DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–0016–P]

RIN 0938–AO66

Medicare Program; Proposed Standards for E-Prescribing Under Medicare Part D

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes the adoption of final uniform standards for an electronic prescription drug program as required by section 1860D–4(e)(4)(D) of the Social Security Act (the Act). It also proposes the adoption of a standard identifier for providers and dispensers for use in e-prescribing transactions under sections 1860D–4(e)(3) and 1860D–4(e)(4)(C)(ii), and section 1102 of the Social Security Act. The standards proposed under section 1860D–4(e)(4)(D) have been pilot tested and evaluated, and the findings indicate that the proposed standards meet the requirements for final standards that can be used for the Medicare Part D e-prescribing programs. The standards proposed in this rule, in addition to the foundation standards that were already adopted as final standards (see 70 FR 67568), represent an ongoing approach to adopting standards that are consistent with the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) objectives of patient safety, quality of care, and efficiencies and cost saving in the delivery of care.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 15, 2008.

ADDRESSES: In commenting, please refer to file code CMS–0016–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention CMS–0016–P, P.O. Box 8014, Baltimore, MD 21244–8014.

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 (one original and two copies) to the following address ONLY: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS–0016–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses: If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHS 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.)

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

Submission of comments on paperwork requirements: You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: Denise M. Buenning, (410) 786–6711.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code (CMS–0016–P) and the specific ''issue identifier'' that precedes the section on which you choose to comment.

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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (800) 743–3951.

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I. Background

A. Legislative History

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Social Security Act (the Act) to establish

a voluntary prescription drug benefit program.

Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MA–PD), are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and pharmacist. This would include information about eligibility, benefits (including drugs included in the applicable formulary, any tiered formulary structure and any requirements for prior authorization), the drug being prescribed or dispensed and other drugs listed in the medication history, as well as the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed. The MMA directed the Secretary to promulgate uniform standards for the electronic transmission of such data.

There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, would be required to comply with any applicable final standards that are in effect.

Section 1860D–4(e)(4) of the Act generally required the Secretary to conduct a pilot project to test initial standards recognized under 1860D–4(e)(4)(A) of the Act, prior to issuing the final standards in accordance with section 1860D–4(e)(4)(D) of the Act. The initial standards were recognized by the Secretary in 2005 and then tested in a pilot project during calendar year (CY) 2006. The MMA created an exception to the requirement for pilot testing of standards where, after consultation with the National Committee on Vital and Health Statistics (NCVHS), the Secretary determined that there already was adequate industry experience with the standard(s). The first set of such standards, the ''foundation standards,'' were recognized and adopted through notice and comment rulemaking as final standards without pilot testing. See 70 FR 67568.

Based upon the evaluation of the pilot project, and not later than April 1, 2008, the Secretary is required to issue final uniform standards under section 1860D–4(e)(4)(D). These final standards must be effective not later than 1 year after the date of their issuance.

In the e-prescribing final rule at 70 FR 67589, we also discussed the estimated start-up costs for e-prescribing for providers and/or dispensers. Based on industry input, we cited approximately $3,000 for annual support, maintenance, infrastructure and licensing costs. Physicians at that time reported paying user-based licensing fees ranging from $80 to $400 per month. For further discussion of the start-up costs associated with e-prescribing, see the regulatory impact analysis section of this proposed regulation, and the e-prescribing final rule at 70 FR 67589.

For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

B. Regulatory History

In the e-prescribing final rule at 70 FR 67589, we also discussed the estimated start-up costs for e-prescribing for providers and/or dispensers. Based on industry input, we cited approximately $3,000 for annual support, maintenance, infrastructure and licensing costs. Physicians at that time reported paying user-based licensing fees ranging from $80 to $400 per month. For further discussion of the start-up costs associated with e-prescribing, see the regulatory impact analysis section of this proposed regulation, and the e-prescribing final rule at 70 FR 67589.

In the November 7, 2005 final rule, we addressed the issues of privacy and security relative to e-prescribing in general. We noted that disclosures of protected health information (PHI) in connection with e-prescribing transactions would have to meet the minimum necessary requirements of the Privacy Rule if the entity is a covered entity (70 FR 6161). It is important to note that health plans, prescribers, and dispensers are HIPAA covered entities, and that these covered entities under HIPAA must continue to abide by the applicable HIPAA standards including these for privacy and security. E-prescribing provisions do not affect or alter the applicability of the Privacy Act to a particular entity. Entities which are covered by the Privacy Act and the HIPAA Privacy Rule must comply with provisions of both. Entities are responsible for determining whether they fall under the Privacy Act.

We continue to agree that privacy and security are important issues related to e-prescribing. Achieving the benefits of e-prescribing require the prescriber and dispenser to have access to patient medical information that may not have been previously available to them. Section 1860–D(e)(2)(C) of the Act requires that disclosure of patient data in e-prescribing must, at a minimum, comply with HIPAA's privacy and security requirements.

Although HIPAA standards for privacy and security are flexible and scalable to each entity's situation, they provide comprehensive protections. We will continue to evaluate additional standards for consideration as adopted e-prescribing standards. For further discussion of privacy and security and e-prescribing, refer to the final rule at 70 FR 67581 through 82.

1. Foundation Standards

After consulting with the NCVHS, the Secretary found that there was adequate industry experience with several potential e-prescribing standards. Upon adoption through notice and comment rulemaking, these standards were called ''foundation'' standards, because they would be the first set of final standards adopted for an electronic prescription drug program. Three standards were adopted for purposes of e-prescribing in the E-Prescribing and the Prescription Drug Program final rule, published November 7, 2005 (70 FR 67568). Two of these standards, Accredited Standards Committee (ASC) X12N 270/271; and The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), were previously adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and have been in effect since 2001.

These foundation standards are as follows:

For the exchange of eligibility information between prescribers and Medicare Part D sponsors: Accredited Standards Committee (ASC) X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company. 004010X092A1 (hereafter referred to as the ASC X12N 270/271 standard).

For the exchange of eligibility inquiries and responses between dispensers and Medicare Part D sponsors: The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide Version

5, Release 1 (Version 5.1) for NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunications Standard).

For the exchange of new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers: NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), hereafter referred to as NCPDP SCRIPT 5.0.

a. Exemptions to Foundation Standard Requirement for Nonprescribing Providers

In 42 CFR 423.160(a)(3)(iii) we exempt entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser from the requirement to use the NCPDP SCRIPT Standard 5.0 adopted by this section in transmitting such prescriptions or prescription-related information.

Industry comments indicated that while the e-prescribing standards we proposed were proven to have adequate industry experience in the ambulatory setting, the NCPDP SCRIPT Standard was not proven to support the workflows and legal responsibilities in the long-term care setting. As such, we exempted entities from the requirement to use the NCPDP SCRIPT standard when that entity is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser. The CY 2006 pilot project tested for such entities' use of the foundation standards in ''three-way prescribing communications'' between facility, physician, and pharmacy. (For a more detailed discussion see the November 7, 2005 final rule (70 FR 67583).

b. Use of HL7 or NCPDP SCRIPT Standard To Conduct Internal Electronic Transmittals for Specified NCPDP SCRIPT Transactions

In the E-Prescribing and the Prescription Drug Program final rule, published November 7, 2005 (70 FR 67568), we responded to comments on whether Medicare Part D plans should be required to use the standards for e-prescribing transactions taking place within their own enterprises. In the final rule we stated that entities may use either HL7 or NCPDP SCRIPT standards to conduct internal electronic transmittals for the specified NCPDP SCRIPT transactions. However, entities are required to use the NCPDP SCRIPT Standard if they electronically send prescriptions for Medicare beneficiaries outside the organizations, such as to a non-network pharmacy. Any pharmacy that already accepts e-prescriptions, even if only as a part of a larger legal entity, must be able to receive electronic prescription transmittals for Medicare beneficiaries via NCPDP SCRIPT from outside the enterprise.

c. Exemption for Computer-Generated Facsimiles

The November 7, 2005 final rule also exempted entities that transmit prescriptions or prescription-related information by means of computer-generated facsimile (faxes) from the requirement to use the adopted NCPDP SCRIPT standard. ''Electronic media'' was already defined by regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), so e-prescribing utilized the same definition. As a result, faxes that were generated by a prescriber's computer and sent to a dispenser's computer or fax machine which prints out a hard copy of the original computer-generated fax (that is, ''computer-generated'' faxes) fell within the definition of ''electronic media'' for e-prescribing. Absent an exemption, computer-generated faxes would be required to comply with the adopted foundation standards. The November 7, 2005 final rule exempted computer-generated faxes from having to comply with the NCPDP SCRIPT standard.

In June 2007, CMS proposed to eliminate this exemption. See 72 FR 38195 through 38196 for a discussion of the elimination of this exemption.

2. Updating e-Prescribing Standards

In the November 7, 2005 final rule (70 FR 67579), we discussed the means for updating e-prescribing standards. If an e-prescribing transaction standard has also been adopted under 45 CFR parts 160 through 162 (that is, as HIPAA transaction standards), the updating process for the e-prescribing transaction standard must be coordinated with the maintenance and modification of the applicable HIPAA transaction standard. As the final rule adopted and incorporated by reference the relevant HIPAA transaction standards (the ASC X12N 270/271 and the NCPDP Telecommunication Standard), the e-prescribing standards can be modified through a parallel rulemaking whenever the HIPAA transaction standards are modified. A streamlined process was created for updating adopted e-prescribing standards that were not also HIPAA transaction standards. This is done by identifying backward compatible later versions of the standards. This version updating and maintenance of the implementation specifications for the adopted non-HIPAA e-prescribing standards will allow for the correction of technical errors, the elimination of technical inconsistencies, and the addition of functions that support the specified e-prescribing transaction. To do this, we adopted a process for the Secretary to identify a subsequent version(s) of a standard where the new version(s) are backwards compatible with the adopted standard. Use of such subsequent versions of an adopted standard is voluntary. Because HIPAA transaction standards are presently not backward compatible and the HIPAA transactions standards regulation does not currently address the use of subsequent versions of adopted standards that are backward compatible to the adopted standards, the streamlined process cannot presently be used for those HIPAA transactions standards that are also e-prescribing standards.

Subsequent industry input indicated that the adopted NCPDP SCRIPT 5.0, should be updated with a later version of the standard NCPDP SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill), hereafter referred to as NCPDP SCRIPT 8.1.

Using the streamlined process, HHS published an Interim Final Rule on June 23, 2006 (71 FR 36020) updating the adopted NCPDP SCRIPT standard, thereby permitting either version to be used. For more information, see the June 23, 2006 interim final rule with comment (71 FR 36020).

