

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-0016-F and CMS-0018-F]

RINs 0938-AO66 and 0938-AO42

Medicare Program; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)

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

ACTION: Final rule.

SUMMARY: This final rule adopts uniform standards for medication history, formulary and benefits, and fill status notification (RxFill) for the Medicare Part D electronic prescribing (e-prescribing) drug program as required by section 1860D-4(e)(4)(D) of the Social Security Act (the Act). In addition, we are adopting the National Provider Identifier (NPI) as a standard for identifying health care providers in e-prescribing transactions. It also finalizes the June 23, 2006 interim final rule with comment period that identified the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8.1 (“NCPDP SCRIPT 8.1”) as a backward compatible update of the NCPDP SCRIPT 5.0 (“NCPDP SCRIPT 5.0”), until April 1, 2009. This final rule also retires NCPDP SCRIPT 5.0 and adopts the newer version, NCPDP SCRIPT 8.1, as the adopted standard. Finally, except as otherwise set forth herein, we are implementing our compliance date of 1 year after the publication of these final uniform standards. This is the second set in a continuing process of issuing e-prescribing final standards for the Medicare Part D program,

DATES: *Effective Date:* These regulations are effective on June 6, 2008. The incorporation by reference of the publications listed in this final rule is approved by the Director of the **Federal Register** June 6, 2008.

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SUPPLEMENTARY INFORMATION:

I. Background

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, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug Plans (MAPDs) and other Medicare Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and dispensing pharmacy and the dispenser. This includes 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. Section 101 of the MMA established section 1860D-4(e)(4)(D) of the Act, which directed the Secretary to promulgate final 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 prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals, directly or through an intermediary, are required to comply with any applicable final standards that are in effect.

Section 1860D-4(e)(4) of the Act generally requires the Secretary to conduct a pilot project to test initial standards recognized under section 1860D-4(e)(4)(A) of the Act, prior to issuing final standards in accordance with section 1860D-4(e)(4)(D) of the Act. Section 1860D-4(e)(4)(C)(ii) of the Act 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 standards. Such standards could be recognized by the Secretary and adopted through notice and comment rulemaking as final standards without pilot testing.

We exercised this option in the E-Prescribing and Prescription Drug Program final rule, published on

November 7, 2005 (70 FR 67568), when we adopted three “foundation standards” that met the criteria for adoption without pilot testing. Those foundation standards are as follows:

- The National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide, Version 5, Release 0 (Version 5.0), hereinafter referred to as “NCPDP SCRIPT 5.0,” for communicating prescription or prescription related information between prescribers and dispensers for the transactions listed at § 423.160(b)(2).

- Accredited Standards Committee (ASC) X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1 for communicating eligibility information between Medicare Part D sponsors and prescribers.

- NCPDP Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1) and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1) supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for NCPDP Data Record in the Detail Data Record, hereinafter referred to as “NCPDP Telecom 5.1” for communicating eligibility information between Medicare Part D sponsors and dispensers.

In that same final rule, we established three exemptions to the use of the NCPDP SCRIPT foundation standard. The first exemption provided for entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile. We ultimately modified this exemption in the CY 2008 Physician Fee Schedule final rule with comment period, which was published November 27, 2007 (72 FR 66222). (For a more in-depth discussion of the computer-generated facsimile exemption, please see the preamble discussion in the November 27, 2007 final rule with comment at 72 FR 66334.)

The second exemption required the use of either HL7 or the adopted NCPDP SCRIPT standards in electronic transmittals of prescriptions or prescription related information when the sender and recipient are part of the same legal entity (for example, within a staff model HMO). The third exemption was when an entity is required by law to issue a prescription for a patient to a nonprescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser. This

exemption was established to accommodate many legitimate business needs of entities in the long-term care setting.

The November 7, 2005 final rule (70 FR 67579) also established a means of addressing the industry's desire for a streamlined standards updating and maintenance process that could keep pace with changing business needs. That process provided that a standard could be updated with a new version, and identified whether and when the update/maintenance would necessitate notice and comment rulemaking. Where it is determined that the notice and comment rulemaking is not required, the new version is adopted by incorporating the new version by reference through a **Federal Register** publication. In that case, use of either the new or old version would be considered compliant. "Backward compatible" new versions of standards are eligible for recognition through this process. This version updating and maintenance of the implementation specifications for the adopted identifying and e-prescribing standards allows for the correction of technical errors, the elimination of technical inconsistencies, and the addition of functions that are unnecessary for the specified e-prescribing transaction.

Subsequent industry input indicated that the adopted e-prescribing standard for the transactions listed at § 423.160(b)(2) should be updated to permit the use of NCPDP SCRIPT 5.0 or a later version of the standard, NCPDP SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005, hereinafter referred to as NCPDP SCRIPT 8.1.

Using the streamlined process established in the November 7, 2005 rule, we published an interim final rule with comment period on June 23, 2006, updating the adopted NCPDP SCRIPT standard, thereby permitting either NCPDP SCRIPT 5.0 or 8.1 to be used. (For more information, see section III of this final rule and the June 23, 2006 interim final rule with comment period (71 FR 36020).)

Previously, six initial standards were recognized by the Secretary in 2005 and then tested in a pilot project during calendar year (CY) 2006. Based upon the evaluation of the pilot project, the Secretary issued a report to Congress on the pilot results. The Secretary is required to issue this set of final uniform standards for e-prescribing by no later than April 1, 2008. These final standards must be effective not later than 1 year after the date of their issuance.

Based on the pilot results as detailed in the report to Congress, we issued a notice of proposed rulemaking on November 16, 2007 (72 FR 64900) and solicited comments from stakeholders and other interested parties on industry experience with certain standards. In that proposed rule (72 FR 64906 through 64907), we also solicited comments regarding the impact of adopting NCPDP SCRIPT 8.1 and retiring SCRIPT 5.0. Those comments and our responses are addressed in section III. B.1. of this final rule.

For a complete discussion of the statutory basis for this final rule and the statutory requirements at section 1860D-4(e) of the Act, please refer to the E-Prescribing and the Prescription Drug Program proposed rule published November 16, 2007 (72 FR 64901).

II. Pilot Testing of Initial Standards

In the November 16, 2007 proposed rule (72 FR 64901), we discussed the provision at section 1860D-4(e)(4)(A) of the Act which requires the Secretary develop, adopt, recognize or modify "initial uniform standards" for e-prescribing in 2005 and pilot test these initial e-prescribing standards in 2006. To fulfill this requirement, the Secretary ultimately recognized (based in part on NCVHS input) six "initial" standards in a September 2005 "Request for Applications". For more information on the pilot test findings, refer to the November 16, 2007 proposed rule (72 FR 64904 through 64906).

In the November 16, 2007 proposed rule (72 FR 64903) we noted that, as we had not published a final rule identifying the foundation standards at the time the Request for Applications was published, the proposed foundation standards were included among the Request for Applications list of "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.

The Request for Applications also specified that pilot sites would use NCPDP SCRIPT 5.0. With the Secretary's adoption of the updated NCPDP SCRIPT 8.1, the Agency for Healthcare Research and Quality (AHRQ), in its capacity as the administrator of the pilot project, gave pilot sites the option to voluntarily use NCPDP SCRIPT 8.1 in place of NCPDP SCRIPT 5.0.

As a result, all grantees/contractors in the pilot sites voluntarily decided to use the updated NCPDP SCRIPT 8.1 in their various testing modalities.

The initial standards and the results of the pilot test are as follows:

- *Formulary and benefits information*—NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (hereinafter referred to as NCPDP Formulary and Benefits 1.0), to provide prescribers with information from a plan about a patient's drug coverage at the point of care.

The Medicare Part D e-prescribing formulary and benefits standard must provide a uniform means for pharmacy benefit payers (Medicare Part D sponsors) to communicate a range of formulary and benefits information to prescribers via point-of-care (POC) systems. These include general formulary data; formulary status of individual drugs; preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and co-payment. NCPDP Formulary and Benefits 1.0 enables the prescriber to consider this information at the point of care and make the most appropriate drug choice without extensive back-and-forth administrative activities with the pharmacy or the health plan. The pilot sites demonstrated that NCPDP Formulary and Benefits 1.0 can be successfully implemented between prescriber and plan, and is ready to be used as part of the e-prescribing program under Medicare Part D.

- *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 (hereinafter referred to as the Medication History Standard), provides a uniform means for prescribers and payers to communicate about the list of drugs that have been dispensed to a patient. It may provide information that would help identify potential drug interactions. This Medication History Standard meets the requisite objectives, functionality and criteria required by the MMA for use in the Medicare Part D e-prescribing program and has been widely adopted by the prescribing industry. The pilot sites found that the Medication History Standard supported the exchange of this information, and is ready to be used for the Medicare Part D e-prescribing program.

