard as well. Currently, a health plan can use proprietary files, the ASC X12 820, and other formats in a Stage 1 Payment Initiation transmission to its financial institution.

Our decision to adopt the CCD+Addenda instead of the X12 835 TR3, or any other electronic format, for the Stage 1 Payment Initiation health care EFT standard was based mostly on written and verbal testimony given at the December 3, 2010 NCVHS hearing. At that hearing, there was overwhelming support for use of the CCD+Addenda. The reasons for support appeared to have two bases: First, the CCD+Addenda was seen by testifiers as a successful electronic format, reportedly used for nearly all health care claim payments transmitted via EFT in Stage 2 Transfer of Funds transmissions between financial institutions, and, to a lesser extent,

used by many in Stage 1 Payment Initiation from a health plan to a health plan's financial institution.

While some industry representatives implied in testimony that other electronic formats were used in the Stage 1 Payment Initiation, including the ASC X12 820 and flat files, none of those that testified stated that an X12 835 was ever used. Further, no one suggested in written or verbal testimony that an X12 820 or flat file be the standard.

At one point during the testimony of December 3, 2011, NCVHS asked representatives from NACHA, ASC X12, and the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information (CORE), whether there was any consideration given to using the ASC X12 835 as the electronic format that transmits a health plan's order, instruction, or authorization for a health care EFT to its financial institution. The representatives replied that no consideration had been given, and did not disagree with the co-chair when he stated that the apparent choice was only between an ACH File and proprietary formats.³¹

As well, at the NCVHS hearing and in written testimony, no proprietary formats were suggested as a possible standard for the Stage 1 Payment Initiation.

The second basis for adopting the CCD+Addenda, as presented by testimony in the NCVHS hearing, was that NACHA is recognized as an organization that has been successful in the development of its implementation specifications and operating rules for ACH files. NACHA was perceived by testifiers to be a trusted developer and maintainer of implementation

³¹ Co-chair Walter Suarez, NCVHS Subcommittee on Standards, Administrative Simplification under the Patient Protection and Affordable Care Act Standards and Operating Rules for Electronic Funds Transfer (EFT) and Remittance Advice (RA), December 3, 2010, hour 5:05:30 in audio recording: http://hhs.granicus.com/MediaPlayer.php?publish_id=11

specifications and operating rules for electronic formats, although NACHA is not recognized as an SSO under HIPAA.

In addition to basing our decision on the testimony, and the February 17, 2011 NCVHS recommendation to the Secretary that resulted from the hearings and testimony, we adopt the CCD+Addenda as one of the health care EFT standards for Stage 1 Payment Initiation because many of the issues with regard to reassociation, discussed in section I.D. of this interim final rule with comment period, arise because of the multiple translations that occur as the health care EFT travels from the health plan, through the ACH Network, to the health care provider. By adopting the CCD+Addenda as one of the health care EFT standards, we are adopting the same electronic format for Stage 1 Payment Initiation as is used in Stage 2 Transfer of Funds between banks, thus eliminating one translation/reformatting of the data wherein the TRN segment might be omitted or transmitted erroneously. By transmitting the payment/payment information in a CCD+Addenda to its financial institution, a health plan will have more assurance that the Addenda Record holding the TRN Segment will not be altered or omitted by the financial institution before it arrives at the health care provider's financial institution.

C. Impacted Entities

The health care EFT standards are expected to decrease BIR costs; therefore, the segments of the health care industry, non-health care industry, and society that will be affected by the implementation of the standards include the following:

- Health Care Providers:
 - ++ Offices of Physicians
 - ++ Hospitals
 - ++ Nursing Homes and Residential Care facilities

- ++ Dentists
- ++ Suppliers of Durable Medical Equipment
- ++ Pharmacies
- ++ Other Providers (home health agencies, dialysis facilities, etc.)
- Health Plans
- ++ Commercial health plans
- ++ Government health plans
- Financial institutions
- Clearinghouses and Vendors
- Patients
- Environment

All HIPAA covered entities would be affected by the standards adopted in this interim final rule with comment period. HIPAA covered entities include all health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard.

Table 9 outlines the number of entities that may be impacted by the health care EFT standards, along with the sources of those data.

TABLE 9: TYPE AND NUMBER OF AFFECTED ENTITIES

Type	Number	Source
Health Care Providers – Offices of Physicians (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)

Type	Number	Source
Health Care Providers - Hospitals	5,764	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf
Health Care Providers – Nursing and Residential Care Facilities not associated with a hospital	66,464	<p>The number of providers was obtained from the 2007 Economic Census Data – Health Care and Social Assistance (sector 62) using the number of establishments: http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0762A1&-geo_id=01000US&-dataitem=* and http://factfinder.census.gov/servlet/IBQTable?_bm=y&-fds_name=EC0700A1&-skip=100&-ds_name=EC0762SLLS1&-NAICS2007=62&-lang=en</p> <p>~NAICS code 623: Nursing Homes & Residential Care Facilities n=76,395 x 87 percent (percent of nursing and residential care facilities not associated with a hospital) = 66,464</p>
Other Health Care Providers – Offices of dentists, chiropractors, optometrists, mental health practitioners, speech and physical therapists, podiatrists, outpatient care centers, medical and diagnostic laboratories, home health care services, and other ambulatory health care services, resale of health care and social assistance merchandise (durable medical equipment)	384,192	<p>The number of providers was obtained from the 2007 Economic Census Data – Health Care and Social Assistance (sector 62) using the number of establishments: http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0762A1&-geo_id=01000US&-dataitem=* and http://factfinder.census.gov/servlet/IBQTable?_bm=y&-fds_name=EC0700A1&-skip=100&-ds_name=EC0762SLLS1&-NAICS2007=62&-lang=en</p> <p>~NAICS code 621: All ambulatory health care services (excluding offices of physicians) = 313,339 (547,561 total - 234,222 offices of physicians) ~NAICS code 62-39600(product code): Durable medical equipment =70,853</p>

Type	Number	Source
Health Care Providers – Independent Pharmacies	18,000	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf
Health Care Providers – Pharmacy chains	200	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf
Health Plans – Commercial	1,827	Impacted commercial health plans are health insurance issuers; that is, insurance companies, services, or organizations, including HMOs, that are required to be licensed to engage in the business of insurance in a State. Includes companies offering Medicaid managed care. This number represents the most recent number as referenced in "Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, 2011 Federal Register (Vol. 76), July, 2011," from www.healthcare.gov .
Health Plans – Government	60	Represents the 56 Medicaid programs, Medicare, the Veteran's Administration (VHA), Indian Health Service (IHS), and TRICARE
Health Plans – All	1,887	Insurance issuers (n=1,827) + Government agencies (N=60)
Clearinghouses and Vendors	162	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf , based on a study by Gartner.
Third Party Administrators	750	Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rulemaking http://www.gpo.gov/fdsys/pkg/FR-2011-08-22/pdf/2011-21193.pdf
Financial Institutions that can transmit EFT through ACH Network	15,000	2010 ACH Rules: <i>A Complete Guide to Rules & Regulations Governing the ACH Network</i> , National Automated Clearing House Association, 2010.