3. National Provider Identifier (NPI)

In the November 7, 2005 final rule (70 FR 67578), we discussed the use of the National Provider Identifier (NPI) for the Medicare Part D e-prescribing program once it became available. The NPI is the standard that was adopted in the final rule published on January 23, 2004 (69

FR 3434) as the unique health identifier for health care providers that are HIPAA covered entities for use in the health care system. Health plans, health care clearinghouses, and those health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard (known as ''covered health care providers'') are considered ''covered entities'' which must use the identifier in connection with HIPAA standard transactions. For a discussion of the NPI, see the final rule published on January 23, 2004 (69 FR 3434).

In the November 7, 2005 final rule (70 FR 67578), in response to comments received in the February 4, 2005 proposed rule, we indicated that we would include the NPI in the 2006 pilots to determine how it worked with e-prescribing standards. However, we also noted that accelerating NPI usage for e-prescribing might not be possible, as we might not have had the capacity to issue NPIs to all providers involved in the e-prescribing program by January 1, 2006. At the time the Request for Application was released, we had just begun to use the National Plan/Provider Enumeration System (NPPES) to process provider requests for NPIs. Upon reconsideration and in view of the short time period allowed for pilot testing, it was determined that the focus should be on standards testing and not on NPI as it would constitute a simple bench testing of the identifier and would have no substantive results. Therefore, NPI was not assessed during the pilots, which used other identifiers to accomplish their testing of the standards as outlined in the Request for Application.

C. Pilot Testing of Initial Standards

The MMA required the Secretary to develop, adopt, recognize or modify ''initial uniform standards'' relating to the requirements for the e-prescribing programs in 2005. To ensure the efficient implementation of the e-prescribing program requirements, the MMA called for pilot testing of these initial e-prescribing standards in 2006. To fulfill this requirement, the Secretary ultimately recognized (based on NCVHS input) six ''initial'' standards, which are discussed below. A Request for Applications (RFA) was issued in September 2005 that laid out the details for how these initial standards were to be pilot tested (Available through *http://www.grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html).* The pilot test was conducted under four cooperative agreements and one contract that the Agency for Healthcare Research and Quality (AHRQ) entered into on behalf of CMS. The final pilot site reports are available at *http://www.healthit.ahrq.gov/erxpilots.*

1. Initial Standards

[If you choose to comment on issues in this section, please include the caption ''Initial Standards'' at the beginning of your comments.]

As HHS had not yet published a final rule identifying the foundation standards at the time the RFA was published, it conditionally included the proposed foundation standards among the ''initial standards'' to be tested. Any proposed foundation standards that were not adopted as foundation standards were to be tested as initial standards in the pilot project. Furthermore, if the proposed foundation standards were ultimately adopted as foundation standards, those standards nevertheless were to be used in the pilot project to ensure interoperability with the initial standards. A summary of the initial standards follows:

- Formulary and benefit information—The formulary and benefits standard, NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (version 1.0), hereinafter referred to as the NCPDP Formulary and Benefits Standard 1.0, is intended to provide prescribers with information from a plan about a patient's drug coverage at the point of care.
- Exchange of medication history—The medication history standard, included in the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard, Version 8 Release 1 and its equivalent NCPDP Prescriber/Pharmacist Interface SCRIPT Implementation Guide, Version 8, Release 1, is intended to provide a uniform means for prescribers and payers to communicate about the list of drugs that have been dispensed to a patient.
- Structured and Codified SIG—The standard tested was NCPDP's proposed Structured and Codified SIG Standard 1.0. Structured and Codified SIG—instructions for taking medications (such as ''by mouth, three times a day'')—that are currently expressed as free text at the end of a prescription.
- Fill status notification function—The Fill Status Notification, or RxFill, was included in the NCPDP SCRIPT 5.0, and the updated NCPDP SCRIPT 8.1 but it previously was not proposed as a foundation standard due to lack of industry experience. The dispenser uses the prescription fill status transaction to notify the prescriber if a patient has picked up a prescribed medication at the pharmacy.
- Clinical drug terminology (RxNorm)—RxNorm, a standardized nomenclature for clinical drugs developed by the National Library of Medicine (NLM), provides standard names for clinical drugs (active ingredient + strength + dose form) and for dose forms as administered to a patient.
- Prior authorization messages—The pilot sites tested to determine the functionality of new versions of the ASC X12N 275, Version 4010 with HL7 and ASC X12N 278, Version 4010A1 to obtain certification from the plan to a provider that the patient meets criteria for a drug to be covered.

The RFA also specified that pilot sites would use NCPDP SCRIPT 5.0. With the Secretary's recognition of the updated NCPDP SCRIPT 8.1, AHRQ, in its capacity as the administrator of the pilot project, gave pilot sites the option to voluntarily use NCPDP SCRIPT 8.1. Accordingly, all grantees/contractor in the pilot sites voluntarily employed the updated NCPDP SCRIPT 8.1 in their various testing modalities.

2. Grantees/Contractor and Testing Criteria

[If you choose to comment on issues in this section, please include the caption ''Grantees/Contractor and Testing Criteria'' at the beginning of your comments.]

The initial standards were tested in five healthcare/geographic settings to determine whether they were ready for broad adoption. Grantees/contractor tested whether the initial standards allowed participants to effectively communicate the necessary information between all participants in the transactions, such as the pharmacy, pharmacy benefits manager (PBM), router, plan and prescriber. They also tested how the initial standards worked with the foundation standards. Pilot sites also tracked generally anticipated e-prescribing outcomes, such as a reduction in medical errors. For more information on testing parameters and criteria, go to *http://www.grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html.*

One of the strengths of the pilot project was the diversity and uniqueness of the five grantees/contractor. Grantees/contractor represented the spectrum of communities involved with e-prescribing, including most practice settings, and focused on utilization by pharmacists, physicians, nurses, and technology vendors. Applications were considered based on specific

characteristics/criteria. Each pilot site focused on different perspectives of the functionality and impact of initial standards by evaluating them in different sectors of the healthcare system, different geographies, and different practice settings using different technology application vendors, pharmacies and other stakeholders in the e-prescribing industry. The grantees selected were Achieve Healthcare Information Technologies, L.L.P., Eden Prairie, Minnesota; Brigham and Women's Hospital, Boston, Massachusetts; RAND Corporation, Santa Monica, California; SureScripts, L.L.C., Alexandria, Virginia. The contractor that was selected was the University Hospitals Health System, Cleveland, Ohio. For more information on the pilot project criteria, refer to the Request for Application at *http://www.grants.nih.gov/guide/RFA–HS–06–001.html.*

3. Pilot Test Findings

[If you choose to comment on issues in this section, please include the caption ''Pilot test findings'' at the beginning of your comments.]

a. Standard for Formulary and Benefits

In the February 4, 2005 proposed rule, we discussed how the adoption of the formulary and benefit standard would enhance e-prescribing capabilities under Medicare Part D by making it possible for the prescriber to obtain information on the patient's benefits, including the formulary status of drugs that the physician is considering prescribing. At that time, we proposed characteristics for a formulary and benefit standard (for a more detailed discussion refer to 70 FR 6262 through 6263). We proposed that if those characteristics for formulary were met by a standard and there was adequate industry experience with it, we would consider adopting it as a foundation standard. The NCVHS, in a September 2, 2004 letter to the Secretary (*http://www.ncvhs.hhs.gov*), had recommended the development of an NCPDP formulary and benefit standard, based on an RxHub protocol, to address the need for these desirable characteristics. RxHub submitted this protocol to NCPDP for approval and it was included in the October 2005 release of NCPDP Formulary and Benefit standard 1.0. However, the timing of its release in October 2005 was too late for the Formulary and Benefit standard 1.0 to be considered for approval as a foundation standard in the November 7, 2005 final rule. Also, there was little to no industry experience with the standard. Because of this and other concerns about its interoperability with other standards, at that time we did not adopt NCPDP Formulary and Benefit standard 1.0 as a foundation standard, but agreed to include it in pilot testing. For more details, refer to 70 FR 67573.

Formulary and benefits data standards must provide a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

The NCPDP Formulary and Benefits Standard 1.0 enables the prescriber to consider this information during the prescribing process, and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the health plan.

The NCPDP Formulary and Benefits Standard 1.0 was implemented live in all pilot sites, and technology vendors were certified prior to production. This standard works in tandem with the eligibility request and response (ASC X12N 270/271). Once the individual is identified, the appropriate drug benefit coverage is located and transmitted to the requestor.

The pilot sites demonstrated that the NCPDP Formulary and Benefits Standard 1.0 can be successfully implemented between prescriber and plan. The NCPDP Formulary and Benefits Standard 1.0 is quite broad, and there are a number of complex data relationships supported by the standard. This complexity creates a certain level of confusion as to how to properly use the data and leads to implementation issues. While complex, the standard can support the transaction, and is ready for implementation as part of the e-prescribing program under Medicare Part D.

Formularies by their very nature are complex. They consist of hundreds of pages of drug names, dosages, etc., that frequently change due to updates in formulations, coverage decisions, etc. In addition, each drug plan has their own formulary that they use for coverage purposes. Coverage of benefits is sometimes a fluid issue; coverage can change from day to day, depending, for example, as to whether a Medicare Part D beneficiary has met out-of-pocket spending thresholds, or has experienced a life-changing situation that might affect their benefit delivery for example, entering a long-term care facility). Adoption of this standard for formulary and benefits transactions between plans and providers may deliver added value in approximating patients' drug coverage and lead to patient-specific, real-time benefit information.

b. Standard for Medication History

A medication history standard provides a way for prescribers, dispensers, and payers to communicate about a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe. It may provide information that would be of use in helping to identify drug interactions, including the dispensing pharmacy and the prescribing physician. This standard is relatively mature and widely adopted by the prescribing industry. It has been useful in preventing medication errors, as well as understanding medication management compliance. Results demonstrate there is a difference in how the standard is implemented based on the source of the medication history.

In the February 4, 2005 proposed rule, we discussed how the adoption of the medication history standard would enhance e-prescribing capabilities under Medicare Part D by making it possible for the prescriber to obtain information on the medications the patient is already taking, including those prescribed by other providers. At that time, we proposed characteristics for a medication history standard (for a more detailed discussion refer to 70 FR 6262 through 6263). We proposed that if those characteristics for medication history were met, and there was adequate industry experience with them, we would consider adopting foundation standards. The NCVHS, in a September 2, 2004 letter to the Secretary (*http://www.ncvhs.hhs.gov*), had recommended the rapid development of an NCPDP medication history standard based on an RxHub protocol. The NCPDP SCRIPT standard 8.1, based on the RxHub protocol, was released in October 2005, featuring those desirable characteristics. However, the timing of its release in October 2005 was too late for the standard to be considered for approval as a foundation standard in the November 7, 2005 final rule, and there was little to no industry experience with the standard. Because of this and other concerns about its interoperability with other standards, at that time we did not adopt the NCPDP SCRIPT standard as a foundation standard for medication history, but agreed to include it in pilot

testing. For more details, refer to 70 FR 67573.