• *Structured and Codified Sig*—NCPDP Structured and Codified Sig Standard 1.0, (hereinafter referred to as NCPDP Structured and Codified Sig 1.0), provides a standard structured code set for expressing patient instructions for taking medications (such as “by mouth, three times a day”). These instructions are currently generally provided as free text at the end of a prescription. Pilot sites tested NCPDP Structured and Codified Sig 1.0 and found that it needed additional work on field definitions and examples, field naming conventions, and clarifications of field use. There were contradictions with other structured fields, and there were limitations on the ability to capture directions for use of topical drugs (such as the area of application). Analysis showed that NCPDP Structured and Codified Sig 1.0 was not able to meet the requisite objectives, functionality and criteria required by the MMA for use in the Medicare Part D e-prescribing program.

• *Fill status notification*—The Fill Status Notification, or RxFill, was included in NCPDP SCRIPT 5.0 and the updated NCPDP SCRIPT 8.1, but it previously was not proposed as a foundation standard due to a lack of adequate industry experience. RxFill is a function within versions 5.0 and 8.1 of the NCPDP SCRIPT standard that 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). This information can provide prescribers with information regarding their patients’ adherence to a prescribed medication regimen, especially for those patients with chronic conditions such as hypertension and diabetes, which require medication management. It also has the potential to assist in combating fraud and abuse, and contribute to preventing prescription drug diversion. While the standard was technically capable of performing the function, the pilot sites’ experiences and observations indicated there was no marketplace demand for this information. Prescribers had previously expressed concerns about being inundated with data if they were to receive fill status notifications every time a patient picked up a prescription at the pharmacy, and weren’t sure how useful the information that the Fill Status Notification transaction generated would be in their medical practices. Dispensers were concerned about having to make

significant business process changes, such as, having to check to make sure that fill status notification information was being transmitted by their pharmacy to those prescribers who requested it. The proposed rule therefore relayed that adoption of RxFill “May cause an unnecessary administrative burden on prescribers and dispensers.” (72 FR 64905). As such, in the proposed rule, we asked about the marketplace demand for Fill Status Notification and solicited stakeholder comments regarding their potential utilization of RxFill for the Fill Status Notification transaction. Those comments and our responses are addressed in section III.C.1. of this final rule.

• *Clinical drug terminology*—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. 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. National Drug Codes (NDCs) for specific drug products (where there are often many NDCs 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. There are often several NDCs for any specific drug product, which are linked to a specific drug product code in RxNorm. RxNorm links its drug product codes 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.

The pilot sites demonstrated that RxNorm had significant potential to simplify e-prescribing, create efficiencies, and reduce dependence on NDCs among dispensers. In some testing, RxNorm erroneously linked some NDCs to lists of ingredients rather than to the drugs themselves and sometimes the NDCs linked by RxNorm did not match to the semantic clinical drug (SCD), which always contains the ingredient(s), strength and dose form, in that order. This indicates 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). Analysis showed that, as of the time of the pilot study, RxNorm was not able to meet the requisite objectives, functionality and criteria required by section 1860D–4(e)(3) of the Act for use for Medicare Part D e-prescribing.

• *Prior authorization*—The Accredited Standards Committee (ASC) X12N 275 Version 4010 with HL7, and ASC X12N 278, Version 4010 and addendum 4010A1, (hereinafter collectively referred to as the Prior Authorization standard), were utilized in concert to allow prescribers to obtain certification from a plan that a patient meets the coverage criteria for a given drug. Prior Authorization is a very complex standard to implement, involving four different standards and multiple payer requirements. The pilot sites found that the combination of the ASC X12N 278, and the ASC X12N 275 with the HL7 Prior Authorization (PA) attachment was cumbersome, confusing and required 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.

Investigators agreed that the HIPAA Prior Authorization standard—the ASC X12N 278 Version 4010, and Addendum 4010A—was not adequate to support e-prescribing prior authorization because it was designed for service or procedure prior authorizations, not for medication prior authorization. Modifications to the standard would need to be made prior to adoption as a final standard for the Medicare Part D e-prescribing program.

As required by section 1860D–4(e)(4)(C)(iv)(II), the Secretary issued a report to Congress, “Pilot Testing of Initial Electronic Prescribing Standards,” in April 2007 on the results of the pilot test of the initial standards. The report is available at <http://www.healthit.ahrq.gov/erxpilots>.

III. Provisions of and Analysis and Response to Public Comments for the June 23, 2006 Interim Final Rule With Comment Period and the November 16, 2007 Proposed Rule

A. June 23, 2006 Interim Final Rule With Comment Period

Using the streamlined process established in the November 7, 2005 rule, we published an interim final rule with comment on June 23, 2006 updating the adopted NCPDP SCRIPT standard, thereby permitting either NCPDP SCRIPT 5.0 or 8.1 to be used for the covered transactions listed below

effective June 23, 2006. Version 8.1 of the NCPDP SCRIPT standard is an update to Version 5.0, and we had determined that it was backward compatible with the adopted NCPDP SCRIPT Version 5.0. (Although Version 8.1 of the NCPDP SCRIPT standard has additional e-prescribing functionalities, we did not adopt any of these additional functionalities at that time.) Use of Version 8.1 of the NCPDP SCRIPT standard for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following functions, therefore constituted compliance with the adopted e-prescribing standard:

- 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.

We received 5 timely public comments on this interim final rule with comment period. The following is a summary of the comments and our responses:

Comment: All commenters supported the voluntary use of the backward compatible functions of version 8.1 of the NCPDP SCRIPT standard. Four commenters recommended that it be adopted as soon as reasonably possible, and that NCPDP SCRIPT 5.0 be retired as soon as reasonably practicable. They also indicated that NCPDP SCRIPT 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 notice and comment rulemaking is required. The commenter stated that backward compatibility must be viewed as just one factor in making a determination to adopt a modified standard.

Response: We agree with the commenters who supported the retirement of NCPDP SCRIPT 5.0 in favor of NCPDP SCRIPT 8.1. Regarding the comment that backward compatibility should not be the single criterion for determining if notice and comment rulemaking is used for the purpose of adopting a modified standard and that we should look for

and support other effective alternatives to the backward compatibility issue, we note that we are required by law to employ notice and comment rulemaking to modify an adopted e-prescribing standard. We are also required by section 1860D–4(e)(3) of the Act to ensure, among other things, that the adopted standards meet certain objectives and design criteria. Based on these various statutory requirements and our own policies, we analyze various factors in addition to backward compatibility such as the standard modification’s impact on affected entities relative to cost and benefit projections, productivity and workflow losses/gains, etc., as well as industry and stakeholder feedback by both the written comment process and input from the NCVHS. (For more information, see the June 23, 2006 interim final rule with comment (71 FR 36020).

B. November 16, 2007 Proposed Rule

In the November 16, 2007 proposed rule (72 FR 64900) we discussed the results of the pilot test, and based largely on those results, we proposed the following:

- To retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as a final standard for the transactions listed at § 423.160(b)(1).
- To adopt a final e-prescribing standard for the medication history transaction.
- To adopt a final e-prescribing standard for the formulary and benefits transaction.
- To adopt the National Provider Identifier (NPI) as a standard for identifying health care providers in e-prescribing transactions.
- To establish a compliance date of 1 year after the publication of the final uniform standards.

We received 70 timely comments on the November 16, 2007 proposed rule from dispensers and physicians; national retail drug store chains; vendors; national healthcare industry professional and trade associations; a standards development organization (SDO); state pharmacy associations; a state department of health; healthcare plans and systems; consumer/beneficiary advocacy groups; national prescription information exchange networks; long-term care industry representatives; corporations and pharmaceutical manufacturers, and a federal government agency. These documents frequently contained multiple comments on the various proposals and issues detailed in the proposed rule.

We also received comments outside the scope of the proposed rule. These included one set of comments on another, unrelated notice of proposed rulemaking, and comments on Medicare program operations that are outside the scope of this final rule. The relevant and timely comments within the scope of the proposed rule that we received and our responses to those comments, are discussed in the following sections.

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

In section III.A. of this final rule we discussed the identification of NCPDP SCRIPT 8.1 as a backward compatible update to NCPDP SCRIPT 5.0. In that discussion, we noted that under the interim final rule with comment, the use of NCPDP SCRIPT 8.1 was voluntary. Commenters to this rule recommended that NCPDP SCRIPT 8.1 be adopted as soon as possible and that NCPDP SCRIPT 5.0 be retired.

Therefore, in the November 16, 2007 proposed rule (72 FR 64906 through 64907), we summarized comments received on the voluntary use of NCPDP SCRIPT 8.1 and proposed to revise § 423.160(b)(1) and (c) to replace the NCPDP SCRIPT 5.0 standard with NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(1) (see section III.A. of this final rule). We also solicited additional comments on the retirement of NCPDP SCRIPT 5.0.

Comment: Most commenters supported the adoption of NCPDP SCRIPT 8.1, and retirement of NCPDP SCRIPT 5.0, for the transactions listed at § 423.160(b)(1). They noted that NCPDP SCRIPT 8.1 will provide a uniform communications mechanism for prescribers, dispensers, and payers, support reconciliation of useful data from a larger number of sources, and raise awareness of the availability of medication history and, subsequently, its use among prescribers. Some commenters noted that the industry is already using NCPDP SCRIPT 8.1, so there would be limited impact of converting to NCPDP SCRIPT 8.1 to only those few still using NCPDP SCRIPT 5.0. They indicated that conversion from NCPDP SCRIPT 5.0 to NCPDP SCRIPT 8.1 would not require any significant enhancements for the majority of entities. Seven commenters supported ultimately moving to NCPDP SCRIPT 10.5, but only one commenter recommended bypassing NCPDP SCRIPT 8.1 and adopting version NCPDP SCRIPT 10.5 directly.