D. Scope and Methodology of the Regulatory Impact Analysis

This impact analysis analyzes the costs and benefits to be realized by implementation of the ACH CCD+Addenda for the health care EFT Stage 1 Payment Initiation and the ASC X12 835 TRN Segment for the data content for the Addenda Record. It does not analyze the costs and benefits of the other provisions/changes that are made in this interim final rule with comment period. For instance, we do not provide an analysis of the cost or benefit of amending the definition of the health care payment and remittance advice transaction title or definition. While these amendments may have a positive impact in terms of clarifying policy, we do not believe that there are any costs or quantitative benefits directly associated with such provisions/changes.

While we assume that adoption of the health care EFT standards will impact a broad range of health care providers, as illustrated in Table 9, we will only be examining the costs and benefits of the health care EFT on two types of providers: hospitals and physician practices. We will not analyze the impact to pharmacies, nursing and residential care facilities, dentists, or suppliers of durable medical equipment.

There are two reasons for narrowing the scope of this analysis to only two categories of health care providers we: (1) have very little data on the adoption rate or usage of EFT among pharmacies, dentists, suppliers of durable medical equipment, nursing homes, and residential care facilities. The lack of data for these types of health care providers has been noted in other studies on administrative simplification;³² and (2) assume that the greatest benefits will be gained by hospitals and physician practices as they receive the majority of health care claim payments.

³² Kahn, James, "Excess Billing and Insurance-Related Administrative Costs," in The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary, edited by Yong, P.L., Saunders, R.S., & Olsen, L.A., The National Academies Press: 2010.

For this reason, our estimates of savings to health care providers is conservative. We welcome comments from industry and the public as to our assumptions.

We include health care clearinghouses and vendors as impacted entities in Table 9. However, we did not calculate costs and benefits in our impact analysis for these entities, although they are entities that may be required to make the most software and system changes in order to transmit the health care EFT to financial institutions on behalf of health plans. We did not calculate costs and benefits to health care clearinghouses and vendors in this cost analysis because we assume that any associated costs and benefits will be passed on to the health plans, and will be included in the costs and benefits we apply to health plans.

We include financial institutions as impacted entities. The number of financial institutions reflected in Table 9 are the number of NACHA member financial institutions, that is, the number of financial institutions that can transmit EFT through the ACH Network. We calculated the costs to financial institutions of this interim final rule with comment period based on the fee that financial institutions are assessed by NACHA for transmitting a single EFT and the estimated increase in EFT attributable to the implementation of the health care EFT standards. We calculated that, between 2013 and 2023, the sum cost to all financial institutions would be less than \$4,000 dollars. Because of the negligible negative impact to financial institutions, we have not included the costs to financial institutions in our impact analysis. While we also assume that the increase in health care EFT will have benefits to financial institutions, we have not calculated those benefits in this impact analysis. The focus of this interim final rule with comment period is on the benefits to the health care industry.

Although we acknowledge the impact to ERISA (Employee Retirement Income Security Act) and non-Federal government plans, we did not include the costs or benefits of such "health

plans" - or other employers who might be defined as "health plans" - in our analysis due to the lack of data with regard to these types of health plans. Only a very small percentage of employers with self-insured health plans conduct their own health care transactions. The majority employ third party administrators (TPAs). For our analysis, we use the number of TPAs (750) estimated in the "Summary of Benefits and Coverage and the Uniform Glossary; Notice of Proposed Rule Making," published in the August 22, 2011 **Federal Register**. Self-funded and non-Federal government health plans meet the definition of covered entities under HIPAA while TPAs, in general, do not. However, TPAs employed by self-funded and non-federal government health plans will ultimately be the party that implements the health care EFT standards. Ostensibly, these TPAs will pass on their costs and benefits to the self-funded and non-federal government health plans that they serve. Therefore, we will estimate the costs and benefits to TPAs in this analysis, and assume that TPAs will be impacted similarly to the 1,827 commercial health insurance issuers indicated in Table 9. In this RIA, we will not separate the analysis of the costs and benefits of TPAs and commercial health insurers, and, hereinafter, we will refer to both collectively as "commercial health plans" for purposes of this analysis.

We use the total number of health insurance issuers as the number of commercial health plans that will be affected by this interim final rule with comment period, and will use this number – plus the number of TPAs - in our impact analysis. A health insurance issuer is an insurance company, insurance service, or insurance organization, including an HMO, that is required to be licensed to engage in the business of insurance in a State, and that is subject to State law that regulates insurance. While the category of "health insurance issuers" represents a larger number of health plans than those included in the NAICs codes for "Direct Health and

Medical Insurance Carriers" (897 firms) we believe the category of health insurance issuers is a more accurate representation of companies conducting HIPAA transactions.

We did not analyze the costs and benefits of the health care EFT standards on Medicare, as our research has demonstrated that there will be no substantive impact to this government health plan. Medicare already requires that their contracted payers use the CCD+Addenda as the Stage 1 Payment Initiation. As well, Medicare requires that all health care providers accept and enroll in EFT when they enroll as a participating provider in the Medicare program in order to receive payments.³³ Therefore, health care providers who receive Medicare payments for health care claims are already benefiting from Medicare's use of the CCD+Addenda. Because of existing policies, Medicare has high health care provider and health plan usage rates of EFT.

For illustrative purposes, we will analyze the impact to Medicaid and other government health plans separately from commercial health plans, although the costs and benefits of the government health plans other than Medicare will be similar to those of the commercial health plans. Companies that provide Medicaid managed care plans are included in the category of commercial health plans.

We estimate that, because of the time savings that will be quantified in the analysis of benefits, patients will benefit downstream from a health care delivery system that spends less time on administrative tasks. While we will detail this benefit to patients, we will not attempt to quantify it in monetary terms. Society at large will also be further impacted by the beneficial aspects the use of EFT will have on the environment, and we will quantify those benefits.

Table 10 summarizes the sectors that will be analyzed in the impact analysis.