The pilot sites found that the proposed medication history standard included as a transaction in the NCPDP SCRIPT 8.1 is well structured, supports the exchange of information, would not impose an undue administrative burden on prescribers and dispensers, is compatible with other health IT standards, and is ready to be used as part of the e-prescribing program under Medicare Part D.

c. Standard for Structured and Codified SIG

Patient instructions for taking medications are placed at the end of a prescription. These are called the *signatura,* commonly abbreviated SIG. Currently, the Food and Drug Administration (FDA) provides some terminology for SIGS, for example, route of administration and unit of presentation. However, there is no standardized format or vocabulary for SIGs, leaving room for misinterpretation and error. A standard structure and code set for expressing SIGs has the potential to enhance patient safety, although free text capability must be preserved for special circumstances. Pilot sites used a variety of approaches including review of the proposed NCPDP Structured and Codified SIG standard 1.0, identification of test cases, using live transactions and selecting samples of prescriptions with a wide variety of SIGs, recreating each test case in a laboratory environment, and then developing a test harness that would include functions of an electronic information exchange application. Another approach was to analyze an initial sample that would be statistically valid with an attempt to represent each distinct SIG using the proposed standard's 128 data fields.

The pilot sites found that the proposed Structured and Codified SIG format needs additional work with reference to field definitions and examples, field naming conventions and clarifications of field use. It is imperative that the prescriber's instructions be translated exactly into e-prescribing and pharmacy practice management systems to reduce medication errors, decrease healthcare costs and improve patient safety. Contradictions with other structured fields exist, and there are limitations on directions for topical drugs (such as the area of application). The *pro re nata* (PRN) or ''as needed'' designation could be interpreted as either ''as needed'' or ''as required'', and the standard does not allow for quick revisions for new drug administration. Mistranslations and contradictions in dosage/timing directions leave room for misinterpretation and error. Analysis shows that the NCPDP's proposed Structured and Codified SIG Standard 1.0 is not sufficiently developed for use for Medicare Part D e-prescribing in its current state.

d. Standard for Fill Status Notification

The Fill Status Notification standard is a function within the NCPDP SCRIPT 8.1, but it was not named a foundation standard due to lack of adequate industry experience. The standard enables a pharmacy to notify a prescriber when the prescription has been dispensed (medication picked up by patient), partially dispensed (partial amount of medication picked up by the patient), or not dispensed (medication not picked up by patient, resulting in the medication being returned to stock).

Pilot sites found that the NCPDP SCRIPT 8.1 standard supports the activities of a pharmacy sending messages to the prescriber as to the status of a prescription. The challenges encountered were not related to the structure and format of the standard, but in its implementation. RxFill is intended to encourage adherence and compliance with medication therapy. Although the transaction is technically capable of performing that function, the pilot sites' experiences and observations indicate there is no marketplace demand for this information, and may cause an unnecessary administrative burden on prescribers and dispensers. Prescribers expressed concerns about being inundated with data if they were informed every time a prescription was filled or not filled, and were unsure of the usefulness of the information. Moreover, implementing the Fill Status transaction would require significant business process changes at pharmacies as well as development of common rules for determining when a prescription becomes a ''no-fill.'' We question the marketplace demand for Fill Status Notification and solicit comments regarding both stakeholders' and industry's potential utilization of RxFill.

e. Standard for Clinical Drug Terminology: RxNorm

RxNorm is a vocabulary resulting from a collaboration between the Food and Drug Administration (FDA) and the National Library of Medicine (NLM) that provides standard names for clinical drugs (active ingredient + strength + dose form), and for dose forms as administered to a patient. These concepts are relevant to how a physician would order a drug. It provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. NDCs (National Drug Codes) for specific drug products (where there are often many NDC codes for a single product) are linked to that product in RxNorm. NDCs for specific drug products identify not only the drug but also the manufacturer and the size of the package from which it is dispensed. NDCs are relevant to how a pharmacy would dispense the drug. RxNorm links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.

RxNorm terminology was evaluated in the context of the NCPDP SCRIPT 8.1 for new prescriptions, renewals, and changes. RxNorm was included in the pilot to determine how well the RxNorm information can be translated from the prescriber's system to the dispenser's system while maintaining the prescriber's intent. The grantees/contractor tested this standard in a laboratory setting, specifically to gain understanding of the completeness and accuracy of RxNorm.

The pilot sites demonstrated that RxNorm has significant potential to simplify e-prescribing, create efficiencies, and reduce dependence on NDCs among dispensers. It was able to represent both new prescriptions and renewal requests. In some testing, RxNorm erroneously linked some NDCs to lists of ingredients rather than to the drugs themselves. Testing also revealed cases in which the NDC codes linked by RxNorm did not match to a semantic clinical drug (SCD), which always contains the ingredient(s), strength and dose form, in that order. This indicates there was either an error in matching to the correct RxNorm concept, or an error with RxNorm itself, with more than one term being available for the same clinical drug concept (that is, unresolved synonymy). There is currently no central repository containing a list of all NDC codes, nor a reference guide that indicates all of the NDCs associated with a particular drug. (On August 29, 2006, FDA published a proposed rule [71 FR 51276] which would result in the creation of an electronic drug registration and listing system for which FDA would issue all NDCs, registrants would be required to keep information up to date, and there would be a centralized electronic repository for these NDCs. Through the Structured Product Labeling (SPL) for

each marketed drug product, the NDCs would be linked to the drug product code, proprietary name, established name of the active ingredients, Unique Ingredient Identifiers [UNII], active ingredient strengths and pharmaceutical dosage form.) As with other vocabulary standards, RxNorm will never cover 100 percent of what is needed in every circumstance, so some provisions for exceptions will be needed. One example encountered in the pilots was the lack of standard names and identifiers for pharmacy-compounded drugs. Analysis shows that, as of December 2006, RxNorm was not sufficiently developed for effective and accurate use for Medicare Part D e-prescribing.

f. Standard for Prior Authorization

The prior authorization standard incorporates real-time prior authorization functionality in the ASC X12N 278 Version 4010A1 Health Care Services Review transaction. Originally there were two models that were to be considered, solicited (prescriber proactively solicits prior authorization criteria/forms from plan) and unsolicited (questions appear via prompts on a point-of-care software system). The solicited model is rarely used and usually results in a paper-based response, versus the unsolicited model which employs e-prescribing technology. Upon consultation between the pilot sites and AHRQ as the administrator of the pilot project, AHRQ advised that the pilot sites use the unsolicited model using the NCPDP Formulary and Benefits Standard 1.0 specification as it would provide a better test of prior authorization in an e-prescribing environment.

Prior authorization is a very complex standard to implement, necessitating an understanding of four different standards and multiple payer requirements. The combination of ASC X12N 278, ASC X12N 275 and the HL7 prior authorization (PA) attachment is cumbersome, confusing and requires expertise that may limit adoption. Because health plans typically require prior authorization only for a small subset of drugs, the pilot sites had limited live experience with this standard. Nevertheless, they pilot tested the ASC X12N 278 version 4010A1 and ASC X12N 275 version 4010 with the HL7 PA attachment and identified several issues that need to be addressed before this standard should be adopted as an e-prescribing final standard, including some inconsistencies between ASC X12N 278 Version 4010A1 and ASC X12N 275 Version 4010 that need to be addressed. Investigators agreed that the HIPAA-named prior authorization standard—the ASC X12N 278 version 4010A1—was not adequate to support prior authorization because it was designed for service or procedure prior authorizations, not for medication prior authorization. One of the challenges of the ASC X12N 275 version 4010 with the HL7 PA attachment is that it did not allow vendors to make questions mandatory, which would ensure that the information required is complete and reduce the need for back-and-forth communication that takes place between plan prior authorization representatives and prescribers. Standards modifications would need to be made prior to adoption as a final standard for the Medicare Part D e-prescribing program.

g. Use of Standards in the Long-Term Care (LTC) Setting

Healthcare Delivery in long-term care (LTC) settings is unique for several reasons. Nurses are frequently the primary caregivers, with off-site physicians who monitor care; specialized long-term care pharmacies are located off-site with drugs being delivered to the facility. While the participants in the Achieve study were drawn from a convenience sample, the setting provided a special opportunity for understanding e-prescribing's impact on an entirely different patient population, provider type, and prescription delivery system.

In long-term care, a prescription order typically remains an open order with no end date or a date far in the future. A prescriber may need to modify this order and notify the pharmacy. Changes might include dose, form, strength, route, modifications of frequency, or a minor change related to the order. Also, in the long-term care environment, there is a need to send a refill request from a facility to a pharmacy. An example is when a medication supply for a resident is running low (2–3 doses remaining), and a new supply is needed from the pharmacy. The facility needs a way to notify the pharmacy that a refill for the medication is needed. E-prescribing was evaluated within the unique context of long-term care workflow from facility to pharmacy.

The primary purpose of the long-term care pilot site was to test the NCPDP SCRIPT 8.1 in the long-term care setting and found that modifications were required in order to ensure accurate transmission of the data. Through partner agreement, ''work-arounds'' were identified and implemented. These work-around requests were formally submitted by the pilot site grantee to NCPDP in the form of a DERF (Data Element Request Form) to modify the standard as needed. When an updated version of the NCPDP SCRIPT Standard becomes available that can accommodate the unique prescription workflow of the LTC setting, we will consider removing the current exemption. We solicit industry and other interested stakeholder comments on the impact and timing of lifting this exemption.

II. Provisions of the Proposed Rule

A. Proposed Retirement of NCPDP SCRIPT 5.0 and Adoption of NCPDP SCRIPT 8.1 as a Final Standard

[If you choose to comment on issues in this section, please include the caption ''Adoption of NCPDP SCRIPT 8.1'' at the beginning of your comments.]

We propose to revise § 423.160(b)(1) to replace the NCPDP SCRIPT 5.0 standard with the NCPDP SCRIPT 8.1. Those providers and dispensers using e-prescribing to provide for the electronic communication of a prescription or prescription-related information would be required to use the NCPDP SCRIPT 8.1 for the following transactions:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill prescription request transaction.
- Refill prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.

On June 23, 2006, we published an interim final rule with comment (71 FR 30620) to solicit comments as to whether the NCPDP SCRIPT 8.1 was a backward compatible update to NCPDP SCRIPT 5.0. We received 5 timely public comments on this interim rule with comment. The comments came from a standards setting organization, two national industry associations, and two private corporations actively involved in e-prescribing. All commenters supported the voluntary use of the backward compatible Version 8.1 of the NCPDP SCRIPT Standard. Four recommended that it be adopted as soon as reasonably possible, and that Version 5.0 be retired as soon as reasonably practical. They also indicated that Version 8.1 was already in widespread use throughout their

respective industries. One commenter indicated a concern with making backward compatibility ''the criteria'' for determining if a notice and comment rulemaking is required. That commenter felt that backward compatibility must be viewed as just one factor in making a determination to update, as opposed to modify, a standard.