Response: NCPDP SCRIPT 8.1 is already in widespread use, has adequate industry experience, and supports the

e-prescribing transactions for which it was pilot tested (with the exception of long-term care e-prescribing applications). Therefore, we believe at this time that NCPDP SCRIPT 8.1 should be adopted in place of NCPDP SCRIPT 5.0 at § 423.160(b)(2)(ii) and (c). In keeping with the pilot findings, the exception to this standard at § 423.160(a)(3)(iii) for e-prescribing in long-term care settings will be retained until a subsequent version of NCPDP SCRIPT is adopted that will support transactions in that setting.

Regarding the comment that we bypass NCPDP SCRIPT 8.1, and adopt NCPDP SCRIPT 10.5, NCPDP SCRIPT 10.5 has not yet been approved by the NCPDP Board of Directors and the Accredited National Standards Institute (ANSI).¹ Based on the Department's criteria consistently applied to the adoption of e-prescribing standards, NCPDP SCRIPT 10.5 will not be considered by the Secretary for adoption until such time as that SDO/ANSI approval process has been completed.

Comment: A number of commenters favored adoption of NCPDP SCRIPT 8.1, but with the caveat that CMS not preclude stakeholders who need to use the advanced functionalities of NCPDP SCRIPT 10.2 or higher, such as those in long-term care settings, from doing so voluntarily. One commenter noted that any version of NCPDP SCRIPT 10.0 or higher would be acceptable. Others said that NCPDP SCRIPT 10.2 or 10.3 would be the appropriate standard for use in long-term care. We also received comments that the agency should retire NCPDP SCRIPT 8.1 in favor of NCPDP SCRIPT 10.5 by the year 2010, and one commenter supported the current adoption of NCPDP SCRIPT 8.1, but with adoption of NCPDP SCRIPT 10.5 within a year's time.

Response: By their very nature, standards are subject to updating and modifications as new business needs, workflows and other issues are identified and resolved. We recognize industry's desire for adoption of the most current and robust versions of standards. We note that, in instances where a subsequent standard is backward compatible with previously adopted standards, the streamlined process described earlier can allow for use of subsequent versions of the adopted standard as well as the previously adopted version of the

standard. Under this process, the Secretary may identify a subsequent backward compatible version(s) of an adopted non-HIPAA standard, and, with publication of an interim final rule with comment in the **Federal Register**, adopt such subsequent versions of the standard for voluntary use. As new backward compatible versions of non-HIPAA e-prescribing standards such as NCPDP SCRIPT are identified, they could be adopted under this process for voluntary use as an alternative to NCPDP SCRIPT 8.1.

With regard to the recommendation that we adopt versions of standards "X.X or higher," we cannot adopt versions of standards that do not currently exist. Notice and comment rulemaking requires a meaningful opportunity to comment. It is not possible to comment meaningfully on a version of a standard that is not yet in existence, and as such, is not available for public review.

Comment: One commenter suggested voluntary use of the Get Message and Password Change transactions supported by NCPDP SCRIPT 8.1.

Response: The NCPDP SCRIPT 5.0 standard includes standards for the Get Message and Password Change transactions (70 FR 67594). The NCPDP SCRIPT 8.1 standard also includes standards that support these transactions. Those who elect to electronically transmit prescription and prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals, directly or through an intermediary, are required to comply with final standards that are in effect.

We will finalize the recognition of NCPDP SCRIPT 8.1 as a backward compatible version of the adopted NCPDP SCRIPT 5.0, but in response to the comments that were received to that interim final rule with comment, as of April 1, 2009, we will retire NCPDP SCRIPT 5.0 and leave NCPDP SCRIPT 8.1 as the adopted standard. To effectuate this, we are—

- Redesignating and amending proposed § 423.160(b)(1) as § 423.160(b)(2)(ii) to apply to transactions on or after April 1, 2009;
- Adding a new § 423.160(b)(1) to identify which paragraphs are applicable to which timeframes; and
- Adding new § 423.160(b)(2)(i) to apply to transactions before April 1, 2009 and adding the appropriate regulatory citations to § 423.160(b) to identify where each standard is incorporated by reference, if applicable.

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

In the November 16, 2007 proposed rule (72 FR 64907), we discussed that if NCPDP SCRIPT 8.1 is adopted in place of NCPDP SCRIPT 5.0 at § 423.160(b)(1), we would also add a new § 423.160(b)(3) to adopt the NCPDP SCRIPT 8.1 Medication History Standard for electronic medication history exchange among the Medicare Part D sponsor, prescriber, and the dispenser when e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals.

We also discussed how the adoption of the NCPDP SCRIPT 8.1 Medication History Standard 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 medication history availability and use among prescribers.

Comment: Most commenters supported the adoption of the NCPDP SCRIPT 8.1 Medication History Standard, noting that over time, medication history will help reduce adverse drug events, doctor shopping, and prescription drug diversion/fraud, and provide for emergency prescription drug histories in case of natural disasters. One commenter believes that large scale implementation of the NCPDP SCRIPT 8.1 Medication History Standard will result in significant challenges as well as useful refinement of the standard.

A number of commenters supported adoption of the standard, but only on a voluntary basis between trading partners, noting that requiring use of the medication history function could cause some current e-prescribers to revert to paper prescribing if they cannot meet the compliance date. One commenter on the NCPDP SCRIPT 8.1 Medication History Standard stated that the pilot test was performed in a closed system and is not scalable in larger deployments, and also indicated that the medication history transaction, while relatively mature in the prescribing sector, is not widely used in the dispensing sector. The commenter recommended that the use of the standard be encouraged but not required.

Response: The Medication History Standard was tested in four of five pilot project sites, among community physicians, dispensers, plans and payers. The testing included the two national prescription information exchange networks. While tested within closed systems, the pilot project

¹ ANSI accredits the procedures of national standards development organizations. Accreditation by ANSI signifies that the procedures used by the standards body in connection with the standard's development meet the Institute's requirements for openness, balance, consensus and due process. Refer to www.ansi.org for additional information.

evaluators determined that the testing adequately supported concluding that the standard met the requisite objectives, functionality and criteria (including not imposing an undue burden on the industry thanks to there being adequate health care industry experience with the standard) for adoption as a Medicare Part D e-prescribing standard. The pilot project demonstrated that the NCPDP SCRIPT 8.1 Medication History Standard works effectively, and includes the functionality and meets the e-prescribing standards criteria and objectives identified in sections 1860D-4(e)(2) and 1860D-4(e)(3) of the Act, and we will adopt it as a standard. We note that, while Medicare Part D sponsors are required to support all e-prescribing functions for which standards have been adopted, prescribers and dispensers are not required to do so. As a result, prescribers and dispensers who currently use e-prescribing but do not utilize the medication history function will not be required to conduct transactions using the NCPDP SCRIPT 8.1 Medication History Standard. However, if they choose to conduct an electronic medication history transaction in the context of e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals, they must use the adopted standard. Regarding the comment that some current e-prescribers might revert to paper prescribing if they are required to use the NCPDP SCRIPT 8.1 Medication History Standard by the proposed compliance date, we refer back to comments received from a wide spectrum of the industry, that NCPDP SCRIPT 8.1 is already in widespread use, and the Medication History function already resides on the standard. Most providers need only to enable the function on their software system. For those who already enjoy the benefits of e-prescribing, reverting to paper would constitute a setback for their practices. We assume that they would continue to build upon the investment they have already made in their e-prescribing systems and become current, within the time allowed, with the adopted standards for those e-prescribing functionalities they choose to transact.

Comment: Commenters made a number of recommendations about the completeness and availability of medication history data to prescribers and dispensers. Several noted that information about all medications should be made available through the medication history transaction,

including controlled substances (which cannot be e-prescribed under current law), over-the-counter drugs, drugs for which the beneficiary paid in cash, and drugs not covered under Medicare Part D, including those prescribed in the hospital setting. Other commenters recommended that medication history should be available 24 hours a day, 7 days a week through downloads to any prescriber and pharmacy, and that medication history data should not be limited to those who subscribe to any given e-prescribing system or network. One commenter suggested that any Medicare Part D e-prescribing standard for medication history should accommodate family and medical history information that supports linkage of these data sources to an electronic health record system.

Response: Our intent for the scope of this final rule is to establish standards that will be used to support the Medicare electronic prescription program. These standards will provide additional common language and terminology for those operating in the Medicare Part D e-prescribing environment that will further the electronic exchange of information in a data format that is consistent and recognizable.