³³ 42 CFR Parts 405, 424, and 498, "Medicare Program; Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges: Final rule," published in Federal Register June 27, 2008.

TABLE 10. SECTORS THAT WILL BE ANALYZED IN IMPACT ANALYSIS

Commercial Health Plans (includes TPAs and health insurance issuers)
Government Health Plans (Medicaid, VHA, TRICARE, IHS)
Physician Practices (includes offices of mental health specialists)
Hospitals
Health care patients
Environment

In general, the high and low range approach used in this impact analysis illustrates both the range of probable outcomes, based on our analysis, as well as the uncertainty germane to a mandated application of a standard on an industry with highly complex business needs and processes.

E. Costs

1. Costs for Health Plans (health insurance issuers and TPAs)

We know from the December 2010 NCVHS testimony that some commercial health plans are currently using the CCD+Addenda in the Stage 1 Payment Initiation, and that they are already inputting the TRN Segment in the Addenda Record. For lack of other data, we will assume that 85 percent of the estimated 2,637 (or approximately 2,242) commercial health plans do not use the CCD+Addenda or do not input the TRN Segment in the Addenda Record.

For the commercial health plans that do not use the CCD+Addenda or do not use it according to the implementation specifications detailed in this interim final rule with comment period, there will be system and business process changes required in order to originate the CCD+Addenda with a TRN Segment in the Addenda Record.

Creating a CCD+Addenda and inputting or translating data into a CCD+Addenda is a comparatively simple and inexpensive technical process. A health plan that does not currently use the CCD+Addenda for the Stage 1 Payment Initiation transmits the data in some other form – flat file, an ASC X12 TR3 820, or a proprietary format. Translating the data into a

CCD+Addenda can be done with commercial off-the-shelf (COTS) software for personal use that can be purchased for as little as \$200, and set up in less than 15 minutes. However, it is more complicated and therefore more expensive to coordinate the treasury/accounts payable systems and processes (which would transmit the CCD+Addenda) with the claims systems and processes (which would transmit the health care remittance advice) in order for a health plan to assure duplicate TRN Segments are included in both the health care EFT and ERA. As noted previously, duplicate TRN Segments in the Addenda Record of the CCD+Addenda and in the ERA are essential to allowing automated reassociation on the health care provider side.

We have estimated that it will cost health plans, on average, \$4,000 to \$6,000 to implement the health care EFT standards. This is a one-time cost to health plans to install COTS software or amend systems, change processes, train staff, and/or communicate/contract for required implementation specifications for the CCD+Addenda (Table 11). The low range of costs was derived by considering the cost of high end, commercially available software that can originate a CCD+Addenda and can be integrated into most corporate accounts-payable systems. The high range of costs takes into consideration the possible difficulties associated with coordinating the health plan's payment or treasury systems with the claims processing systems so that the TRN Segment is duplicated in both the ERA and the health care EFT. It is possible that some health plans may require customization of the software.

There may be a number of commercial health plans that would have costs greater than the high range of costs we have estimated; for example, commercial health plans that currently send Stage 1 Payment Initiation in a proprietary format. As well, we assume that there are as many commercial health plans that will have minimal to no costs; for example, health plans that must

simply update their vendor contracts to accommodate this change without any additional operational costs.

We estimate the maintenance, update or subscriber fees to be \$2,000 to \$3,000 annually for the 2 years after the first year of implementation. Subscriber fees are often assessed by software vendors that maintain and update the COTS software on the part of the health plan industry. From our research, we could not find any subscriber or update fees that were more than \$500 a year, but we have estimated much higher maintenance and subscriber costs in order to account for costs that may be associated with adjustments in software or a health plan's business processes in the first few years of the standards' implementation.

Although we assume health plans will start to transition to the health care EFT standards before the formal implementation date of January 1, 2014, for simplicity we have included all one-time implementation costs in the year 2014. Subscriber and maintenance costs will occur in 2015 and 2016. See Table 11.

TABLE 11. COST TO COMMERCIAL HEALTH PLANS OF IMPLEMENTING THE HEALTH CARE EFT STANDARDS*

Year	LOW Cost to Implementing health care EFT standards	HIGH Cost to Implementing health care EFT standards	Number of health plans that will have to make changes to implement the health care EFT standards (85% of 1,827 health insurance issuers + 750 TPAs)	LOW Annual Cost (in millions)	HIGH Annual Cost (in millions)
2014	\$4,000	\$6,000	2,242	\$9.2	\$13.8
2015	\$2,000	\$3,000	2,242	\$4.6	\$6.9
2016	\$2,000	\$3,000	2,242	\$4.6	\$6.9
Total (in millions)				\$18.3	\$27.5

*Based on 2010 dollars.

For Medicaid, CHIP, and IHS, we have used similar cost factors with an identical range. Medicaid is actually 56 different programs, each of which administers a number of health plans, and includes more than 600 managed care plans.³⁴ We have included the Medicaid managed care plans in the commercial health plans category, the costs of which were previously calculated. For purposes of this cost estimate, we have counted each of the 56 Medicaid programs as an individual health plan.

As was the case with commercial health plans, we are aware that certain State Medicaid programs use the health care EFT standards already. However, it is difficult to obtain the exact number of programs that use it. Therefore, we have made the same assumption we made for commercial health plans: We estimate 85 percent of Medicaid, CHIP, and IHS health plans will need to make software and/or system changes in order to implement the health care EFT standards (see Table 12).

TABLE 12. COST TO MEDICAID, CHIP, AND INDIAN HEALTH SERVICES*

Year	LOW Cost to Implementing Health Care EFT Standards	HIGH Cost to Implementing Health Care EFT Standards	Number of Health Plans That will have to Make Changes to Implement the Health Care EFT standards (85% of 60)	LOW Annual Cost (in Millions)	HIGH Annual Cost (in Millions)
2014	\$4,000	\$6,000	51	\$0.20	\$0.31
2015	\$2,000	\$3,000	51	\$0.10	\$0.15
2016	\$2,000	\$3,000	51	\$0.10	\$0.15
Total in millions				\$0.41	\$0.61

*Based on 2010 dollars.

³⁴ "Medicaid Managed Care Trends," Medicaid Managed Care Enrollment Report, Centers for Medicare and Medicaid Services, <http://www.cms.gov/MedicaidDataSourcesGenInfo/downloads/09Trends.pdf>

2. Cost for Physician Practices and Hospitals

We estimate there will be no direct costs to physician practices and hospitals to implement the health care EFT standards. The health care EFT standards are required for the Stage 1 Payment Initiation of the health care EFT between a health plan and its financial institution. While we assume in this impact analysis that the impact to physician practices and hospitals will be positive in terms of giving some assurance that the TRN Segment is transmitted to the health care provider's financial institution, the standards adopted herein do not affect how a provider's financial institution transmits the TRN Segment to the provider. Therefore, the health care provider is not required to change or amend systems or processes.