We continue to find that the NCPDP SCRIPT 8.1 is backward compatible to the adopted NCPDP SCRIPT 5.0. Both versions are the same, except that Version 8.1 contains the additional feature of medication history. One commenter expressed that it has been their experience that, while capable of processing Version 5.0, the industry is already implementing Version 8.1, and that few, if any, of their trading partners are using Version 5.0. This is supported by industry reports that numerous software systems now using Version 8.1 have been certified for use by electronic prescribing networks.

Regarding the comment that backward compatibility should not be the sole criterion for determining whether use of a subsequent version requires an update or a modification of an e-prescribing standard, we note that it is not the sole criterion. The ''backward compatibility'' of a subsequent version of an adopted standard simply indicates that entities may voluntarily upgrade their systems with the subsequent version that is ''backward compatible,'' and still be compliant with the adopted standard. With the backward compatible version, entities may conduct transactions with other entities that continue to use the adopted version of the standard with no deleterious effect on the transmission of information or the transaction itself. We also note that we are required by law to employ notice and comment rulemaking to modify an adopted standard or when entities would be required to transition to a subsequent version. Through the rulemaking process, we must notify the public as to the proposed modifications, receive public comment on our proposals, and take into consideration an analysis of factors such as the modification's impact on affected entities relative to cost, benefit projections, productivity, etc., as well as industry and stakeholder feedback provided by means of the written comment process. We are soliciting comments regarding the retirement of Version 5.0 and the adoption of Version 8.1 as the adopted standard for the e-prescribing functions outlined in 42 CFR 423.160(b)(1), and based on the proposed compliance date described in section II.E. of this proposed rule.

B. Proposed Adoption of an E-Prescribing Standard for Medication History Transaction

[If you choose to comment on issues in this section, please include the caption ''Medication History'' at the beginning of your comments.]

In the Foundation Standards final rule, 70 FR 67568, we discussed the need for medication history standards, and that we were unaware of any standard for these transactions that clearly met the criteria for adequate industry experience. As a result, a standard for medication history was tested in the 2006 pilot project.

The NCVHS noted in its September 2, 2004 letter to the Secretary that medication history information was communicated between payers and prescribers using proprietary messaging standards, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange. The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocol as a basis. In September 2005, RxHub announced that its propriety data transaction format for Medication History which they had submitted to NCPDP, had been approved and incorporated into the NCPDP Script Standard, and approved by the American National Standard Institute (ANSI). NCVHS considered ANSI accreditation to be one criterion in their recommendation process for adoption of e-prescribing standards, and HHS adopted this as a criterion for determining adequate industry experience. (See 70 FR 67568, 67577 for a discussion of all the criterion considered by NCVHS.) The resulting NCPDP SCRIPT standard was recognized by the Secretary as an initial standard, then pilot tested in accordance with the MMA.

The pilot sites demonstrated that the standard can be successfully implemented among a variety of e-prescribing partners and, while complex, the standard can support the Medication History transaction, and is ready for implementation under Medicare Part D.

If NCPDP SCRIPT 8.1 is adopted in place of NCPDP SCRIPT 5.0 at § 423.160(b)(1) as proposed above, we also propose to add § 423.160(b)(3) to adopt the NCPDP SCRIPT 8.1 for electronic medication history transactions among the plan sponsor, prescriber, and the dispenser when e-prescribing for covered Medicare Part D drugs for Medicare Part D eligible individuals. The medication history transaction in the NCPDP SCRIPT 8.1 standard is based on the proprietary file transfer protocol developed by RxHub, which is currently being used to communicate this information in many e-prescribing products.

Adoption of the NCPDP SCRIPT 8.1 standard for the medication history transaction will provide a uniform communications mechanism for prescribers, dispensers and payers, support reconciliation of useful data from a large number of sources, and raise awareness of its availability and use among providers. Cost savings to the public will be generated based on reductions in the number of preventable adverse drug events (ADEs). Significantly, systems that utilize this proposed transaction in the NCPDP SCRIPT 8.1 standard will be substantially more effective at ADE reduction than those merely utilizing the original foundation standards by allowing prescribers to see what medications have been prescribed by other providers in the past.

C. Proposed Adoption of an E-prescribing Standard for Formulary and Benefit Transactions

[If you choose to comment on issues in this section, please include the caption ''formulary and benefit transactions'' at the beginning of your comments.]

As a result of pilot testing, we are proposing to add § 423.160(b)(4) to adopt the NCPDP Formulary and Benefit Standard 1.0, for the transaction of communicating formulary and benefit information between the prescriber and the plan sponsor when e-prescribing for covered Medicare Part D drugs for Medicare Part D eligible individuals. This standard is based on a proprietary file transfer protocol developed by RxHub, which is currently being used to communicate this information in many e-prescribing products. The RxHub protocols were submitted to NCPDP for accreditation, and the resulting standard was recognized by the Secretary as an initial standard and pilot-tested in accordance with the MMA.

The NCPDP Formulary and Benefits Standard 1.0 was implemented live in all pilot sites. This standard works in tandem with the eligibility request and response (ASC X12N 270/271). Once the individual is identified, the appropriate drug benefit coverage is located and transmitted to the requestor.

The pilot sites demonstrated that the NCPDP Formulary and Benefits Standard 1.0 can be successfully

implemented among a variety of e-prescribing partners, and while complex, the standard can support the transaction, and is ready for implementation under Medicare Part D.

Adoption of this standard for formulary and benefits transactions between plan sponsors and prescribers may deliver added value in approximating patients' drug coverage and lead to patient-specific, real-time benefit information. The NCPDP Formulary and Benefits Standard 1.0 enables the prescriber to consider this information during the prescribing process, and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the plan sponsors. As prescribers prescribe based on the coverage offered by a patient's plan formulary, plans will experience reduced costs through paying for drugs that are specific to their formularies for which they have negotiated favorable rates. Patients will see reduced costs in not having to pay increased out-of-pocket expenses for prescribed drugs that are not on their plan's formularies.

D. Adoption of the National Provider Identifier (NPI) as a Standard for Use in E-Prescribing Transactions

[If you choose to comment on issues in this section, please include the caption ''Adoption of the National Provider Identifier'' at the beginning of your comments.]

We are proposing to add § 423.160(b)(5) to adopt the National Provider Identifier as a standard for use in e-prescribing transactions among the plan sponsor, prescriber, and the dispenser. The NCPDP SCRIPT standard 8.1, which we are proposing for adopting in this proposed rule, supports the use of NPI.

While the NPI was not tested in the pilot project, we have reason to believe that there is adequate industry experience with the NPI which would support its use in e-prescribing transactions under section 1860D–4(e)(4)(C)(ii). Use of the NPI is already required in order to conduct HIPAA-compliant transactions which require the identity of HIPAA covered health care providers; and the compliance date for the NPI, May 27, 2007, has already passed. The NPI is in widespread use by HIPAA covered entities in HIPAA transactions. Although the NCPDP SCRIPT transaction is not a HIPAA transaction, the prescribers and dispensers that conduct it would be HIPAA covered entities, and as such, they would already be using NPI as they conduct their HIPAA transactions. They would, therefore, already be familiar with the NPI, even though they may not currently use it in the NCPDP SCRIPT transaction. Furthermore, NPI meets the objectives and design criteria laid out at section 1860D–4(e)(3) of the Act, so adoption of the NPI for use in e-prescribing standards is supported by section 1860D–4(e)(3)(A) of the Act as well. Finally, as uniform identifiers are necessary to conduct electronic transactions such as those in the e-prescribing program, adoption of NPI is also supported by section 1102 of the Act.

We generally solicit comments from the industry and other stakeholders on the adoption of NPI as an e-prescribing standard, and we specifically request comments as to whether use of the NPI in HIPAA-compliant transactions constitutes adequate industry experience for purposes of using NPI as a covered health care provider identifier in Medicare Part D e-prescribing transactions.

E. Proposed Compliance Date

In accordance with section 1860D–4(e) of the Act, the Secretary must issue certain final uniform standards for e-prescribing no later than April 1, 2008, to become effective not later than 1 year after the date of their promulgation. Therefore, in accordance with this requirement, the Secretary proposes a compliance date of 1 year after the publication of the final uniform standards. The Secretary also proposes adopting NCPDP SCRIPT 8.1 as the e-prescribing standard for the transactions listed in section III. C. of this proposed rule, effective 1 year after the publication of the final uniform standards. We solicit comments regarding the impact of these proposed dates on industry and other interested stakeholders and whether an earlier compliance date should be adopted.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement 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 PRA requires that we solicit comment on the following issues:

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Standards for an Electronic Prescribing Program (§ 423.160)

The emerging and increasing use of health care electronic data interchange (EDI) standards and transactions have raised the issue of the applicability of the PRA. It has been determined that a regulatory requirement mandating the use of a particular EDI standard constitutes an agency-sponsored third-party disclosure as defined under the PRA.

As a third-party disclosure requirement subject to the PRA, Medicare Part D sponsors offering qualified prescription drug coverage must support and comply with electronic prescription standards relating to covered Medicare Part D drugs, for Medicare Part D enrolled individuals as would be required under § 423.160.

However, the requirement that Medicare Part D sponsors support electronic prescription drug programs in accordance with standards set forth in this section, as established by the Secretary, does not require that prescriptions be written or transmitted electronically by prescribers or dispensers. After the promulgation of this set of final standards, these entities will be required to comply with the proposed standards only if they transmit prescription information electronically as discussed in section 1860D–4(e)(1) and (2) of the Act.

Testimony presented to the NCVHS indicates that most health plans/PBMs currently have e-prescribing capability either directly or by contracting with another entity. Therefore, we do not believe that conducting an electronic prescription drug program would be an additional burden for those plans. We solicit industry and other interested stakeholder comments and input on this issue.

Since these standards are already familiar to industry, we believe the requirement to adopt them constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to OMB for its review of these information collection requirements.

If you comment on any of these information collection requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: William Parham, III, CMS–0016–P, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn: Carolyn Lovett, CMS Desk Officer, CMS–0016–P, *Carolyn_lovett@omb.eop.gov.* Fax: (202) 395–6974.

IV. Response to Comments

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

V. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Analysis'' at the beginning of your comments.]