We agree that the more complete a medication history is, the more useful it will be to the prescriber. However, prescriptions paid for in cash that are not adjudicated through insurance claims systems, and over-the-counter medications, for example, may not be captured by the patient's Medicare Part D sponsor medication history, and therefore would not be available for communication using the standard. The suggestion that we include family and medical history information in the NCPDP SCRIPT 8.1 Medication History Standard is outside of the scope of this rule. While the MMA does provide for the establishment of appropriate medical history standards, no initial standards were identified for this function. The NCPDP SCRIPT 8.1 Medication History Standard is the product of NCPDP, a voluntary consensus standards development organization. Only NCPDP could expand the NCPDP SCRIPT 8.1 Medication History Standard to encompass medical history. Despite its limited function, we believe that the NCPDP SCRIPT 8.1 Medication History Standard will facilitate the flow of available medication history data from Medicare Part D sponsors, and we expect this will have a positive impact on medication errors and ADEs.

Comment: Several commenters noted operational and business flow

shortcomings that could limit the utility of medication history. One commenter indicated that the current criteria for medication history match is higher than that for formulary and benefits, and that current experience with one prescription information exchange network demonstrates a 50 to 65 percent match rate for submitted eligibility requests. Another commenter mentioned that many physicians are unable to access all medication history information, and that physicians should be able to add medications to the medication history without having to generate a prescription. Another commenter noted that as the pilot results showed, clinicians' willingness to access medication history was limited due to incomplete information, and that further testing of the standard is needed prior to adoption to clarify requirements for completeness and usability of information, and to determine where the information can be most effectively introduced and exchanged within the provider's workflow. Another commenter noted that the current medication history transaction does not support drug utilization review and medication management.

Response: In the November 16, 2007, proposed rule, we acknowledged that many physicians were unaware of the medication history function likely because, while it resides within the widely used NCPDP SCRIPT 8.1 suite of functional standards, most users have apparently not activated this feature on their e-prescribing systems. We expect that, as the standard achieves widespread use, industry feedback to the SDO will result in improvements and modifications that support more robust and complete medication history capacities. While industry input indicates there may be many reasons for less than a 100 percent match rate, including incomplete access to eligibility data, data inconsistencies and inaccuracies, etc., they also indicate that this could be corrected through the use of a unique identifier. While there is significant opportunity to improve the use of medication history, we believe that adopting the standard and expanding its use will help identify and drive process improvements.

We have adopted the NCPDP SCRIPT 8.1 Medication History Standard as proposed with two technical changes. We redesignated the standard from § 423.160(b)(3) to § 423.160(b)(4) and added a reference to the paragraph regarding the incorporation by reference of this standard.

3. Proposed Adoption of an E-prescribing Standard for Formulary and Benefits

In the November 16, 2007, proposed rule (72 FR 64907), we discussed that, as a result of pilot testing, we proposed to add § 423.160(b)(4) to adopt NCPDP Formulary and Benefits 1.0, as a standard for electronic transactions communicating formulary and benefits information between the prescriber and the Medicare Part D sponsor when e-prescribing for covered Medicare Part D drugs for Medicare Part D eligible individuals.

Comment: We received many comments supporting adoption of the NCPDP Formulary and Benefits 1.0, which noted that the pilot test demonstrated that NCPDP Formulary and Benefits 1.0 was technically capable of communicating the intended information to support this transaction. A prescription information exchange network also concurred, relaying that they began certifying physician software vendors and payers for formulary and benefits functionality last year, and have had good results implementing it since that time. A few commenters also pointed to the inherent complexities associated with implementing the standard, saying that without real-time information, patient information is often outdated and lacks detail, which can lead to higher co-pays and confusion for patients. They said that plans, carriers, and pharmacy benefit managers (PBMs) should be required to provide accurate, timely and complete formulary and benefits information. One commenter recommended that plans not be required to conduct the transaction, but if they do so, they must use the standard. Several commenters indicated that use of the transaction be voluntary among trading partners.

Response: Based on pilot test results and industry comments on the proposed rule, we agree that NCPDP Formulary and Benefits 1.0 has met the requisite objectives, functionality and criteria requirements of the MMA for use in the Medicare Part D e-prescribing program, and we will adopt it as a standard.

E-prescribing under Medicare Part D, as outlined in section 101 of the MMA, is voluntary for providers and dispensers. However, Medicare Part D sponsors must support the use of, and comply with, these standards when electronically transmitting prescriptions or prescription-related information for covered Medicare Part D drugs for Medicare Part D eligible individuals.

We do not believe that there would be any additional value gained from continued pilot testing of the standard.

We acknowledge that formularies are complex, frequently change due to updates in coverage decisions, and that coverage benefits are fluid, sometimes changing from day to day. Currently, the industry practice is to send formulary and benefits information periodically and in batch-file format. We agree that the capacity to provide this information on a real-time basis is an important step toward realizing the full potential of the benefit of the standard, and expect that, as the standard gains widespread use, marketplace forces will encourage incorporation of real-time transaction capacities into the formulary and benefits e-prescribing process. In the meantime, we believe that additional testing, not of the standard itself but of the ability to provide real-time benefit responses, is desirable as the industry seeks to maximize e-prescribing system capabilities, and it is our understanding that industry efforts are underway to test real-time transactions through electronic prescription information exchange networks.

Also, as the NCPDP commented, there is an effort underway to bring industry participants together for further analysis and testing to address any remaining NCPDP Formulary and Benefits 1.0 implementation issues, which result from missing or incomplete data, and are not the result of the standard functioning inadequately for the transaction. NCPDP also is following up on a Healthcare Information Technology Standards Panel (HITSP) recommendation that NCPDP evaluate data element/list requirements and propose solutions to any outstanding issues.

Comment: Several commenters stated the need to restrict the “list of alternative drugs” to only those products that are bioequivalent or that have received the “AB” designation from the Food and Drug Administration (FDA), preventing the prescribing of potentially inappropriate or unsafe therapeutic substitutions. They supported adoption of the standard, but not the current version that includes “preferred” or “formulary alternatives lists.”

Response: NCPDP Formulary and Benefits 1.0 supports a codified way of sending information that includes “preferred” or “formulary alternatives lists,” if a health plan offers such products. The standard does not assess the appropriateness of the alternatives, rather it merely conveys the applicable formulary requirements, including any step therapy requirements, of a given patient’s health coverage. The Medicare Part D program provides for formularies in which therapeutically non-equivalent

and non-bioequivalent drugs are offered in each category and class of a Medicare Part D drug formulary. (See § 423.120(b)(2).) The Medicare Part D program allows Medicare Part D sponsors to have utilization review management procedures, including step therapy guidelines, within approved formularies. Our adoption of NCPDP Formulary and Benefits 1.0 applies specifically to e-prescriptions for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals. As such, we believe that it should support conveying formulary information about the non-equivalent and non-bioequivalent drugs that are part of an approved Medicare Part D sponsor’s formulary.

We have adopted the NCPDP Formulary and Benefits 1.0 standard as proposed with two technical changes. We redesignated the standard from the proposed § 423.160(b)(4) to § 423.160(b)(5) and added a reference to the paragraph regarding the incorporation by reference of this standard.

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

In the November 16, 2007, proposed rule (72 FR 64908), we proposed to add § 423.160(b)(5) to adopt the National Provider Identifier (NPI) as a standard identifier for health care providers for use in e-prescribing among the Medicare Part D sponsor, prescriber, and the dispenser. NCPDP SCRIPT 8.1, which we proposed to adopt, supports the use of the NPI.

We solicited comments from the industry and other stakeholders on the adoption of the NPI as an e-prescribing standard, and we specifically requested 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.

Comment: Commenters generally acknowledged industry familiarity with the NPI from having used it in HIPAA standard transactions. While most commenters supported the use of the NPI on electronic prescriptions to identify the prescriber and the dispenser, they agreed that the NPI must not be used for routing transactions (message envelope), or sender/receiver-level information used in e-prescribing routing transactions, as it does not offer the clarity needed for routing data to destinations. However, it can be used to identify an organization or a provider involved in electronic prescribing

transactions. We received several comments about how the adoption of the NPI as a health care provider identifier for use in e-prescribing would improve the ability to uniquely identify a prescriber, but that the NPI must be used to identify a prescriber at the individual versus organizational level. A number of commenters urged CMS to provide more specific guidance on the use of the NPI in e-prescribing.

Three commenters opposed the adoption of the NPI as a standard identifier for use in Medicare e-prescribing because they contend that, as it is currently constructed, the NPI does not convey appropriate location and routing information which is essential to the e-prescribing process. One commenter said the NPI works as a name, but not as an address (that is, the location and setting of the prescriber). Another commenter stated that they do not use the NPI for e-prescribing because its use would force the industry to incur significant implementation costs. This commenter took issue with CMS' assumption that experience in using NPI in HIPAA-covered transactions constitutes adequate industry experience for adopting it for use in e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals. One other commenter stated that, since it was not pilot tested, the NPI should be adopted only after pilot testing has been conducted and evaluated.

Response: Our intention in proposing the use of the NPI in e-prescribing transactions was to extend the functionality of the NPI from HIPAA-covered transactions to non-HIPAA e-prescribing transactions so that those with NPIs could use one identifier for both HIPAA-covered transactions and non-HIPAA e-prescribing transactions, versus a separate identifier(s), and allow the identification of both an individual prescriber and the dispensers. As the NPI has the ability to identify health care providers such as prescribers and dispensers, and as NCPDP SCRIPT 8.1 supports the NPI, its use in the e-prescribing of Medicare Part D covered drugs for Medicare Part D eligible individuals would fulfill the function for which it was intended. If the NPI is used as we proposed, as that of an identifier of individual, non-institutional health care providers, and not for routing or location purposes, we see nothing that would preclude its use for purposes of identification, or that would require pilot testing. Therefore, in NCPDP SCRIPT 8.1, the NPI would be used in the PVD Provider Segments to identify the prescriber or the dispenser. However, the NPI would not be used in

the UIH Interactive Interchange Control Segment to route the transaction.