However, the impact analysis assumes that physician practices and hospitals will increase their usage of EFT or, in some cases, will begin accepting EFT for health care claim payments for the first time on account of the adoption of the health care EFT standards. The cost for this enrollment – less than \$200 per provider over 5 years – is included in section IV. of this interim final rule with comment period. This cost of enrollment will also be reflected in the RIA summary of costs and benefits and the accounting statement.

F. Benefits

Our analysis of benefits is similar to analyses included in other recent regulations that implement administrative simplification mandates under the Affordable Care Act. The implementation of the health care EFT standards, as well as other administrative simplification regulatory initiatives such as operating rules for the HIPAA standard transactions, are expected to streamline administrative health care transactions, make the standard transactions more consistent, and decrease dependence on manual intervention in the transmission of health care and health care payment information. These improvements, in turn, will drive more physician

practices, hospitals and health plans to utilize electronic transactions in their operations. Each move from a non-electronic, manual exchange of information to an electronic transaction brings with it material savings in terms of less money spent on paper, postage, and equipment required for paper-based transactions, as well as cost avoidance in terms of time savings for staff.

For health plans, we expect direct savings from the transition from a paper-based payment system (for example, paper checks) to EFT. These savings are found in the amount of staff time saved, as well as material savings such as postage, paper, and printing.

For physician practices and hospitals, we expect downstream savings from a decrease in the amount of time a physician practice or hospital staff spends in manually reassociating the ERA with health care EFT. Though we expect some direct savings as well in terms of paper savings, our analysis will concentrate on health care provider staff time savings.

1. Savings for Health Plans

We assume health plans will generate savings from increased usage by physician practices and hospitals of EFT for health care claim payments. As noted previously in this impact analysis, this estimated increase will be due to a number of factors; however, we will only calculate the savings derived from increased EFT usage attributable to implementation of the health care EFT standards.

As noted in section III.A.2. of this interim final rule with comment period, we estimate a 6 to 8 percent annual increase in the use of EFT from 2014 through 2018 and a 4 to 6 percent increase from 2019 through 2023 that will be attributable to implementation of the health care EFT standards. We have included these ranges in order to reflect the uncertainty inherent in making a causal claim in a complex, multifactorial environment such as the U.S. health care industry.

There have been a number of different analyses and case studies with regard to the possible savings realized when a health plan switches from paper checks to EFT for health care claim payments. A 2007 analysis by McKinsey and Company concluded that the "system wide cost" of using paper checks for health care claim payments was \$8.00 per check.³⁵ This included printing and mailing the checks from the payer side, and manually reconciling and depositing the check on the health care provider side. We have not used the McKinsey's conclusion because we do not know what methodology was used and wanted to be specific about the difference between health care provider savings and health plan savings.

In another example, United Healthcare reports that it costs the company \$30.7 million to pay 145 million health care claims with paper checks compared with the cost of \$2.7 million to pay the same amount of claims using EFT.³⁶ This is a difference of about \$0.19 a claim. We did not use United Healthcare's savings estimate since, apparently, it is based on single claims, and the metric we used is based on health care claim payments. A single health care claim payment from a health plan covers payment for multiple claims submitted by a provider.

For our calculations, we use data from the Financial Management Service (FMS), a bureau of the United States Department of Treasury. We use FMS data because they are the lowest estimates, and because we consider them the most valid. According to FMS, it costs the U.S. government \$0.11 to issue an EFT payment compared to \$1.03 to issue a check payment — a difference of \$0.92 per check.³⁷ This estimate includes the cost of material such as postage, envelopes, and checks, but does not include labor costs. FMS processes millions of transaction,

³⁵ "Overhauling the US Healthcare Payment System," conducted by McKinsey & Company, published in *The McKinsey Quarterly*, June 2007.

(http://www.mckinseyquarterly.com/Overhauling_the_US_health_care_payment_system_2012).

³⁶ "E-Payment Cures for Healthcare," presentation by J.W. Troutman (PNC Healthcare), D. Lisi (United Healthcare), B.C. Mayerick (Department of Veterans Affairs), April 26, 2010, <https://admin.nacha.org/userfiles/File/Healthcare%20Resource/Epayers%20Cures%20for%20Healthcare.pdf>.

³⁷ www.fms.treas.gov/eft/index.html

and there are economies of scale that may not be experienced by health plans. As a result, the \$0.92 estimate is probably less than the amount plans will experience. Table 12 summarizes the estimated increase and savings based on the Department of Treasury's numbers.

The "LOW" savings (Tables 13 and 14, Column 4) are based on a 4 to 6 percent percentage point annual increases in EFT usage attributable to the health care EFT standards, while the "HIGH" savings (Tables 13 and 14, Column 5) are based on an 6 to 8 percentage point annual increases in EFT usage attributable to implementation of the health care EFT standards.

TABLE 13: SAVINGS BY MEDICAID, CHIP, AND INDIAN HEALTH SERVICE ATTRIBUTABLE TO IMPLEMENTATION OF HEALTH CARE EFT STANDARDS*

Year (Column 1)	LOW Number Increase in EFT transactions from Previous Year Attributable to Implementation of Health Care EFT Standards (in millions) (Column 2)	HIGH Number Increase in EFT Transactions from Previous Year Attributable to Implementation of Health Care EFT Standards (in millions) (Column 3)	LOW Savings for Health Plans Based on 6% (first 5 years) to 4% Increase in Usage Attributable to Health Care EFT Standards (\$0.92 per transaction) (in millions) (Column 4)	HIGH Savings for Health Plans Based on 8% (first 5 years) to 6% Increase in Usage Attributable to Health Care EFT Standards (\$0.92 per transaction) (in millions) (Column 5)
2013	0.00	0.0	\$0.00	\$0.00
2014	0.86	1.15	\$0.79	\$1.06
2015	1.12	1.49	\$1.03	\$1.37
2016	1.46	1.94	\$1.34	\$1.79
2017	1.89	2.53	\$1.74	\$2.32
2018	2.46	3.28	\$2.27	\$3.02
2019	2.13	3.20	\$1.96	\$2.95
2020	2.56	3.84	\$2.36	\$3.53
2021	3.07	4.61	\$2.83	\$4.24
2022	3.69	5.53	\$3.39	\$5.09
2023	4.43	6.64	\$4.07	\$6.11
Total	23.68	34.22	\$21.78	\$31.48

*Based on 2010 dollars.