We have examined the impacts of this rule as required by Executive Order 12866 of September 30, 1993, as further amended; the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354); 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); and Executive Order 13132 of August 4, 1999.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties, and further amended by Executive Order 13422) directs 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). According to Executive Order 12866, a regulatory action may reasonably be ''significant'' if it meets any one of a number of specified conditions, including if the action may reasonably be anticipated to lead to:

- An annual effect on the economy of $100 million or more, adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- A serious inconsistency or otherwise interfering with an action taken or planned by another agency;
- Material alteration in the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

This proposed rule is anticipated to have an annual benefit on the economy of $100 million or more and will have ''economically significant effects.'' We believe that prescribers and dispensers that are now e-prescribing have already largely invested in the hardware, software and connectivity necessary to e-prescribe. We do not anticipate that the proposed modification of the NCPDP SCRIPT 5.0 to the NCPDP SCRIPT 8.1 at § 423.160(b)(1), the adoption of NCPDP SCRIPT 8.1 for the Medication History transaction, the adoption of the NCPDP Formulary and Benefit Standard 1.0 for formulary and benefit transactions, and the adoption of NPI for use in e-prescribing transactions will result in significant costs. We solicit industry and other interested stakeholder comments and input on this issue. We anticipate that the ability to utilize electronic formulary and benefit inquiries will result in administrative efficiencies and increased prescribing of generic drugs versus brand name drugs, and the access to medication history at the point of care will result in reduced adverse drug events (ADEs). The benefits accruing from these transactions will have an economically significant effect on Medicare Part D program costs and patient safety. As this is a significant rule under Executive Order 12866, we are required to prepare a regulatory impact analysis (RIA) for this rule.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of $6.5 million to $31.5 million in any 1 year for the health care industry). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's regulation that set forth the current size standards for health care industries at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (refer to the 620000 series).

Based on our initial analysis, we expect this proposed rule will not have a significant impact on a substantial number of small entities because, while many prescribing physician practices and independent pharmacies would be small entities, e-prescribing is voluntary for prescribers and pharmacies. For prescribers and dispensers that have already implemented e-prescribing, the adoption of NCPDP SCRIPT 8.1 would in most cases be accommodated through software upgrades whose cost would already be included in annual maintenance fees. Medicare Part D sponsors are required to support e-prescribing, and would incur some costs to support the NCPDP Formulary and Benefit Standard 1.0 and the NCPDP SCRIPT 8.1 medication history transaction. However, using the SBA revenue guidelines, the majority of Medicare Part D plan sponsors would not be considered small entities as they represent major insurance companies with annual revenues of over $31.5 million. We also do not anticipate that the proposed requirement to use NPI in e-prescribing would have any effect on Medicare Part D plans, providers or dispensers as they are already using the NPI in HIPAA-covered transactions.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a core-bed Metropolitan Statistical Area and has fewer than 100 beds. This proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs covered under Medicare Part D and not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, for purposes of our obligations under section 1102(b) of the Act, we are not providing an analysis.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires

Federal agencies to prepare written statements before promulgating any general notice of proposed rulemaking of any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. Since only Medicare Part D plan sponsors are required to support e-prescribing, this proposed rule does not include any mandate that would result in this spending by State, local or tribal governments. We acknowledge that there may be transaction costs borne by payers and pharmacy benefit managers (PBMs), but, based on our analysis, they would fall below the $110 million threshold. We would expect that many Medicare Part D plan sponsors already support the exchange of formulary, benefits and medication history data, because the standards we are proposing are based on proprietary transactions developed by Rx-Hub, which are already in use in the current e-prescribing environment.

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 costs on State and local governments, preempts State law, or otherwise has Federalism implications. Every State allows for the electronic transmission of prescriptions. In recent years, many States have more actively legislated in this area. The scope and substance of this State activity, however, varies widely among the States.[1] The MMA addresses preemption of State laws at section 1860D–4(e)(5) of the Act as follows:

(5) Relation to State Laws. The standards promulgated under this subsection shall supercede any State law or regulation that—

(A) Is contrary to the standards or restricts the ability to carry out this part; and

(B) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

In the final rule (70 FR 67568 through 67594), we interpreted this section of the Act as preempting State law provisions that conflicted with Federal electronic prescription program drug requirements that are adopted under Medicare Part D. We viewed it as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards, or that restrict the ability to carry out (that is, stand as an obstacle to) the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Medicare Part D drugs for Medicare Part D enrolled individuals.

Consequently, for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B). Furthermore, there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted. This interpretation closely reflected the language of the statute, and it is consistent with the presumption against Federal preemption of State law [2] and with the fundamental Federalism principles set forth in section 2 of Executive Order 13132. It is also consistent with the Department of Health and Human Service's (HHS) general position of deferring to State laws regulating the practice of pharmacy and the practice of medicine.

In the final rule at 70 FR 67568 through 67594, we acknowledged that some industry representatives believed that the Congress intended this preemption provision to be much broader. For instance, some expressed the position that this statutory provision preempts all State laws that would in any way restrict the development of e-prescribing for all providers and payors. This position was based on the belief that the Congress intended to preempt the field of e-prescribing through this provision in the MMA. It would have required an interpretation that the word ''and'' between paragraphs (A) and (B) was disjunctive, that is, that ''and'' means ''or'' in this context. Under this interpretation, the operative language would be ''restricts the ability to carry out this part'' in paragraph (A), which arguably would have enabled the standards and requirements adopted for the Federal electronic prescription drug program to preempt all State laws and regulations that restricted the Secretary's ability to carry out the goals of an electronic prescription drug program, even if they were not related to covered Medicare Part D drugs, or Medicare Part D covered individuals. They contended that some States had existing statutory or regulatory barriers that could impede the success of e-prescribing; for example, laws and regulations that were drafted with only paper prescriptions in mind, which may not be well-suited to e-prescribing applications.

We determined that this interpretation did not comport with the use of the word ''contrary'' in the statutory language which generally establishes ''conflict preemption.'' This interpretation would seem to render paragraph (B) virtually meaningless and serve to establish ''field preemption.''

We invited public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically asked for comment on whether this preemption provision applied only to transactions and entities that are part of an electronic prescription drug program under Medicare Part D or to a broader set of transactions and entities. We also asked for comment on whether this preemption provision applied to only electronic prescription transactions or to paper transactions as well. For the same reasons given above, we have determined that States would not incur any direct costs as a result of this proposed rule. However, as mandated by section 1860D–4(e) of the Act, and under the Executive Order, we are required to minimize the extent of preemption, consistent with achieving the objectives of the Federal statute, and to meet certain other conditions. We believe that, taken as a whole, this proposed rule would meet these requirements. We do seek comments from States and other entities on possible problems and on ways to minimize conflicts, consistent with achieving the objectives of the MMA, and will be undertaking outreach to States on these issues.

We have consulted with the National Association of Boards of Pharmacy directly and through participation in NCVHS hearings and we believe that the approach we suggested provides both States and other affected entities the best possible means of addressing preemption issues. We will consult further with States before issuing the final rule. This section constitutes the Federalism summary impact statement required under the Executive Order.

The objective of this regulatory impact analysis is to summarize the cost and benefits of implementing the standards we are proposing in this rule for the conversion from NCPDP SCRIPT 5.0 to NCPDP SCRIPT 8.1 at § 423.160(b)(1), the adoption of

[1] Catizone, Carmen A., National Association of Boards of Pharmacy, Testimony before the NCVHS, July 29, 2004.

[2] See *Davies Warehouse Co.* v. *Bowles*, 321 U.S. 144, 153, 64, S.Ct. 474, 88 L.Ed. 635 (1944), *Pharmaceutical Research and Manufacturers of America* v. *Walsh*, 538 U.S. 644, 661, 123 S.Ct. 1855, 1867, 155 L.Ed.2d 889 (2003).

standards for the electronic communication of formulary and benefit and medication history information, and the adoption of NPI for use in e-prescribing transactions. These proposed actions build upon the e-prescribing requirements published as a final rule on November 7, 2005 (70 FR 67568) which included adoption of three foundation standards for e-prescribing. The final rule contained an impact analysis that addressed the cost of those foundation standards, and it also discussed in concept the benefits of e-prescribing in general. In the e-prescribing final rule at 70 FR 67589, we noted that commenters suggested that the estimated start-up costs for e-prescribing could be at least $1,500 and perhaps exceed $2,000. For average e-prescribing software implementation, according to a 2003 CITL Report, ''The Value of Computerized Provider Order Entry,'' a basic-e-prescribing system cost $1,248 plus $1,690 for annual support, maintenance, infrastructure and licensing costs. The total first year cost averaged approximately $3,000. The Journal of Healthcare Information Management has published that physicians reported paying user-based licensing fees ranging from $80 to $400 per month, although we believe through anecdotal information that these licensing fees have decreased over time to between $300 and $800 annually. For further discussion of the start-up costs associated with e-prescribing, see the e-prescribing final rule at 70 FR 67589. This proposed rule builds on the final rule analysis, and we refer to it to assure that costs and benefits are not counted twice. We solicit industry and other interested stakeholder comment and input on this issue.

A. Overall Impact

According to 2006 CMS data, approximately 24 million beneficiaries were enrolled in a Medicare Part D plan, (either a stand-alone Prescription Drug Plan or a Medicare Advantage Drug Plan). Another 7 million retirees were enrolled in employer or union-sponsored retiree drug coverage receiving the Retiree Drug Subsidy (RDS); 3 million in Federal retiree programs such as TRICARE and the Federal Employees Health Benefits Plans (FEHBP) and 5 million receiving drug coverage from alternative sources, including 2 million who have coverage through the Veterans' Administration. The breadth of Medicare's coverage suggests that e-prescribing under Medicare Part D could impact virtually every pharmacy and a large percentage of the physician practices in the country. Standards established for Medicare Part D beneficiaries will, as a matter of economic necessity, be adopted by vendors of e-prescribing and pharmacy software, and as a result, would extend to other populations unless they are manifestly unsuited for the purpose. However, we note again that e-prescribing is voluntary for both prescribers and dispensers under the Medicare Part D electronic prescribing program.

Our pilot testing and industry collaboration activities were partially intended to prevent the development of multiple, ''parallel'' e-prescribing environments, with their attendant incremental costs. In general, we attempted to avoid imposing an undue administrative burden on prescribing health care professionals, dispensing pharmacies and pharmacists. The standards we are proposing here, like the foundation standards adopted previously, are maintained by an accredited standards development organization. These proposed standards have been shown through pilot testing to work effectively with the foundation standards.

B. Costs

Because e-prescribing is voluntary, we anticipate that entities who currently do not now e-prescribe and who will not implement e-prescribing during the period reflected in the regulatory impact analysis will incur neither costs nor benefits.

Entities that do not now e-prescribe, but that will implement e-prescribing during the period reflected in the regulatory impact analysis will incur the costs and benefits associated with the foundation standards (which we discussed in the final rule at 70 FR 67568), but we do not claim either in this analysis. We assume that implementation of the NCPDP SCRIPT standards would not significantly affect the implementation cost; that is, the cost to implement the foundation standards and these two standards is not significantly higher than the cost of implementing the foundation standards alone. However, these entities could incur some additional costs for the purchase of new e-prescribing products that include these two transactions in the standard format. They would also incur the benefits of the two proposed standards. We solicit industry and other interested stakeholder comment and input on these issues.

We assume that since these standards are new and not currently deployed and implemented in vendor products, that entities do not exist that e-prescribe now and who have software that conducts these two transactions using the NCPDP SCRIPT standards.