Based on our analysis of the comments received, we will adopt the NPI for use in e-prescribing to identify the individual healthcare prescriber and the dispenser. We note that, in doing this, we do not alter the compliance dates or other requirements under HIPAA for covered entities with respect to e-prescribing transactions that are also HIPAA covered transactions. For instance, we do not intend to alter any provisions requiring the use of the NPI for identifying institutional providers in HIPAA transactions, including those HIPAA transactions which are also e-prescribing transactions. We will also provide specific guidance in the future regarding how the NPI should and should not be used in e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals.

Comment: A number of commenters noted that not all prescribers are covered entities under HIPAA, and expressed concern that if the NPI were mandated as the sole identifier for prescribers, prescribers who do not have an NPI may not be able to engage in e-prescribing.

Response: While not all providers are required by HIPAA to obtain an NPI, they are all permitted to do so. Moreover, we believe that most, if not all, providers who treat Medicare beneficiaries, already have an NPI, either because they are HIPAA-covered entities, or if not, because as providers they are otherwise identified on HIPAA transactions (for example, as a rendering physician) or on submitted paper claims, as Medicare requires the use of the NPI on paper claims.

Comment: One commenter suggested that the DEA number be used to clarify the identity of the prescribing provider when the NPI number is not adequately specific. Another noted that the DEA number is still required for prescribing controlled substances, but it is unclear as to whether prescribers will need to use their DEA number in the e-prescribing of controlled substances once it is allowable under law.

Response: Not all providers prescribe controlled substances and thus, not all providers have DEA numbers. As e-prescribing of controlled substances is still not allowed by law, we cannot speculate as to the potential role of the DEA number in that process. We also note that as the intent of the NPI is to consolidate multiple and/or proprietary prescriber identifiers for use in the Medicare program, it would appear to be counterproductive to use one number, namely the DEA number, to clarify another number, the NPI.

Comment: One commenter requested that CMS allow adequate time for adoption.

Response: We will monitor industry feedback regarding this issue and respond accordingly.

Comment: One commenter stated that dispensers should not be deemed to be in violation of e-prescribing standards if the prescriber does not have an NPI or fails to include an NPI in an e-prescribing message, and questioned what effect that may have on the dispenser's compliance with e-prescribing regulations.

Response: If a prescriber is e-prescribing under the Medicare Part D program, the prescriber is required to use the adopted standards, in this case, the NPI, to identify an individual e-prescribing provider. By the compliance date of this final rule, we expect that providers who participate in Medicare, including those who submit paper claims, will have already have obtained their NPI for claims reimbursement purposes.

Absent an NPI, prescribers likely would not be engaged in e-prescribing. However, in the instance of a dispenser receiving an e-prescription for a Part D covered drug for a Part D eligible individual from a prescriber without an NPI, the prescriber, not the dispenser, would be considered to be in violation of Part D e-prescribing regulations.

We have adopted the NPI as a standard identifier as proposed with a technical change. We redesignated this standard from the proposed § 423.160(b)(5) to § 423.160(b)(6).

5. Proposed Compliance Date

In accordance with sections 1860D-4(e)(1) and 1860D-4(e)(4)(D) 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, we proposed a compliance date of 1 year after the publication of the final rule. We also proposed adopting NCPDP SCRIPT 8.1 as the e-prescribing standard for the transactions listed in section II.A. of the proposed rule (72 FR 64906), effective 1 year after publication of the final rule. We solicited comments in the proposed rule regarding the impact of these proposed dates on industry and other interested stakeholders, and whether an earlier compliance date should be established.

Comment: Many commenters supported a compliance date of 1 year after issuance of the final rule, stating that based on their respective industry feedback and experience with NCPDP

SCRIPT 8.1, 1 year should be adequate time for the industry to work toward implementation of these standards with minimum impact. A few thought that industry compliance prior to that time could be achieved. A few other commenters said that the proposed compliance date is extremely aggressive and does not take into consideration vendor system development life cycles, release dates of supporting systems, and time and resources required for health systems to adopt and deploy the needed infrastructure to attain the expected financial and safety benefits of e-prescribing. One commenter stated that the proposed implementation date is problematic for Medicare Part D sponsors that own dispensers that have already begun to adopt e-prescribing, because having to retrofit standards into existing systems may be more costly and time consuming. This commenter suggested an additional year or two beyond the proposed compliance date to allow adopters to bring current e-prescribing systems into compliance. Another recommended that providers be given a minimum of 2 years to comply. Two commenters requested that we consider contingency plans if the industry is unable to meet the 1 year compliance timeframe. One commenter recommended that CMS conduct a study to identify pharmacy preparedness, and that once the final rule is released, that CMS monitor the progress of the industry in implementing the standards, and develop an extended adoption timeframe as warranted.

Response: Section 1840D-4(e)(4)(D) of the Act requires that final e-prescribing standards be promulgated by the Secretary by April 1, 2008, with implementation no more than 1 year following that date, which would place the latest possible implementation date at April 1, 2009. We agree that, based on comments received, adoption of these standards with the 1 year compliance date imposes no undue burden on the industry, and concur with commenters who supported the proposed 1 year compliance date.

Based on industry feedback, numerous e-prescribing software systems now using NCPDP SCRIPT 8.1 have been certified for use by electronic prescribing networks. The NCPDP Formulary and Benefits 1.0 standard is based on a proprietary transaction developed by RxHub, which is currently being used to communicate this information in many e-prescribing products. The NCPDP SCRIPT 8.1 Medication History Standard is already contained in NCPDP SCRIPT 8.1, which is in widespread use. We anticipate that

any e-prescribing software vendor or service has already, or will provide, these standards upgrades as part of a monthly subscription charge or annual maintenance fee, and that it would not require massive systems changes that would be overly burdensome. We have received no extensive stakeholder or vendor feedback that upgrades to current e-prescribing systems are more burdensome than installations of new e-prescribing systems. There will always be modifications to standards to which e-prescribing systems must be retrofitted, and we trust that industry software vendors will anticipate these modifications and accommodate standards upgrades to make their use by existing customers as smooth and seamless a transition as possible. We cannot delay the implementation date for the standards adopted under section 1860D-4(e)(4)(D) of the Act, which is set by statute, and continue to believe that 1 year is adequate time to accomplish any system changes necessitated by the adoption of these final standards. However, we will monitor industry feedback relative to their ability to meet the 1 year compliance timeframe and determine the need for any other action based on that information within the applicable statutory parameters.

We are adopting a compliance date of 1 year after publication of the final standards as proposed. Therefore, to clarify the compliance dates for the revised and existing standards, we have revised § 423.160(b) as follows:

- Redesignated the proposed paragraphs (b)(1) through (b)(5) (we proposed to add new paragraphs (b)(3) through (b)(5)) as paragraphs (b)(2) through (b)(6).
- Added a new paragraph (b)(1) that identifies the compliance dates for each standards in paragraphs (b)(2) through (b)(6).
- In newly redesignated (b)(2) (the prescription standard), revised the standard to separately identify the NCPDP SCRIPT 8.1 and NCPDP SCRIPT 5.0 based on the compliance dates of these standards.

C. Related Issues Included in and Analysis and Response to Public Comments for the November 16, 2007 Proposed Rule

In the November 16, 2007 proposed rule, we requested comments on various issues related to the e-prescribing process. We received numerous comments on those and other issues and we discuss those comments and our responses below.

1. Fill Status Notification (RxFill)

In the November 16, 2007 proposed rule, we explained that the Fill Status Notification within the NCPDP SCRIPT 8.1 enables a pharmacy to notify a prescriber when the prescription has been dispensed, partially dispensed, or not dispensed. The pilot test demonstrated that the standard was technically capable of performing this function, but pilot sites questioned whether prescribers would be inundated with data, and dispensers would be burdened by the business process changes that would ensue. We solicited industry comments regarding RxFill's usefulness.

Comment: Many commenters noted that RxFill contains useful functionality, such as monitoring patient adherence to a medication regimen, or identifying drug diversion/abuse. However, most recommended that the transaction be used on a voluntary basis among trading partners, noting that the need for information provided by RxFill varies by prescriber. One commenter predicted that physician demand for this standard will increase dramatically following the rollout of the 2008 Physician Quality Reporting Initiative (PQRI) measures, as performance on these measures is influenced by patient compliance with therapy.

Several commenters stated that the NCPDP SCRIPT 8.1 Medication History Standard offers prescribers and dispensers similar but richer information, making RxFill unnecessary.

A number of commenters noted that there were business process and implementation issues associated with RxFill. Others noted shortcomings in the standard, such as omission of features such as pharmacy receipt, patient pick up, reason for refusal of fill, and the placement of the order in the prescription filling process. They recommended additional analysis and testing prior to adoption.