TABLE 14. ESTIMATED SAVINGS BY COMMERCIAL HEALTH PLANS ATTRIBUTABLE TO IMPLEMENTATION OF HEALTH CARE EFT STANDARDS*

Year (Column 1)	LOW Number Increase in EFT transactions from Previous Year Attributable to Implementation of Health Care EFT Standards (in millions) (Column 2)	HIGH Number Increase in EFT Transactions from Previous Year Attributable to Implementation of Health Care EFT Standards (in millions) (Column 3)	LOW Savings for Health Plans Based on 6% (first 5 years) to 4% Increase in Usage Attributable to Health Care EFT Standards (\$0.92 per transaction) (in millions) (Column 4)	HIGH Savings for Health Plans Based on 8% (first 5 years) to 6% Increase in Usage Attributable to Health Care EFT Standards (\$0.92 per transaction) (in millions) (Column 5)
2013	0.00	0.0	\$0.00	\$0.00
2014	1.11	1.48	\$1.02	\$1.36
2015	1.44	1.93	\$1.33	\$1.77
2016	1.88	2.50	\$1.73	\$2.30
2017	2.44	3.25	\$2.25	\$2.99
2018	3.17	4.23	\$2.92	\$3.89
2019	2.75	4.12	\$2.53	\$3.79
2020	3.30	4.95	\$3.04	\$4.55
2021	3.96	5.94	\$3.64	\$5.46
2022	4.75	7.13	\$4.37	\$6.56
2023	5.70	8.55	\$5.25	\$7.87
Total	30.51	44.09	\$28.07	\$40.56

*Based on 2010 dollars.

Table 15 illustrates the total costs and savings for commercial and governmental health plans.

TABLE 15. HEALTH PLANS' LOW AND HIGH RANGE OF COSTS AND SAVINGS*

	LOW (in millions)	HIGH (in millions)
Commercial Health Plans		
Savings	\$28.07	\$40.56
Costs	\$18.34	\$27.58
Medicare and VHA		
Savings	\$0	\$0
Costs	\$0	\$0
Medicaid, CHIP, and IHS health plans		

	LOW (in millions)	HIGH (in millions)
Savings	\$21.78	\$31.48
Costs	\$.41	\$.61
TOTAL		
Savings	\$49.85	\$72.04
Costs	\$18.75	\$28.13

*Based on 2010 dollars

2. Savings for Physician Practices and Hospitals

For physician practices and hospitals, the greater savings to be garnered is the cost avoidance that comes from a decrease in health care provider administrative staff time dedicated to BIR tasks. These might be considered "cost avoidance," in contrast to direct savings, because the decrease in time needed for a staff member to manually conduct functions that can be done electronically does not necessarily mean that money is saved. Rather, it means that the staff time, previously deployed on BIR tasks, can instead be dedicated to other areas, such as customer service for an increasing number of patients.

Calculating cost avoidance is more difficult than calculating material savings, because we must draw assumptions about the business processes a health care provider uses. Nevertheless, there has been research in the area of staff time spent on the administration of health care, specifically in the area of physician practices, from which we can draw some conclusions.

As an example, the VHA did a study of cost avoidance after implementing an "E-payment system" in 2003 with the 1,675 health care "payers" from whom they collect health care claim payments. The new E-payment system implemented a number of different changes to how payers paid VHA claims, including: (1) enabling the VHA to accept ERA (X12 835 TR3) and health care EFT, and urging health plans to transmit remittance advice and payment

electronically; (2) routing the payment to a single lockbox bank; and (3) routing the health care EFT and ERA together for accounts receivable posting.³⁸

Notably, in order to facilitate the reassociation of the health care EFT and ERA, the VHA required that payers use the CCD+Addenda to transmit the health care EFT with the same TRN Segment as that included in the associated ERA.

In cases where health plans transmitted both the health care EFT and the ERA electronically, the VHA found two substantial consequences resulted from the new system. There was a: (1) 71 percent reduction in the time between when a claim was submitted and when the payment was received by the VHA, from 49 days down to 14 days; and (2) 64 percent time savings for accounts receivable and related tasks by 2010. The first result is especially important when applied to small physician practices for which cash-on-hand is crucial for continuity of operations. The second consequence resulted in \$9.3 million in annual cost avoidance for the VHA. In a clear example of how cost avoidance can be of benefit, the 64 percent time saving resulted in the VHA being able to handle 2.5 times the number of claims that were processed before the E-payment system was implemented in 2003 without adding additional staff.

While the VHA found a 64 percent time savings for accounts receivable and related tasks after implementation of its E-payment system, we calculate that there will be a 10 to 15 percent time savings for the health care providers to receive and post payments after implementation of the health care EFT standards. We have estimated a much lower percentage of time savings because the VHA E-payment system was much more comprehensive in its approach to

³⁸ "E-Payment Cures for Healthcare," presentation, Barbara C. Mayerick, Department of Veterans Affairs, April 26, 2010, <https://admin.nacha.org/userfiles/File/Healthcare%20Resource/Epayments%20Cures%20for%20Healthcare.pdf> and "Comments from VHA Health Care as Health Care Provider," testimony by Barbara Mayerick for NCVHS December 3, 2010 hearing: http://hhs.granicus.com/MediaPlayer.php?publish_id=11.

automating accounts receivable process compared to the health care EFT standards adopted in this interim final rule with comment period. However, some of the VHA savings can be attributed to the fact that the VHA E-payment system required payers to use the CCD+Addenda, and we therefore estimate that time savings can likewise be directly attributed to implementation of the health care EFT standards adopted herein.

We estimate that implementation of the health care EFT standards will save a percentage of staff time for two reasons: First, as demonstrated above, there is a direct causal relationship between making payment by EFT more efficient and consistent and an increase in utilization of EFT by physician practices and hospitals. For every health care EFT a physician practice receives from a health plan, there will be time saved because staff will not have to manually open checks, fill out deposit slips and make deposits, create and update spreadsheets or other tools to track check payments, and manually file and organize the paperwork. Second, the standardization of the electronic format and implementation specifications of the Stage 1 Payment Initiation transmission will allow for some assurance that the health care provider will be able to receive a TRN Segment that matches an accompanying ERA. This will decrease staff time necessary to manually oversee the receipt of payment and manually reassociate the health care EFT with the associated ERA. This second benefit of the health care EFT standards will save time not only for health care providers that are increasing their EFT usage, but also for those that currently use EFT with some payers; that is, it will allow for automation of current EFT claim payments that may not be fully automated due to erroneous or missing TRN Segments in the EFT.