Entities that e-prescribe now using a software product that cannot conduct the two transactions and cannot be upgraded to conduct them (for example, stand-alone Microsoft Word-based prescription writers) are not required to conduct the two new transactions, and if they decide not to conduct them, they would incur neither cost nor benefit. However, if they decide to upgrade their entire e-prescribing system to take advantage of the benefits of these new transactions, they would incur costs. However, we have no clear sense of how many entities would fall into this category.

Entities that e-prescribe now using a product that could be upgraded to conduct the two transactions would incur no cost or benefit if they decide not to upgrade. This would also apply to entities that e-prescribe now using a product that can conduct the two transactions using nonstandard (Non NCPDP SCRIPT) formats, but the functionality is not used. Based on our research, this category likely is the one in which most current e-prescribers fall. If they decide to upgrade, they would incur the cost of the upgrade (unless the upgrade is included in their maintenance agreement) and any testing costs, and would incur the benefits of the two transactions.

Entities that e-prescribe now using a product that can conduct the two transactions using nonstandard formats, and who use the transactions would have to upgrade. They would not enjoy all the benefits of the two new transactions since they would have already been performing them in some manner, but definitely would incur cost savings due to the increased interoperability of using the NCPDP SCRIPT standards. In fact, any entity engaging in e-prescribing would incur benefits due to increased interoperability, as the existence of standards simplifies data exchange product selection and testing. We solicit industry and other interested stakeholder comment and input on these issues.

In the e-prescribing final rule at 70 FR 67589, we also discussed the estimated start-up costs for e-prescribing for providers and/or dispensers. Based on industry input, we cited approximately $3,000 for annual support, maintenance, infrastructure and licensing costs. Physicians at that time reported paying user-based licensing fees ranging from $80 to $400 per month. For further discussion of the start-up costs associated with e-prescribing, see the regulatory impact analysis section of

this proposed regulation, and the e-prescribing final rule at 70 FR 67589.

In the November 7, 2005 final rule, we addressed the issues of privacy and security relative to e-prescribing in general. We noted that disclosures of protected health information (PHI) in connection with e-prescribing transactions would have to meet the minimum necessary requirements of the Privacy Rule if the entity is a covered entity (70 FR 6161). It is important to note that health plans, prescribers, and dispensers are HIPAA covered entities, and that these covered entities under HIPAA must continue to abide by the applicable HIPAA standards including these for privacy and security.

We continue to agree that privacy and security are important issues related to e-prescribing. Achieving the benefits of e-prescribing require the prescriber and dispenser to have access to patient medical information that may not have been previously available to them. Section 1860–D(e)(2)(C) of the Act requires that disclosure of patient data in e-prescribing must, at a minimum, comply with HIPAA's privacy and security requirements.

Although HIPAA standards for privacy and security are flexible and scalable to each entity's situation, they provide comprehensive protections. We will continue to evaluate additional standards for consideration as adopted e-prescribing standards. For further discussion of privacy and security and e-prescribing, refer to the final rule at 70 FR 67581 through 67582.

1. Retail Pharmacy

Because e-prescribing is voluntary for pharmacies, dispensers who do not currently conduct e-prescribing would not incur any costs related to any of the provisions of this rule. However, we recognize that costs would be incurred by those dispensers that currently conduct e-prescribing transactions, as well as those who voluntarily implement e-prescribing during the period reflected in our regulatory impact analysis. Industry estimates are that close to 100 percent of the nation's retail chain pharmacies are connected live to an e-prescribing network, with over 95 percent of those connected to networks capable of receiving and exchanging formulary and benefit and medication history data. This is in contrast to only 20 percent of independent pharmacies that are connected to e-prescribing networks.

The transaction using the NCPDP Formulary and Benefit Standard 1.0 is carried out between the plan and prescriber and, therefore, pharmacies will not incur any cost related to this transaction.

While the NCPDP SCRIPT 8.1 Medication History transaction supports communication between the dispenser and prescriber, its use is, nonetheless, voluntary for both. We assume for purposes of this analysis that the Medication History transaction will be carried out between the plan and prescriber, and therefore preliminarily conclude that pharmacies will not incur costs related to this transaction. We solicit industry and other interested stakeholder comment and input on this issue.

The modification of the NCPDP SCRIPT 5.0 foundation standard to NCPDP SCRIPT 8.1 at § 423.160(b)(1) will impact pharmacies. Pharmacies will have to assure that their software can accept prescription transactions using the 8.1 standard, and they will need to test with prescribers to assure that their electronic transactions are being received and can be processed. We believe there is little, if any, incremental costs associated with these activities. Software vendors are already implementing version 8.1 in their products, and we believe that any needed upgrades will be included in routine version upgrades. The number of current e-prescribers per pharmacy is small, and the testing process is not complicated. We believe that the implementation of the NPI will be accomplished as part of this transition. Prescribers and dispensers already use the NPI to conduct retail pharmacy drug claim transactions.

2. Medical Practices

Medical practices, compared to pharmacies, face a different set of costs in implementing information systems for clinical care and financial management. Unlike pharmacies, where technology has become an important part of operations (especially for larger retail chains), many providers have been cautious in their adoption of health information technology. We assume that, based on industry estimates, anywhere from 5 to 18 percent of physicians are e-prescribing today[3]. Because e-prescribing is voluntary for prescribers, medical practices that do not currently conduct e-prescribing would not incur any costs related to any of the provisions of this rule. However, we recognize that costs would be incurred by those prescribers currently e-prescribing, as well as those who voluntarily begin to e-prescribe during the period reflected in our regulatory impact analysis. If a practice decides to implement e-prescribing at a later time, we anticipate that the software products on the market would be compliant with these standards and, therefore, no additional cost would be incurred. In assessing the cost to prescribers that are currently e-prescribing, many of the e-prescribing software products generally already contain some capability to communicate formulary and benefit and medication history information because they incorporate the RxHub proprietary format on which the proposed standards were based. We expect that any changes that might be necessary as a result of this rulemaking would likely be included in routine version upgrades that are covered by annual maintenance and/or subscription fees. We solicit industry and other interested stakeholder comment and input on this issue. For e-prescribers whose software products are not able to generate NCPDP SCRIPT 8.1 transactions, they will not have the capability to conduct the proposed NCPDP Formulary and Benefit Standard 1.0 and NCPDP SCRIPT 8.1 medication history transaction. Costs would be incurred if they were to replace such software with software that generates transactions that comply with the proposed standards. We anticipate that the NCPDP SCRIPT 8.1 will be accommodated in later software version upgrades where that standard is not already utilized. We believe that the implementation of the NPI will be accomplished as part of this transition. Prescribers and dispensers already should be using the NPI to conduct retail pharmacy drug claim transactions.

3. Medicare Part D Plan Sponsors and Pharmacy Benefit Managers (PBMs)

Plan sponsors will be required to support NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(1), the NCPDP Formulary and Benefit Standard 1.0, and the NCPDP SCRIPT 8.1 Medication History transaction. They will need to assure that their software can receive and create NCPDP Formulary and Benefit Standard 1.0 and NCPDP SCRIPT 8.1 Medication History transaction queries and responses, and that their internal systems and databases can supply the information needed to build the transaction. For example, they will need to be able to extract prescription claims history and format it according to the Medication History transaction in the NCPDP SCRIPT 8.1 Standard. We believe that many plans will have already implemented this functionality because the standards we are proposing are based on proprietary file transfer protocols developed by Rx-

[3] E-Prescribing and the Prescription Drug Program final rule, published November 7, 2005 (70 FR 67568).

Hub that have been included in many e-prescribing products. Plans may need to restructure systems to assure that the data output is in the proper format, but, for the most part, the needed functionality is in place.

We recognize that some Medicare Part D plans may need to make additional investments to support these standards, and we solicit industry and other interested stakeholder comment and input on this issue.

Because plans typically pay the per transaction network fees for eligibility transactions, which likely includes providing a formulary and benefit response as well as a medication history response, Medicare Part D plans will incur increased transaction costs for formulary and benefit and medication history transactions as the frequency in which these transactions are conducted electronically increases.

Through information provided by SureScripts and industry consultants, this transaction fee appears to range from 6 cents to 25 cents per transaction, with the midpoint being 15 cents. In 2006, RxHub, one of the nation's largest electronic prescription and prescription-related information routing networks, estimated that their transaction volume increased 50 percent, from 29 million in 2005 to more than 43 million in 2006. These transactions were real-time requests for patient eligibility and benefits, formulary and medication history information.[4]

Based on CMS data we estimate that approximately 24 million Medicare beneficiaries received Medicare Part D benefits in 2006. (This figure excludes beneficiaries covered under the Retiree Drug Subsidy [RDS] program.) Approximately 825,000,000 claims (prescription drug events) were finalized and accepted for 2006 payment.

Based on CMS data, we estimate that approximately 24 million Medicare beneficiaries received Medicare Part D benefits in 2006. This figure reflects those Medicare beneficiaries enrolled in a Medicare Prescription Drug Plan (PDP) and/or a Medicare Advantage plan with Prescription Drug coverage (MA–PD), for which CMS has prescription drug event data. Approximately 825,000,000 claims (prescription drug events) were finalized and accepted for 2006 payment.

The annual percentage increase in the number of Medicare Part D prescriptions is estimated by CMS at 4.6 percent based on industry estimates (*http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_80415465,00.html*). So that impact comparisons can be made equally across all years, inflation was removed from the price effects. Conservatively, we calculate the increase in the number of Medicare Part D prescriptions and apply the current estimates of 5 and 18 percent electronic prescribing adoption rates to arrive at the number of Medicare Part D electronic transactions, and cost them out at a range of a low of 6 cents per transaction to a high of 25 cents per transaction. We estimate costs for Medicare Part D plans of between $2 million to $46 million per year.

TABLE 1.—TRANSACTION COSTS FOR MEDICARE PART D PLANS

Year	2009		2010		2011		2012		2013	
Number of Medicare Rxs	862,950,000		902,645,700		944,167,402		987,599,102		1,033,028,660	
Expected % of e-prescriptions	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
E-Rx Transaction Cost at $0.06	$2,588,850	$9,319,860	$2,707,937	$9,748,573	$2,832,502	$10,197,997	$2,962,797	$10,666,070	$3,099,085	$11,156,709
E-Rx Transaction Cost at $0.25	$10,786,875	$38,832,750	$11,283,071	$40,619,056	$11,802,092	$42,487,533	$12,344,498	$44,441,959	$12,912,858	$46,486,289

Medicare Part D plan sponsors may negotiate the cost of e-prescribing transactions as part of the dispensing fees included in their pharmacy contracts, and account for these costs in their annual bids to participate in the Medicare Part D program. In these instances, inclusion of these costs may increase the cost of their Medicare Part D bids. However, we anticipate that these costs would be negated by the savings from an increased rate of conversion from brand name to generic prescriptions realized through utilization of the formulary and benefit transaction, which would more than offset the transaction costs, and solicit comments on this assumption.