Response: As stated in the November 16, 2007 proposed rule, we previously referenced industry feedback that had indicated that the adoption of RxFill “may cause an unnecessary administrative burden on prescribers and dispensers” as a basis for not proposing the adoption of RxFill. This feedback was derived from the findings contained in the report to Congress on the results of the CY 2006 e-prescribing pilot (<http://www.healthit.ahrq.gov/erxpilots>). The report noted that the industry feared that adoption of the RxFill standard for electronic fill status notification transactions might result in increased “administrative workflow”

issues, namely being inundated with fill status notifications every time a patient picked up (or conversely, did not pick up) a prescription. However, it is now clear from the comments received in response to the November 16, 2007 proposed rule that the industry, upon further consideration, now perceives there to be no administrative burden associated with the adoption of the RxFill standard. This is a result of the realization by the industry that the prescriber would have to use their e-prescribing system to electronically “flag” or switch on the fill status notification transaction for those patients whose medication adherence they wish to monitor. When a patient picks up a prescription at the pharmacy, they likely sign an electronic signature log. In instances in which the prescriber has switched on the fill status notification transaction in their eRx system, this electronic signature triggers a pharmacy software system update which, in turn, would trigger a fill status notification message using the RxFill standard to be sent back to the prescriber. Prescriber comments in response to the proposed rule indicates that they perceived real value in RxFill for prescribers whose patients with chronic conditions may benefit from closer medication adherence monitoring. In addition, the pilot demonstrated that RxFill supports the transactions for which it was tested. Given the voluntary nature of e-prescribing for dispensers and prescribers under Medicare Part D, prescribers can choose whether or not they want to avail themselves of the information that use of this standard in the electronic Fill Status Notification transaction would provide, and voluntarily incur costs, if any, associated with its use. Therefore, we will revise § 423.160(c) and add a paragraph (M) to § 423.160(b)(2)(ii) to adopt the Rxfill standard by adding the prescription Fill Status Notification 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) to provide for the communication of fill status notification of Medicare Part D prescription drugs for Medicare Part D eligible individuals, among Medicare Part D sponsors, prescribers and dispensers, to the list of transactions for which NCPDP SCRIPT 8.1 is used.

Comment: Several commenters who supported RxFill’s adoption suggested modifications that they believed might make it less burdensome to providers.

These included the suggestion of identifying only key categories of drugs, such as blood pressure or diabetes medications, that would trigger an RxFill notification to a provider from a pharmacy; or an RxFill notification if a patient did not pick up an e-prescribed prescription at their pharmacy within one week to 10 days after its transmission. One commenter also suggested the use of RxFill as a way to auto-populate medication history fields.

Response: We expect that increased use of RxFill will allow the industry to identify a variety of functional and business flow improvements that could be incorporated through the standards maintenance process. The Department will continue to monitor the further development of, and revisions to, this standard and will consider updating the adopted standard when and as appropriate.

2. RxNORM, Structured and Codified Sig, and Prior Authorization

In the proposed rule we identified three of the six initial standards that the pilot results showed were not ready for adoption: RxNORM, NCPDP Structured and Codified Sig 1.0, and the Prior Authorization Standard. We also noted that RxFill was technically ready for adoption, but as previously discussed, we were unsure as to industry’s desire to adopt it as a standard. As a result, we did not propose to adopt these standards, but we solicited public comment on this decision.

Comment: Most commenters agreed that the standards for NCPDP Structured and Codified Sig 1.0, clinical drug terminology (RxNorm) and the Prior Authorization Standard were technically unable to convey the needed information and lacked adequate industry experience. Only one commenter asserted that all six initial standards tested in the CY 2006 pilot could feasibly be implemented by 2009.

Response: We agree that these standards are not ready for implementation, and are not adopting them at this time.

Comment: Many commenters stressed the potential value of these standards, and urged us to work actively with the industry to promptly mitigate the problems and concerns with the standards. Commenters also noted that there are efforts underway to bring industry participants together for further analysis and testing of RxNorm, NCPDP Structured and Codified Sig 1.0, and the Prior Authorization Standard, to expand upon and bring to completion the work begun in the CY 2006 e-prescribing pilot. Several commenters asked that CMS include language “in the standards

that commits it (CMS) to development and pilot testing of the Prior Authorization Standard.”

One commenter who was familiar with the pilot of the initial standards stated that many of the shortcomings of RxNorm that were identified in the pilot test were focused on difficulties in conveying information about drug delivery devices and packages, and not the overall function of the standard in other contexts. They said that while there may have been instances of unresolved synonymy, that at least half of them, if not all of them, have already been resolved.

Commenters stated that they believed the Prior Authorization Standard is an inefficient, time consuming process that is a source of frustration for both physicians and patients, and a process that is ripe for improvement. One commenter recommended additional research on the Prior Authorization Standard to alleviate the manual administrative burden associated with the high volume of prior authorizations in the long-term care setting.

Response: One commenter asked that CMS include language in the standards that commits it to development and pilot testing of the prior authorization standard. We note that standards are guidelines, rules or characteristics for activities, and are the purview of the standards development organizations and not CMS; therefore, the inclusion of such language as part of the technical specifications of a standard would be inappropriate.

We agree that these three standards would contribute significant value to e-prescribing, and will continue to work with the SDOs, industry, and interested stakeholders toward readying these standards for consideration by the Secretary for adoption as final standards for e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals.

3. Exemption for Computer-Generated Facsimiles

The November 2, 2005 foundation standards final rule (70 FR 67568) exempted entities that transmit prescriptions or prescription-related information by means of a computer-generated facsimile from the requirement to use the adopted NCPDP SCRIPT standard for the transactions that, prior to this rule, were listed at § 423.160(b)(1). In response to industry concerns that the exemption was hindering the movement toward computer-to-computer e-prescribing, we included a proposal to eliminate the exemption in the CY 2008 Physician Fee Schedule proposed rule (July 12, 2007

(72 FR 38122, 38196)), effective January 2009. In the November 27, 2007 CY 2008 Physician Fee Schedule Final Rule with Comment, 72 FR 66334, we modified the computer-generated facsimiles exemption, but did not eliminate it entirely, allowing computer-generated facsimiles to be used in the event that an EDI-transmitted prescription fails due to network transmission failures or similar, temporary communication problems that are episodic and nonrepetitive in nature.

In the November 16, 2007 proposed rule (72 FR 64902) we referenced, but did not solicit comments on our inclusion of a proposal to remove the exemption for computer-generated facsimiles in the CY 2008 Physician Fee Schedule proposed rule (72 FR 8196). However, we received comments on this provision in response to our solicitation for comments on the November 16, 2007 proposed rule.

Comment: Several commenters requested that we not eliminate the use of all facsimiles (including computer-generated facsimiles) as a means of transmitting prescriptions and prescription-related information between provider and pharmacy, and vice versa. Commenters stated that if all facsimiles of prescriptions and prescription-related information were eliminated, it would constitute a burden on dispensers and provider offices that would have to revert to paper, which would result in decreased productivity and increased costs. Another commenter stated that use of secure facsimile via computer to computer link or computer to facsimile link, should be allowed when the NCPDP SCRIPT 8.1 standard transmission is "not available" to all prescribers.

Two commenters stated that the elimination of the exemption for computer-generated facsimiles should be delayed until January 2010; and that the provisions of the final rule should be modified to allow its use when transmitting prescription or prescription-related information to dispensers and facilities that do not e-prescribe, or when prescribing controlled substances.

Response: First, we note that transmitting paper prescriptions from one facsimile machine to another for Medicare Part D covered drugs for Medicare Part D eligible individuals, as described by one of the commenters, does not constitute electronic data interchange. Such paper faxing is not subject to the Medicare Part D e-prescribing standards adopted for the e-prescribing of Medicare Part D covered

drugs for Medicare Part D eligible individuals.

In the July 2007 proposed rule, we did not propose the elimination of the use of paper facsimiles as a way to transmit prescriptions and prescription-related information. Rather, we proposed eliminating the exemption for computer-generated e-prescribing facsimiles from the adopted NCPDP SCRIPT standard for the communication of prescriptions and prescription-related information between prescribers and dispensers for the transactions listed at § 423.160(b)(1)(i) through (xii). In the final rule, we acknowledged that computer-generated facsimiles may be needed for prescriptions which fail due to network transmission failures or similar, temporary communication problems that are episodic and non-repetitive in nature and preclude the use of NCPDP SCRIPT. However, this exception applies only to transmission failures, and not simply to those who choose to use e-prescribing software that does not employ the NCPDP SCRIPT standard. We assume the commenter is referring to such a situation when referencing that computer to computer link or computer to facsimile link, should be allowed when the NCPDP SCRIPT 8.1 standard transmission is "not available" to all prescribers.