Given these two elements of cost savings in receiving and posting payments, we estimate that there will be a 10 to 15 percent savings in the time spent receiving and posting payments in a

physician practice every time a physician practice or hospital enroll to receive EFTs from a health plan (in comparison to when a physician practice receives paper checks). We believe this estimate to be low, as a 15 percent savings in time might be achieved solely in terms of the time saved by not having a staff member manually transport and deposit paper checks.

We expect that the forthcoming operating rules required to be adopted for the health care EFT and remittance advice transaction will provide further cost avoidance benefits in terms of time savings.

For our calculations, data on the amount of time that is currently spent on "payment and posting" tasks is taken from Sakowski, et al., 2009.³⁹ Sakowski found that a total of 0.67 nonclinical full time employees (FTEs) were dedicated to BIR activities per physician in a sample of California physician practices. Of those BIR tasks, 14 percent included "payment receiving and posting" tasks, and we estimate there will be time savings in these specific tasks upon implementation of the health care EFT standards. The 14 percent does not include follow-up on payments and the reconciliation of payments received with payments pending. Although the health care EFT standards may streamline these tasks as well, more direct savings are found in receiving and posting payments.

Based on Sakowski and 2010 statistics from the U.S. Bureau of Labor Statistics, we calculate the total time dedicated to receiving and posting payments for all physician practices and hospitals (Table 16, Column 2). The calculation for the total time dedicated to receiving and posting payments for physician practices is: [percent of time full time employee is dedicated to BIR tasks per physician] X [total number of physicians in physician practices] X [percent of BIR

³⁹ Sakowski, J.A., Kahn, J.G., Kronick, R.G., Newman, J.M., & Luft, H.S., "Peering into the black box: Billing and insurance activities in a medical group," *Health Affairs*: 28(4):w544-w554, 2009.

time spent on "payment and posting"]. For hospitals, we used a slightly different methodology based on the ratio of physicians to administrative staff conducting BIR tasks in physician practices.

The total time dedicated to receiving and posting payments is then multiplied by 10 percent for the LOW time savings attributable to the health care EFT standards and 15 percent for the HIGH time savings, the products of which are illustrated in Table 16 and 17, Columns 2 and 3. The 10 to 15 percent time savings occurs every time physician practices and hospitals, as a whole, moves from paper checks to EFT with one health plan. Given our assumptions of the increased use of EFT for health care claim payments, the average hospital and physician practice will begin receiving health care claim payments via EFT from 12 health plans (from whom they had previously received paper checks) between 2014 to 2023 (Table 16 and 17, Col. 5). For simplicity sake, we have projected this movement from paper checks to EFT as spread evenly over ten years, and illustrated in Table 16 and 17 that physician practices and hospitals, as a whole, make the switch with 1.2 health plans a year. We then multiplied each year's time savings by the average salary of a billing and posting clerk in physician practices (Table 16 and 17, Column 4), to arrive at the projected yearly cost savings attributable to implementation of the health care EFT standards. The range of 10 to 15 percent reflects the uncertainty inherent in the estimate of time savings. However, it should be noted that the VHA found a 64 percent time savings across all accounts receivable and related tasks, while our estimate reflects a time savings in "receiving and posting payments" only.

TABLE 16. PHYSICIAN PRACTICE SAVINGS/COST AVOIDANCE ATTRIBUTABLE TO IMPLEMENTATION OF HEALTH CARE EFT STANDARDS

(Col.1)	LOW time savings (in FTEs) attributable to EFT Standard (10% decrease in payment and posting time spent per EFT enrollment) (Col. 2)	HIGH time savings (in FTEs) attributable to health care EFT Standard (15% decrease in payment and posting time spent per EFT enrollment) (Col.3)	Salary per FTE (baseline 2010 Bureau of Labor Statistics, plus benefits and 3% annual increase (Col. 4)	Average number of new EFT enrollment per provider (Col. 5)	Low Cost Avoidance of projected EFT enrollments in millions (Col. 6)	High Cost Avoidance of projected EFT enrollments in millions (Col. 7)
2013	0	0	48,250	0	\$0.00	\$0.00
2014	3,143	4,715	49,698	1.2	\$187.47	\$281.20
2015	2,876	4,079	51,189	1.2	\$176.68	\$250.53
2016	2,950	4,245	52,725	1.2	\$186.65	\$268.57
2017	2,975	4,269	54,306	1.2	\$193.89	\$278.18
2018	3,005	4,314	55,935	1.2	\$201.72	\$289.55
2019	3,035	4,356	57,614	1.2	\$209.81	\$301.14
2020	3,064	4,398	59,342	1.2	\$218.21	\$313.20
2021	3,094	4,441	61,122	1.2	\$226.92	\$325.70
2022	3,129	4,491	62,956	1.2	\$236.38	\$339.31
2023	3,164	4,541	64,845	1.2	\$246.17	\$353.35
Total				12	2,084	3,001

*From Sakowski, et al., 2009, and Bureau of Labor Statistics

TABLE 17. HOSPITAL SAVINGS/COST AVOIDANCE ATTRIBUTABLE TO IMPLEMENTATION OF HEALTH CARE EFT STANDARDS

(Col.1)	LOW time savings (in FTEs) attributable to EFT Standard (10% decrease in payment and posting time spent per EFT enrollment) (Col. 2)	HIGH time savings (in FTEs) attributable to health care EFT Standard (15% decrease in payment and posting time spent per EFT enrollment) (Col.3)	Salary per FTE (baseline 2010 Bureau of Labor Statistics, plus benefits and 3% annual increase (Col. 4)	Average number of new EFT enrollment t per provider (Col. 5)	Low Cost Avoidance of projected EFT enrollments in millions (Col. 6)	High Cost Avoidance of projected EFT enrollments in millions (Col. 7)
2013	0	0	\$48,250	0	\$0.00	\$0.00
2014	1,557	2,335	\$49,698	1.2	\$92.85	\$139.28
2015	1,425	2,020	\$51,189	1.2	\$87.51	\$124.09

2016	1,461	2,102	\$52,725	1.2	\$92.45	\$133.02
2017	1,474	2,114	\$54,306	1.2	\$96.03	\$137.78
2018	1,488	2,137	\$55,935	1.2	\$99.91	\$143.41
2019	1,503	2,157	\$57,614	1.2	\$103.92	\$149.15
2020	1,518	2,178	\$59,342	1.2	\$108.08	\$155.12
2021	1,532	2,199	\$61,122	1.2	\$112.39	\$161.32
2022	1,550	2,225	\$62,956	1.2	\$117.08	\$168.06
2023	1,567	2,249	\$64,845	1.2	\$121.92	\$175.01
Total					\$1,032.	\$1,486