Medicare Part D plan sponsors will not be affected by the proposals to modify the NCPDP SCRIPT 5.0 foundation standard to adopt NCPDP SCRIPT 8.1 for the transactions listed at 42 CFR 423.160(b)(1) because these transactions are conducted between prescribers and dispensers, and plans are not involved.

Medicare Part D plan sponsors will not be significantly affected by the proposal to adopt the NPI as a standard for use in e-prescribing transactions among the plan sponsor, prescriber, and the dispenser because the plans already use the NPI in HIPAA transactions, such as the retail pharmacy drug claim.

4. Vendors

Vendors of e-prescribing software will incur costs to bring their products into compliance with these requirements. However, we consider the need to enhance functionality and comply with industry standards to be a normal cost of doing business that will be subsumed into normal version upgrade activities. Vendors may incur somewhat higher costs connected with testing activities but vendors should be able to address this potential workload on a flow basis. We believe these costs to be minimal, and solicit industry and other interested stakeholder comment and input on this issue.

C. Benefits

The benefits of the proposed adoption of standards for formulary and benefits and medication history transactions take place over a multi-year timeframe. The benefits come in the form of beneficiary cost savings realized by increases in formulary adherence and/or generic versus brand name prescribing by physicians as a result of real-time access to formulary and benefits information, administrative (time and labor cost) savings through reduced call-backs on the part of both physicians and pharmacists, and a reduction of the occurrence of preventable adverse drug events (ADEs) among Medicare beneficiaries, reducing resultant health care costs.

1. Formulary and Benefit Standard—Generic Drug Usage

We assume that, based on industry estimates, approximately 5 percent to 18 percent of group practices are e-prescribing today, and use that range for our assumptions. The formulary and benefit transaction will allow the

[4] RxHub Announces 2006 e-Prescribing Results and Highlights Milestones for 2007, St. Paul, MN, February 23, 2007, *http://www.rxhub.com.*

prescriber to view formulary drugs, alternative preferred drugs in a given class that may offer savings to the patient, and/or to see in advance what other less costly drugs within a given drug classification and/or generic drugs can be substituted for a given brand name prescription drug. This can result in reducing calls to the plan, and/or reducing the number of callbacks from a pharmacy because a prescribed drug is not on a beneficiary's drug plan formulary.

In 2006, 60 percent of Medicare Part D prescriptions in the first two quarters of the program were for generic drugs, and the remaining 40 percent were brand name prescription drugs. During a Medco study of physicians using e-prescribing technology (*http://medco.mediaroom.com/index.php?s=43&item=100*), physicians increased their generic substitution rates by over 15 percent. However, we recognize that not all beneficiaries will accept generic prescription drugs and there are some instances, especially when prescribing for mental health conditions, in which the brand name prescription drug has proven through physician experience to be the more effective drug, and therefore the drug of choice. Therefore, we apply a more conservative 7 percent annual increase in generic prescriptions.

We again apply the previously used 5 and 18 percent e-prescribing estimate range. Based on industry data, we assume the cost of a brand name prescription drug at $111.02 and the cost of a generic drug at $32.23.[5]

While Medicare beneficiaries will be the most direct recipients of the benefit realized by the conversion of brand name to generic prescription drugs, the Medicare program will benefit as well. The Medicare program will save money as it will be paying for an increased number of lower-cost generic prescriptions versus higher-cost, brand-name prescription drugs, as outlined in Table 2, and we solicit comments on both beneficiary and Medicare program savings assumption. We calculate a cost savings of $95 million to $410 million.

TABLE 2.—SAVINGS FROM SWITCH FROM BRAND NAME TO GENERIC DRUGS VIA FORMULARY & BENEFIT TRANSACTION INFORMATION

Year	2009		2010		2011		2012		2013	
Number of Medicare Rxs	862,950,000		902,645,700		944,167,402		987,599,103		1,033,028,661	
Number of Medicare Rxs—BRAND Only	345,180,000		361,058,280		377,666,961		395,039,641		413,211,465	
Expected % of E-Prescriptions	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
Number of Medicare E-Prescriptions	17,259,000	62,132,400	18,052,914	64,990,490	18,883,348	67,980,053	19,751,982	71,107,135	20,660,573	74,378,064
Brand to Generic Rx Conversions as a Result of E-Prescribing	1,208,130	4,349,268	1,263,704	4,549,334	1,321,834	4,758,604	1,382,639	4,977,499	1,446,240	5,206,464
Avg. Cost of Brand Name Drug × Total Elec. Generic Medicare Rxs	$134,126,593	$482,855,733	$140,296,416	$505,067,097	$146,750,051	$528,300,184	$153,500,553	$552,601,992	$160,561,579	$578,021,684
Avg. Cost of Generic Drug × Total Elec. Generic Medicare Rxs	$38,938,030	$140,176,908	$40,729,179	$146,625,045	$42,602,722	$153,369,797	$44,562,447	$160,424,808	$46,612,319	$167,804,349
Estimated Net Cost Savings (Reduction in Brand Drug Rx Payments)	$95,188,563	$342,678,826	$99,567,237	$358,442,052	$104,147,329	$374,930,386	$108,938,107	$392,177,184	$113,949,260	$410,217,334

2. Formulary and Benefit Standard—Administrative Savings

a. Physician and Physician Office Staff

The 2004 Medical Group Management Association (MGMA) survey entitled, ''Analyzing the Cost of Administrative Complexity'' (*http://www.mgma.com/about/default.aspx?id=280*) estimated the staff and physician time spent, on a per physician full time equivalent (FTE) basis, interacting with pharmacies on formulary questions and generic substitutions. Physician time on the phone discussing formulary issues was estimated at almost 16 hours a year; another 14 hours were spent per physician per year on generic substitution issues. Staff spent almost 26 hours per FTE physician on formulary issues, and another 24 hours per FTE physician on generic substitution issues.

Table 3 shows the administrative savings benefit to physicians and physician office staffs of performing formulary and benefit transactions electronically. CMS estimates the number of physicians in active practice who participated in the Medicare program in 2006 at 1,048,243.[6] Based on the same CMS data from 2003 through 2006, it indicates a percentage rise in the number of physicians participating in the Medicare program of .94 percent per year, so we have applied that percentage increase to arrive at an estimated number of Medicare physicians for 2009 through 2013. We also apply the previous assumption that from 5 to 18 percent of prescribers are e-prescribing today. Per the MGMA survey, we assume a physician labor cost of $100 per hour and an average staff labor cost of $22 per hour per physician FTE.

Pilot site experience shows that, among prescribers or their agents who adopted e-prescribing, obtaining prior approvals, responding to refill requests, and resolving pharmacy callbacks were all done more efficiently with e-prescribing than before. Both groups perceived a greater than 50 percent reduction in time to manage refill requests and significant time savings in managing pharmacy call backs.[7] However, we are realistic in our assumption that full implementation would be difficult to achieve, and use an estimate of 25 percent. Our model calculates that physicians and staff would realize savings ranging from $55 million to $206 million at a 25 percent implementation rate.

[5] *http://www.nacds.org/wmspage.cfm?parm1=5507.* National Association of Chain Drug Stores data.

[6] 2006 CMS Statistics, U.S. Department of Health and Human Services CMS Pub. No. 03470, July 2006, Table 22.

[7] Findings from the Evaluation of E-Prescribing Pilot Sites, *http://www.healthit.ahrg.gov.*

TABLE 3.—ADMINISTRATIVE SAVINGS FOR PHYSICIANS AND MEDICAL OFFICE STAFF

Year	2009		2010		2011		2012		2013	
# of Medicare Physicians	1,078,081	1,078,081	1,088,215	1,088,215	1,098,444	1,098,444	1,108,769	1,108,769	1,119,191	1,119,191
Expected % of e-rx prescribers	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
Estimated # of Medicare physicians e-prescribing	53,904	194,055	54,411	195,879	54,922	197,720	55,438	199,578	55,960	201,454
Total MD hrs spent on formulary and generic substitution pharmacy calls (30 hrs) × labor cost ($100/hr)	$161,712,150	$582,163,740	$163,232,250	$587,636,100	$164,766,600	$593,159,760	$166,315,350	$598,735,260	$167,878,650	$604,363,140
Total staff hrs spent on formulary and generic substitution pharmacy calls (50 hrs) × labor cost ($22/hr)	$59,294,455	$213,460,038	$59,851,825	$215,466,570	$60,414,420	$217,491,912	$60,982,295	$219,536,262	$61,555,505	$221,599,818
Total Labor Costs	$221,006,605	$795,623,778	$223,084,075	$803,102,670	$225,181,020	$810,651,672	$227,297,645	$818,271,522	$229,434,155	$825,962,958
Total Anticipated Labor Savings (25%)	$55,251,651	$198,905,945	$55,771,019	$200,775,668	$56,295,255	$202,662,918	$56,824,411	$204,567,881	$57,358,539	$206,490,740

b. Pharmacists

In Table 4, we draw a correlation from the potential administrative savings realized by physicians and staff for pharmacists. If each physician and their office staff save a total of 80 hours a year by using the formulary and benefit transaction and reducing the time spent on the phone with pharmacists, we assume that pharmacists are saving the equivalent amount of time by not making these calls. Since the MGMA survey assumes a pharmacist labor rate of $60 per hour, our model predicts that, at an annualized cost savings, pharmacists would realize an annualized cost benefit savings ranging from a low of $65 million to a high of $242 million at 25 percent implementation.

TABLE 4.—ADMINISTRATIVE SAVINGS FOR PHARMACISTS

Year	2009		2010		2011		2012		2013	
# of Medicare Physicians	1,078,081	1,078,081	1,088,215	1,088,215	1,098,444	1,098,444	1,108,769	1,108,769	1,119,191	1,119,191
Expected % of e-prescribers	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
Estimated # of Medicare physicians e-prescribing	53,904	194,055	54,411	195,879	54,922	197,720	55,438	199,578	55,960	201,454
Total MD and staff hrs spent on formulary and generic substitution pharmacy calls (80 hrs) × pharmacist labor cost ($60/hr)	$258,739,440	$931,461,984	$261,171,591	$940,217,760	$263,626,613	$949,055,616	$266,104,650	$957,976,416	$268,605,943	$966,981,024
Total Anticipated Labor Savings (25%)	$64,684,860	$232,865,496	$65,292,898	$235,054,440	$65,906,653	$237,263,904	$66,526,162	$239,494,104	$67,151,486	$241,745,256

3. Medication History Standard—Reduction of Adverse Drug Events (ADEs)

Automating the transmission of medication history information will simplify medication reconciliation through transitions in care and, in so doing, provide a safer and more effective health care system. Consumers will benefit from a safer medication delivery system, and greater convenience.