During the time period allotted for comment following the issuance of the July 2007 proposed rule we received several comments regarding the elimination of the exemption for computer-generated facsimiles. A number of commenters disagreed with the lifting of the exemption, indicating that its elimination could be problematic in performing a certain e-prescribing function, that of prescription refill requests, but only one of those commenters offered substantiation. Absent receipt of any other industry feedback on the impact of the elimination of computer-generated facsimiles on prescription refill requests, and not considering these comments to constitute widespread concern regarding the refill request function, we proceeded in CY 2008 Physician Fee Schedule final rule (72 FR 66334) to amend the exemption to eliminate the exemption except, as noted above, in cases of network failure. Taken in the aggregate, we determined that the 1 year time period was adequate time during which providers and dispensers would have the opportunity to change over to conducting true e-prescribing (computer to computer EDI) and that costs would be mitigated due to the growing volume of e-prescriptions and practice of e-prescribing, with a commensurate reduction in

transmission, software and other costs during that 1 year time period. These changes are due to become effective in January 2009.

Since that time, we have been informed by the industry that the elimination of the exemption for computer-generated facsimiles would have a significant adverse effect in the electronic transmission of prescription refill requests, and interested stakeholders have provided us with more specific information regarding the economic and workflow impact that will result from the modification of the exemption that was not forthcoming during the public comment period. In particular, dispensers have indicated that they use computer-generated facsimiles for a significant volume of refill requests, and that eliminating the exemption would require them to revert to paper facsimiles for those transactions. We are now in the process of examining and considering these data, and may soon issue a proposed solution through the rulemaking process that we intend to finalize prior to the scheduled January 2009 effective date. Through this process the public will, once again, be afforded an opportunity to offer public comment.

4. Elimination of the Exemption for Non-Prescribing Providers (Long Term Care)

In the proposed rule (72 FR 64902 through 64906), we noted that, because NCPDP SCRIPT was not proven to support the workflows and legal responsibilities in the long-term care setting, 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 ("three-way prescribing communications" between facility, physician, and pharmacy), were provided with an exemption from the requirement to use NCPDP SCRIPT 5.0 in transmitting such prescriptions or prescription-related information. We also noted the results of the CY 2006 e-prescribing pilot relative to the use of NCPDP SCRIPT 8.1 in the long-term care setting, namely that workarounds were needed to accommodate the unique workflow needs in long term care. We conveyed that, when an updated version of the NCPDP SCRIPT standard in the long-term care setting, we would consider removing the current exemption. We then solicited comments on the impact and timing of lifting this exemption.

Comment: Commenters generally acknowledged that progress is being made toward accommodating the specific needs of the long term industry in e-prescribing standards, and supported the eventual elimination of the long-term care exemption to the NCPDP SCRIPT standard. They noted that, while NCPDP SCRIPT 8.1 may work well in most instances, each higher level of NCPDP SCRIPT (10.0 or higher) contains more functionality that ultimately will build to that which will be needed for long-term care applications. They noted that one of these higher level standards should be the designated standard for use if/when the exemption for e-prescribing in the long-term care setting is eliminated. Several commenters stated that the exemption for e-prescribing in long-term care could be lifted upon adoption of NCPDP SCRIPT version 10.2. This newer version of the standard is ANSI approved, and, according to these commenters, meets the basic e-prescribing needs of the long-term care industry. Another commenter recommended adoption of NCPDP SCRIPT 10.3, citing its expanded ability to support resupply requests, fill status and census notification messages in the long-term care setting. Still other commenters insisted that CMS should adopt NCPDP SCRIPT 10.5 for use in e-prescribing in the long-term care setting. Commenters also stated that they anticipated that the Certification Commission for Healthcare Information Technology (CCHIT) would begin work in 2009 to launch certification of electronic health records products for long-term care, and that in preparation for that activity, national standards for e-prescribing for long-term care will need to be in place. One commenter stated that the long-term care exemption should remain in place until such time as e-prescribing standards can support the needs of long-term care, taking in account medication management across multiple care settings and providers. Another stated that the exemption should not be lifted until all standards for e-prescribing had been adopted, and the industry had conducted adequate testing. One commenter recommended that CMS should, with this final rule, remove the current exemption for long term care entities from using the Medicare Part D e-prescribing standards, effective with the compliance date of this rule.

Response: While NCPDP SCRIPT 10.2 was approved in July 2007, NCPDP SCRIPT 10.3 is not scheduled for approval until April 2008, and NCPDP SCRIPT 10.5 is not scheduled for

approval until July 2008. We agree with commenters that NCPDP SCRIPT 10.5 appears to meet all of the long-term care business needs that have been identified to date, and therefore would be appropriate for adoption. When NCPDP SCRIPT 10.5 is approved by NCPDP, we will review it with the purpose of ascertaining whether it is backward compatible with the adopted standard, and thus a candidate for the streamlined process outlined earlier that would permit its use in place of NCPDP SCRIPT 8.1, or if rulemaking will be required. We anticipate eliminating the long-term care exemption when rulemaking is utilized to retire the then-existing standard in favor of version 10.5. From feedback received from the industry, NCPDP SCRIPT 10.2 meets the basic needs of the long-term care industry relative to e-prescribing, including the "need no later than" date/time added for special delivery needs. NCPDP SCRIPT 10.3 features this as well as additional functionality, including medication history source and fill number information for de-duplicate processing. NCPDP SCRIPT 10.5 features all of the functionality of these previous NCPDP SCRIPT 10.0 and above versions, and supports federal medication terminologies code sets. We agree with commenters that NCPDP SCRIPT 10.5 appears to meet all of the long-term care business needs identified to date. Therefore, it would be appropriate to adopt the standard with the most robust functions, since this is what vendors will incorporate into their products. As we indicated in the previous discussion, once NCPDP SCRIPT 10.5 is balloted and approved by the NCPDP, and then approved by the Accredited National Standards Institute (ANSI), we will review it with the intent of moving forward if appropriate. However, we note that long-term care facilities may voluntarily use the standard at any time, and we encourage its adoption in that setting.

5. Electronic Prescribing for Controlled Substances

Comment: Several commenters noted that all categories of prescriptions—including controlled substances—should be able to be electronically prescribed, and that to require handwritten prescriptions for controlled substances would necessitate a dual paper/electronic system which would be a major barrier to adoption. For example, a physician noted that one out of every ten prescriptions he wrote could not be e-prescribed because they were for controlled substances. One commenter recommended that it be mandated that prescribers should check

the identification of patients before prescribing for them electronically.

Response: We agree that the inability to e-prescribe controlled substances can hinder broader e-prescribing adoption. The Drug Enforcement Administration (DEA) which has responsibility for administering the Controlled Substances Act, currently requires that controlled substances be prescribed on paper with a written signature. We continue to work with the DEA toward revised requirements that would permit such e-prescribing while maintaining safeguards against drug diversion.

6. Diagnosis on Prescription

Comment: One commenter proposed that Medicare require diagnosis information on electronic prescriptions, arguing that this would allow the pharmacy to evaluate the drug prescribed against the diagnosis and thus identify potential errors.

Response: NCPDP SCRIPT 8.1 does contain an optional field for diagnosis, but requiring its use is outside the scope of our proposed rule. We have not solicited nor have we received any industry feedback on this issue, and therefore cannot attest as to the industry's use and/or perceived value of this feature.

7. Issues Related to State Law

Comment: One commenter urged CMS to take a broader view of the authority to preempt state law than we outlined in the November 7, 2005 final rule (70 FR 67574 through 67576). They stated that the lack of national applicability of the standards we adopt serves as a barrier to broader adoption of e-prescribing.

Response: In the November 7, 2005 final rule, we identified four categories of State law that restrict the ability to carry out Medicare Part D standards, and which pertain to electronic transmission of prescription-related information. We encouraged States to consider the impact on Federal e-prescribing standards of laws that could directly or indirectly impede the adoption of e-prescribing technology and standards on a statewide and national basis. We also urged States to enact legislation consistent with, and complementary to, the goals of the MMA's e-prescribing provisions. This included removing existing barriers to e-prescribing.

The commenter did not identify any specific State laws that stand as an obstacle to Congress's goal of implementing uniform e-prescribing standards that are to be used in e-prescribing of Medicare Part D covered drugs for Medicare Part D

eligible individuals. Therefore, we will not re-evaluate the scope of preemption at this time. We would consider recommendations related to any specific statute or regulation if such laws and recommendations are brought to our attention at some point in the future.

Comment: Another commenter noted that some State laws restrict communication of "sensitive" medication information (for example, drugs indicative of HIV status, substance abuse, genetic disorder, etc.). The commenter recommended that we preempt any State or local statute or regulation that would limit disclosure of a patient's medication history, noting that these laws and regulations are often inconsistent and hard to find, impeding the ability of vendors to display this information to the prescriber at the point of care.

Response: We acknowledge that medication history data will be most valuable to the prescriber when it is complete. However, these laws do provide patients with additional safeguards for certain categories of medical information. We believe that, as medication history becomes more available to prescribers, these limitations will be identified, and may be appropriate for future regulation. We will not, however, address this issue at this time since it is outside of the scope of this final rule.

8. Incentives to e-prescribing

Comment: A number of commenters suggested that CMS should support adequate financial incentives, and should itself provide financial incentives, to physicians and dispensers to assist them with their investments in, and implementation of, e-prescribing.