We note a number of assumptions built into the calculations illustrated in Tables 16 and 17:

- The number of physicians in the United States will grow considerably between 2014 and 2023. Our estimates are based on projections of physician supply and demand by the Association of American Medical Colleges.⁴⁰ In spite of the estimated time savings realized by implementation of the health care EFT standards, overall time spent on payment and posting tasks for physicians will remain constant or even increase due to the increase in physicians (which, in turn, is due to an increase in expected claims over the next twenty years).
- The number of FTEs who spend time on BIR tasks per physician remains constant between 2014 and 2023. While we expect that efficiencies will be developed through administrative simplification and other federal, state and industry initiatives, the

⁴⁰ “Physician Shortages to Worsen Without Increases in Residency Training,” Association of American Medical Colleges fact sheet at https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf, from AAMC Center for Workforce Studies, June 2010 Analysis.

administrative complexity involved in the projected increase in the number of claims may counter balance any decreases in the ratio of administrative staff to clinical staff.

- The salary of a billing and posting clerk FTE increases at a rate of 3% a year.

We project the health care EFT standard and other statutory and regulatory requirements will save staff time by making it possible for health care providers to automate more and more of their BIR tasks.

3. Benefits to Patients

A 2002 study concluded that there is an inverse relationship between administrative complexity and quality of care.⁴¹ The study analyzed data from the National Committee for Quality Assurance's (NCQA) Quality Compass 1997, 1998, and 2000. In essence, the study compared administrative costs to quality indicators and found that "Higher administrative costs were associated with worse quality for virtually every quality measure in each of the four years... The correlation coefficients were remarkably stable from year to year, suggesting that high administrative costs did not facilitate quality improvement over time."⁴²

The study did not describe reasons for this correlation, beyond commentary on excess costs in the U.S. health care industry in general, nor will we attempt to draw any quantifiable patient benefits in our impact analysis. However, as we have illustrated, the average physician practice and hospital is spending an increasing amount of time (60 hours of staff time per week per physician interacting with health plans⁴³) and money (10 to 14 percent of physician practice revenue) on BIR tasks. We can conclude that, overall, the time and money spent on BIR tasks are increasingly encroaching on the time and money spent on delivering quality health care.

⁴¹ Himmelstein, D. U .and Woolhandler, S., "Taking care of Business: HMOs that spend more on administration deliver lower-quality care," International Journal of Health Services, Volume 32, Number 4, 2002.

⁴² Himmelstein, et.al.

⁴³ Casalino, et al.

4. Benefits to the Environment

As an electronic, paperless exchange, the benefits of the use of EFT reverberate through our environment. Table 16 illustrates some of the environmental benefits to using EFT. The calculator was developed under a NACHA initiative entitled "Pay It Green" to persuade consumers to pay bills online and persuade companies to deposit salaries through EFT Direct Deposit based on its positive environmental impacts.⁴⁴ The data entered into the calculator are our estimated number of increased EFT, year after year, attributable to implementation of the health care EFT standards. Table 18 illustrates the environmental savings or cost avoidance that is gained by an estimated increase in EFT usage, attributable to the implementation of the health care EFT standards, from 2014 to 2023.

TABLE 18. BENEFITS TO THE ENVIRONMENT BASED ON INCREASED USAGE OF EFT ATTRIBUTABLE TO HEALTH CARE EFT STANDARDS*

Number of Payments that Move from Paper Check to EFT Attributable To Health Care EFT Standards (in millions) (LOW estimate)	Pounds of Paper Saved**	Pounds of Greenhouse Gas Avoided	Gallons of Gasoline Saved***	Gallons of Wastewater prevented from discharging into rivers and lakes	Pounds of Waste Prevented
50.94	794,000	2,259,000	292,000	7,566,000	905,000

*Taken from calculations derived from NACHA "Pay It Green" Organization, "Direct Deposit Financial Paper Footprint Calculator (<http://www.payitgreen.org/business/dirDepCalculator.aspx>)

** Data on the environmental impact of producing paper for checks was taken from Environmental Defense Fund's Paper Calculator (available at www.edf.org/papercalculator/).

*** Data on the greenhouse gas impact of printing and transporting paper checks and bills was provided by the "Life and Travels of a Paper Check" study done for NACHA. Additional greenhouse gas data related to transportation was calculated using the World Resources Institute's Mobile Combustion Calculator (available at www.ghgprotocol.org).

G. Summary

⁴⁴ <http://www.payitgreen.org/business/dirDepCalculator.aspx>

Although we have calculated savings as a result of usage of the health care EFT standards, our calculations appear significantly lower than analogous calculations in other studies and reports.

For example, the UnitedHealth Group reported in a 2009 working paper that \$108 billion could be saved industry wide over the course of ten years if health care claim payments were required to be paid via EFT and remittance advice was required to be transmitted electronically.⁴⁵ The UnitedHealth Group appeared to base the savings solely on industry-wide adoption of the EFT and the ERA, and not on any associated operating rules or consistent application of standard implementation specifications.

The Healthcare Efficiency Index National Progress Report on Healthcare Efficiency, sponsored by Emdeon, a health care clearinghouse, estimates an annual savings of \$11 billion if the industry were to use EFT for 100 percent of health care claim payments.⁴⁶ Our savings analysis is based on use of EFT for approximately 84 percent of health care claim payments by 2023, but our savings are significantly less than the Healthcare Efficiency reported.

In one recent study, the estimated total BIR costs to the health care industry were estimated at \$361 billion in 2009. From a survey of other studies, the study concludes that \$65 to \$70 billion a year is "excess" cost to physicians. "Excess" was defined as spending above a benchmark comparison with Canadian physicians.⁴⁷

⁴⁵ "The Health Care Cost Containment--How Technology Can Cut Red Tape and Simplify Health Care Administration," UnitedHealth Center for Health Reform & Modernization, Working Paper 2, June 2009, http://www.unitedhealthgroup.com/hrm/UNH_Working_Paper2.pdf

⁴⁶ "The Health Care Cost Containment--How Technology Can Cut Red Tape and Simplify Health Care Administration," UnitedHealth Center for Health Reform & Modernization, Working Paper 2, June 2009, http://www.unitedhealthgroup.com/hrm/UNH_Working_Paper2.pdf

⁴⁷ Kahn, James, "Excess Billing and Insurance-Related Administrative Costs," in The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary, edited by Yong, P.L., Saunders, R. S. , & Olsen, L. A.