Although outpatient ADEs are difficult to estimate, current literature estimates that, as of 2005, there were 530,000 preventable ADEs for Medicare beneficiaries.[8] Moreover, the estimated cost per ADE ranges from $2,000[9] to upwards of $6,000[10] depending on the care setting. We chose to compute the benefits of medication history based on ADEs as a percentage of the total Medicare population. Based on CMS data from 1999 through 2006, the total Medicare population increased on average 1.13 percent per year.[11] We calculated that of the total Medicare population, ADEs occur in about 1.24 percent of that population each year.

Brigham and Women's Hospital discovered in their analysis of ADEs, conducted as part of the CMS e-prescribing pilot project, that e-prescribing could reduce the risk of ADEs by approximately 50 percent.[12] As medication history is a transaction that most directly impacts ADEs (versus formulary and benefit, codified SIG, etc.), we assume that the reduction in the risk of ADEs can be attributed mostly to the use of medication history rather than to e-prescribing in general. The pilot project demonstrated that 50 percent of preventable ADEs could be eliminated via e-prescribing, and possibly more as prescriber familiarity with the medication history function and full clinical decision support tools become available in all e-prescribing software. We also recognize that the Brigham and Women's Hospital ADE analysis brings with it a degree of uncertainty, as it was a by-product of the pilot project itself, and may not accurately represent the experiences of all entities (that is, small rural settings). Given that, we conservatively assume that the number of ambulatory ADEs associated with Medicare Part D beneficiaries could be reduced by 25 percent for the proportion of patients for whom prescriptions are written electronically; we use the same uptake e-prescribing estimates (5 to 18 percent) as earlier for e-prescribing adoption. Table 5 summarizes potential savings to the public based on these assumptions.

[8] Field TS, Gilman BH, Subramanian S, Fuller JC, Bates DW, Gurwitz JH. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 43(12):1171.1176.

[9] Field TS, Gilman BH, Subramanian S, Fuller JC, Bates DW, Gurwitz JH. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 43(12):1171.1176.

[10] Institute of Medicine of the National Academies. Preventing Medication Errors. July, 2006. Field TS, Gilman BH, Subramanian S, Fuller JC, Bates DW, Gurwitz JH. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 43(12):1171.1176.

[11] 2006 CMS Statistics, U.S. Department of Health and Human Services CMS Pub. No. 03470, July 2006, Table 1.

[12] Findings from the Evaluation of E-Prescribing Pilot Sites, *http://www.healthit.ahrq.gov.*

TABLE 5.—POTENTIAL SAVINGS TO PUBLIC DUE TO REDUCTION IN PREVENTABLE ADVERSE DRUG EVENTS (ADES)

Year	2009		2010		2011		2012		2013	
Total Medicare Population Estimates ...	44,577,662	44,577,662	45,081,390	45,081,390	45,590,809	45,590,809	46,105,985	46,105,985	46,626,983	46,626,983
Potential Avoidable ADEs via E-Rx	552,763	552,763	559,009	559,009	565,326	565,326	571,714	571,714	578,175	578,175
% of E-Rx Adoption	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
Avoided ADEs	27,638	99,497	27,950	100,622	28,266	101,759	28,586	102,909	28,909	104,071
Avoided ADEs Estimate (×25%)	6,910	24,874	6,988	25,155	7,067	25,440	7,146	25,727	7,227	26,018
Cost Avoided Estimate (25%×$2k)	$13,819,075	$49,748,671	$13,975,231	$50,310,831	$14,133,151	$50,879,343	$14,292,855	$51,454,280	$14,454,365	$52,035,713
Cost Avoided Estimate (25%×$6k)	$41,457,226	$149,246,012	$41,925,692	$150,932,492	$42,399,453	$152,638,029	$42,878,566	$154,362,839	$43,363,094	$156,107,139

Table 5 shows that the introduction of e-prescribing can potentially realize a cost savings of $13 million to $156 million from avoided ADEs. We solicit industry and other interested stakeholder comment and input on this issue. Besides lower rates of ADEs, the public will also realize other benefits related to the medication history function of e-prescribing. Through improved collaboration and communication between physicians and plans, patients will be more likely to have greater access to information which will encourage them to become more involved in their own treatment, which studies show decreases the probability of experiencing an ADE-related error.[8]

C. Total Impact

This analysis has focused on the costs and benefits of two new e-prescribing standards, and the adoption of NCPDP SCRIPT 8.1 in place of version 5.0. We conclude that the cost of implementing these proposals is minimal, with quantifiable benefits reaped by pharmacies, providers, and beneficiaries. Over time, we expect that these groups will see average benefits in a range from $218.0 million to $863.9 million from the utilization of formulary and benefit and medication history transactions and the promulgation of these standards (Table 6).

D. Alternatives Considered

In developing this proposed rule, we considered a range of alternatives. While required by statute to issue a regulation, we were not required to issue standards for specific functionality if appropriate standards were not available.

We considered not issuing an additional rule, and allowing the foundation standards to become the complete set. Since we had successful results from the pilot project, and the value added by the proposed additional standards is substantial, we chose to proceed. Given the existing foundation standards, our failure to proceed would not have averted many costs, but the lack of a medication history standard, for example, would have limited benefits, particularly for consumers.

We considered proposing the prior authorization and RxNorm standards for adoption, and elected not to do so. In both cases, the decision was based on the results of the pilot project. We expect that both standards, in their current forms and given the current state of the industry, would impose substantial additional costs while delivering marginal additional benefits. In the case of prior authorization, much of the additional cost is likely to be on the health plan side. We expect that software vendors will explore adding this functionality to provider-based systems and that health plans will adopt it as doing so becomes feasible.

In the case of the RxFill standard, we did not get a clear indication from the pilot project as to its added value.

We considered not proposing adoption of the NPI as a standard for Medicare Part D e-prescribing transactions, but, given the need for an identifier in e-prescribing transactions and the fact that large portions of the health care industry are required to use NPI as a HIPAA standard, we felt that adoption at this time was feasible and desirable.

TABLE 6.—COST/BENEFITS FOR THE ADOPTION OF STANDARDS FOR MEDICATION HISTORY AND FORMULARY AND BENEFITS, 2009–2013

[$ Millions]

	2009		2010		2011		2012		2013		Total	
BENEFITS:												
Expected % of E-Prescribing Adoption	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%	5%	18%
Generic versus Brand Name Drugs	$95.1	$342.6	$99.5	$358.4	$104.1	$374.9	$108.9	$392.1	$113.9	$410.2	$521.5	$1,878.2
Administrative—Physician/Office Staff ..	$55.2	$198.9	$55.7	$200.7	$56.2	$202.6	$56.8	$204.5	$57.3	$206.4	$281.2	$1,013.1
Administrative—Pharmacies	$64.6	$232.8	$65.2	$235.0	$65.9	$237.2	$66.5	$239.4	$67.1	$241.7	$329.3	$1,186.1
Reduction in ADEs	$13.8	$49.7	$13.9	$50.3	$14.1	$50.8	$14.2	$51.4	$14.4	$52.0	$70.4	$254.2
Total Benefits	$228.7	$824.0	$234.3	$844.4	$240.3	$865.5	$246.4	$887.4	$252.7	$910.3	$1,202.4	$4,331.6
*COSTS:												
Transaction Costs	$10.7	$38.8	$11.2	$40.6	$11.8	$42.4	$12.3	$44.4	$12.9	$46.4	$58.9	$212.6
NET BENEFITS	$218.0	$785.2	$223.1	$803.8	$228.5	$823.1	$234.1	$843.0	$239.8	$863.9	$1,143.5	$4,119.0

*These costs reflect only transaction costs as outlined in Table 1, and do not take into account the potential costs of systems and/or software upgrades, etc., for which stakeholder/industry information and input is being solicited.

E. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 7 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. This table provides our best estimate of the costs and benefits associated with the adoption of the two new e-prescribing standards, and the adoption of NCPDP SCRIPT 8.1 in place of version 5.0. Costs will be incurred by plans/PBMs paying transaction charges to networks. Generic versus brand name drug benefits will accrue from physicians to beneficiaries; administrative savings to physicians, physician offices and pharmacists; from pharmacists to physicians and physician offices; and from physicians to beneficiaries in the reduction in the number of ADEs.

TABLE 7.—ACCOUNTING STATEMENT: ANNUALIZED MONETIZED TRANSACTION COSTS AND BENEFITS

[$ Millions/year]

	5% Expected annual E-Rx adoption rate	18% Expected annual E-RX adoption rate
COSTS:		
Transaction costs	$58.9	$212.6
Annualized monetized costs:		
7% Discount rate	11.7	42.2
3% Discount rate	11.7	42.3
0% Discount rate	11.8	42.5
Paid by plans/PBMs to networks.		
BENEFITS:		
Generic versus brand name drugs, administrative for physicians and pharmacists, reduction in ADEs	1,202.4	4,331.6
Annualized monetized benefits:		
7% Discount rate	239.6	862.9
3% Discount rate	240.1	864.8
0% Discount rate	240.4	866.3
Generated physicians to pharmacists, pharmacists to physicians, and physicians to beneficiaries.		
NET BENEFIT	1,143.5	4,119.0

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professions, Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble in this proposed regulation, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 423 as follows:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395W–101 through 1395W–152, and 1395hh).

2. Section 423.160 is amended by—

A. Revising paragraph (b)(1).

B. Adding new paragraphs (b)(3), (b)(4), and (b)(5).

C. Revising paragraph (c).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) *Standards*—(1) *Prescription.* The National Council for the Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(i) Get message transaction.

(ii) Status response transaction.

(iii) Error response transaction.

(iv) New prescription transaction.

(v) Prescription change request transaction.

(vi) Prescription change response transaction.

(vii) Refill prescription request transaction.

(viii) Refill prescription response transaction.

(ix) Verification transaction.

(x) Password change transaction.

(xi) Cancel prescription request transaction.

(xii) Cancel prescription response transaction.

* * * * *

(3) *Medication history.* The National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 to provide for the communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers.

(4) *Formulary and benefits.* The National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 for transmitting formulary and benefit information between prescribers and Medicare Part D sponsors.

(5) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify a health care provider in Medicare Part D e-prescribing or prescription-related transactions conducted among Medicare Part D plan sponsors, prescribers, and dispensers when a health care provider's identifier is required.

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, the incorporation by reference of certain publications into this section. You may inspect copies of these publications at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

The publications approved for incorporation by reference and their original sources are as follows:

(1) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and FAX (480) 767–1042 or *http://www.ncpdp.org.*

(i) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, excluding the Prescription Fill Status Notification Transactions (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill).

(ii) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(iii) National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999 and equivalent National Council for the Prescription Drug Program (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record.

(2) Accredited Standards Committee, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (301) 970–4488; and fax: (703) 970–4488 or *http://www.x12.org.*

(i) Accredited Standards Committee (ASC) X12N 270/271–Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company, 004010X092A1.

(ii) [Reserved].

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 19, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 20, 2007.

Michael O. Leavitt,

Secretary.

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