None of these studies specifically examined the impact of the health care EFT standards adopted in this interim final rule with comment period, and the health care EFT standards will only decrease BIR costs by a small percent of total "excess." However, the savings estimated in these studies reflect the extent to which the health care EFT standards, and all subsequent standards adopted under section 1104 of the ACA, may impact U.S. healthcare.

Costs and savings of implementing the health care EFT standards for the health care industry are summarized in Table 19, and range of return on investment is illustrated in Table 20.

TABLE 19. TOTAL COSTS AND SAVINGS OF IMPLEMENTING THE HEALTH CARE EFT STANDARDS FOR HEALTH CARE INDUSTRY

Year	LOW Estimate Total Costs (in millions)*	HIGH Estimate Total Costs (in millions)*	LOW Estimate, Total Savings (in millions)	HIGH Estimate Total Savings (in millions)
Cumulative total over 10 years	\$28	\$38	\$3,166	\$4559

*Includes cost of provider enrollment in EFT described in COI.

TABLE 20. RANGE OF RETURN ON INVESTMENT

	LOW (LOW Savings - HIGH Cost) (in millions)	HIGH (HIGH Savings - LOW Cost) (in millions)
Range of Return on Investment: Entire Industry	\$3,128	\$4,531

H. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4/), in Table 21 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this interim final rule. This table provides our best estimate of the costs and benefits associated with the implementation of the health care EFT standards adopted herein.

TABLE 21. ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2013 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	\$271.5	\$391.3	RIA
3% Discount	Not estimated	\$280.8	\$404.5	RIA
Qualitative (un-quantified) benefits	Wider use of EFT due to adoption of standards; ability to re-associate EFT and RA; increased cost avoidance due to decrease in manual requirements.			
Benefits generated from plans to physician practices and hospitals. It is probable that other providers will experience proportional benefits.				
COSTS				
Annualized Monetized costs				
7% Discount	Not Estimated	\$3.0	\$4.1	RIA and COI
3% Discount	Not Estimated	\$2.8	\$3.7	RIA and COI
Qualitative (un-quantified) costs	None	None	None	
Physician practices and hospitals will have costs associated with enrollment in EFT, if they choose to enroll. Other categories of providers may have similar costs. Health plans will pay costs to software vendors, programming and IT staff/contractors, and clearinghouses.				
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 Subchapter C to read as follows:

PART 160 – GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues 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

2. Amend §160.103 as follows:

- A. Redesignating paragraph (11) to the definition of "transaction" as paragraph (12).
- B. Adding a new paragraph (11) to the definition of "transaction".

The addition read as follows:

§ 160.103 Definitions.

* * * * *

Transaction * * *

(11) Health care electronic funds transfers (EFT) and remittance advice.

* * * * *

PART 162 – ADMINISTRATIVE REQUIREMENTS

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

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d-1320d-9), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, sec. 105 of Pub. L. 110-233, 122 Stat. 881-922, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034

(42 U.S.C. 1320d-2 (note), and secs. 1104 and 10109 of Pub. L.111-148, 124 Stat. 146-154 and 915-917.

Subpart A – General Provisions

4. Amend §162.103 by adding the definition of "Stage 1 payment initiation" to read as follows:

§ 162.103 Definitions.

* * * * *

Stage 1 payment initiation means a health plan's order, instruction or authorization to its financial institution to make a health care claims payment using an electronic funds transfer (EFT) through the ACH Network.

* * * * *

Subpart I—General Provisions for Transactions

5. Amend §162.920 by adding a new paragraph (d) to read as follows:

§162.920 Availability of implementation specifications and operating rules.

* * * * *

(d) The National Automated Clearing House Association (NACHA), The Electronic Payments Association, 1350 Sunrise Valle Drive, Suite 100, Herndon, Virginia 20171 (Phone) 703-561-1100; (Fax) 703-713-1641; E-mail: info@nacha.org; and Internet at <http://www.nacha.org>. The implementation specifications are as follows:

(1) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules, Appendix One: ACH File Exchange Specifications (Operating Rule 59) as referenced in §162.1602.

(2) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules Appendix Three: ACH Record Format Specifications (Operating Rule 78), Part 3.1, Subpart 3.1.8 Sequence of Records for CCD Entries as referenced in §162.1602.

6. Revise the heading of Subpart P to read as follows:

Subpart P--Health Care Electronic Funds Transfers (EFT) and Remittance Advice

§162.1601 [Amended]

7. In §162.1601, paragraph (a) introductory text is amended by removing the phrase "provider's financial institution" and adding the term "provider" in its place.

8. Section 162.1602 is revised to read as follows:

§ 162.1602 Standards for health care electronic funds transfers (EFT) and remittance advice transaction.

The Secretary adopts the following standards:

(a) For the period from October 16, 2003 through March 16, 2009: Health care claims and remittance advice. The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in §162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both of the following standards:

(1) The standard identified in paragraph (a) of this section.

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in §162.920.)

(c) For the period from January 1, 2012 through December 31, 2013, the standard identified in paragraph (b)(2) of this section.

(d) For the period on and after January 1, 2014, the following standards:

(1) Except when transmissions as described in §162.1601(a) and (b) are contained within the same transmission, for Stage 1 Payment Initiation transmissions described in §162.1601(a), all of the following standards:

(i) The National Automated Clearing House Association (NACHA) Corporate Credit or Deposit Entry with Addenda Record (CCD+) implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network as follows (incorporated by reference in §162.920)--

(A) NACHA Operating Rules, Appendix One: ACH File Exchange Specifications; and

(B) NACHA Operating Rules, Appendix Three: ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries.

(ii) For the CCD Addenda Record ("7"), field 3, of the standard identified in 1602(d)(1)(i), the Accredited Standards Committee (ASC) X12 Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), April 2006: Section 2.4: 835 Segment Detail: "TRN Reassociation Trace Number," Washington Publishing Company, 005010X221 (Incorporated by reference in §162.920).

(2) For transmissions described in §162.1601(b), including when transmissions as described in §162.1601(a) and (b) are contained within the same transmission, the ASC X12

Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in §162.920).

CMS-0024-IFC

Dated: November 16, 2011

Donald M. Berwick,

Administrator.

Centers for Medicare & Medicaid Services

Dated: December 28, 2011

Kathleen Sebelius,

Secretary,

Department of Health and Human Services

BILLING CODE: 4120-01-P

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