Response: The Administration supports the adoption of health information technology as a normal cost of doing business. However, other means of encouraging the adoption of e-prescribing are already in place, such as regulations that provide a safe harbor under the federal anti-kickback statute and an exception under the federal Physician Self-Referral ("Stark") Law for certain arrangements involving the donation of e-prescribing and electronic health records technology. These regulations pave the way for increased adoption of health information technology by physicians and other health care providers. We also note that providers may participate in, and receive incentives through, the 2008 Physician Quality Reporting Initiative (PQRI). This project includes measures for patient compliance with therapy, which can be supported through the

utilization of e-prescribing transactions such as fill status notification.

9. "Pharmacist" versus "Dispenser"

Comment: One comment included a recommendation that we refer to "pharmacists", rather than "dispensers" in the final rule because referring to a pharmacist as a "dispenser" ignores the clinical component of pharmacist-patient interactions.

Response: We fully recognize and appreciate the importance of the pharmacist-patient relationship, which provides critical clinical and educational support to the patient. However, we wish to clarify that we have defined the term "dispenser" at 42 CFR 423.159 to mean a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription. Based on this definition, we will continue to use the term "dispenser" when referencing these entities.

Comment: A number of commenters stated that the benefits of e-prescribing will not be fully realized until e-prescribing is included among CCHIT-certified interoperable electronic health records (EHR) featuring robust decision-making software.

Response: We recognize the immediate benefits that e-prescribing as a stand-alone function can bring to the health care community. However, we support the Administration's health information technology initiatives including EHR certification and standards harmonization, and agree that the full benefits of e-prescribing will be realized through the adoption of certified interoperable electronic health records. Additionally, CMS has participated in the development of the medication management use case that will ultimately result in harmonized standards and support interoperable e-prescribing functionality.

10. Mandatory e-prescribing

Comment: One commenter expressed support for the recommendation from the American Health Information Community (AHIC) that the Secretary seek authority to mandate e-prescribing under Medicare. Another commenter opposed mandating e-prescribing, and another suggested it not be mandated until at least 50 percent of prescribers and dispensers are e-prescribing.

Response: Currently, e-prescribing under Medicare Part D, as outlined in the MMA, is voluntary for prescribers and dispensers. Medicare Part D sponsors must support the use of these standards in e-prescribing transactions.

The breadth of this final rule is limited to that statutory authority.

11. Exemption for e-prescribing in a Closed Enterprise

Comment: Several commenters requested clarification regarding whether prescriptions transmitted within a closed enterprise (for example, from prescribers within an HMO plan to a plan-owned pharmacy) are exempted from the use of the NCPDP SCRIPT standard.

Response: Entities may use either HL7 messages or the adopted NCPDP SCRIPT standard to conduct internal electronic transmittals (that is, when all parties to the transaction are employed by, and part of, the same legal entity) for the specified NCPDP SCRIPT transactions as described above.

12. Commercial Messaging

Comment: One commenter said that commercially oriented messages should not be permitted in e-prescribing until adequate standards for content, integrity, and display of these messages have been developed.

Response: We agree that there needs to be an appropriate balance between providing appropriate information at the point of care, and messaging that might steer the prescriber to use specific drugs and therapeutics as specified at section 1860 D-4(e)(3)(D) of the Act. We also recognize the potential for inappropriate messaging to occur in e-prescribing and share concerns about how the provision of certain information may unduly influence physician prescribing patterns. For example, inappropriate messages include those that would steer the filling of a prescription to a particular mail order pharmacy versus a retail pharmacy, and electronic "detailing" messages from a manufacturer promoting a particular brand or brand-name drug over and above that which the Medicare Part D sponsor requires or to which it gives preference. Moreover, if a drug manufacturer engages in this practice to promote unapproved uses for a drug, this could be a violation of the Federal Food, Drug, and Cosmetic Act. We will monitor this as an operational issue and will provide guidance to Medicare Part D sponsors at a future date and, if necessary, propose more specific standards for messaging.

13. E-prescribing Errors

Comment: One commenter noted an increasing number of new errors are associated with electronic prescribing. Computerized Physician Order Entry (CPOE) systems have the potential to contribute to errors in certain situations,

such as the selection of a wrong drug or dose selection from a drop down menu that a dispenser, if they are aware of the error, must then communicate to the prescriber to address. The commenter urged us to consider the potential for new types of errors as the industry implements e-prescribing standards and clarify in the final regulation ways the agency will address or prevent such errors.

Response: We cite this commenter's example to raise the point that no system, whether electronic or paper, is infallible. Just as in paper prescribing, errors can still take place. E-prescribing helps to substantially mitigate some risk, such as illegible prescriber hand writing on a paper script that could be mis-interpreted by the dispenser; and medication history, which supports the reduction of the occurrence of adverse drug events at the prescriber level. We would expect that e-prescribing software systems would employ safeguards and redundancies, such as multiple prompts asking for prescriber review and confirmation of non-conforming information, prior to transmission.

14. Privacy and Medication History

Comment: Two commenters expressed concern with privacy and medication history. One inquired as to who would have access to medication history under the HIPAA Privacy Rule; the other stated that the HIPAA notice of privacy practices should make it very clear that e-prescribing is taking place and that prescription information is part of one's medical record. One commenter felt that individuals should have the right not to participate in either e-prescribing or electronic medical records, and to have the right to determine who has access to their prescription histories.

Response: Patients can always ask their physicians to refrain from requesting their personal medication histories as derived from the patient's Medicare Part D sponsor. While there is no legal guarantee a provider would agree to their request, patients may always ask that their prescribers only use paper prescriptions when prescribing for them.

15. Regular Cycle of Rulemaking

Comment: Two commenters suggested that CMS consider creating a regular cycle of rulemaking in order to keep standards adoption in sync with the rapid pace of standards development by the industry. For example, CMS could issue a new notice of proposed rulemaking for e-prescribing standards every 2 years in a particular month.

Response: The creation of a regular cycle of rulemaking to adopt e-prescribing standards would restrict CMS' ability to adopt standards when they meet the requisite objectives, functionality and other criteria required that CMS employs in deciding whether to adopt e-prescribing standards. We further reiterate that in response to industry's desire for a streamlined updating process that could keep pace with changing business needs, as previously discussed in this final rule, we adopted a process for the Secretary to adopt subsequent version(s) of a standard for voluntary use where the new version(s) are backwards compatible with the adopted standard. The industry's request for a regular cycle of rulemaking clearly indicates a desire to adopt standards as soon as possible, which is contrary to a bi-annual rulemaking process.

16. Medicaid Prescription Requirements

Comment: One commenter raised the issue that federal Medicaid regulations require a prescriber's hand written authorization for dispensers to dispense brand name drugs when an equivalent generic is available, which would appear to be in conflict with federal e-prescribing guidelines.

Response: The issue that the commenter raised applies to prescriptions obtained under their Medicaid benefits. Under section 1860D-4(e) of the Act, e-prescribing regulations apply only to covered Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals. In those instances in which Medicare Part D provides prescription drug coverage for beneficiaries who receive their Medicaid prescription drug benefits through the Medicare program (dual-eligible beneficiaries), Medicare Part D e-prescribing regulations would apply.

IV. 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 solicited public comment on each of these issues for 42 CFR 423.160, "Standards for Electronic Prescribing."

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 must support and comply with the adopted e-prescribing standards relating to covered Medicare Part D drugs, prescribed for Medicare Part D eligible individuals.

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. These entities are required to comply with the adopted standards when they electronically transmit prescription or prescription-related information for covered transactions.

Testimony presented to the NCVHS indicates that most health plans/PBMs currently have e-prescribing capability either directly or through contract with another entity. Therefore, we do not believe that utilizing the adopted standards will impose an additional burden on Medicare Part D sponsors.

Since the standards that have been adopted are already familiar to industry, we believe the requirement to utilize them in covered e-prescribing transactions constitutes a usual and customary business practice. As such, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR section 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.

V. Regulatory Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, as further amended, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties, and as 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). Among other things, a regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

We estimate that this rulemaking will 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 retirement of NCPDP SCRIPT 5.0 in favor of NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(2), the adoption of the NCPDP SCRIPT 8.1 Medication History Standard for the exchange of medication history information, the adoption of the NCPDP Formulary and Benefits 1.0 for formulary and benefits transactions, the adoption of NPI for use in e-prescribing transactions and the adoption of NCPDP SCRIPT 8.1 (RxFill) for electronic fill status notification purposes will result in significant costs. We solicited industry and other interested stakeholder comment and input on this issue.

We anticipate that the ability to utilize electronic formulary and benefits 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 using the adopted standards in 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 final 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 rulemaking will not have a significant impact on a substantial number of small entities because, while many prescribing physician practices and independent dispensers would be small entities, e-prescribing is voluntary for prescribers and dispensers. 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 may incur some costs to support the NCPDP Formulary and Benefits 1.0, the NCPDP SCRIPT 8.1 Medication History Standard, the NCPDP SCRIPT 8.1 standard for fill status notification (RxFill), and the National Provider Identifier (NPI). However, using the SBA revenue guidelines, the majority of Medicare Part D 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 requirement to use NPI in e-prescribing would have any effect on Medicare Part D sponsors, prescribers or dispensers as they likely 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 604 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 rule will 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 Part A 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.

Comment: It was recommended by one commenter that CMS prepare a regulatory impact analysis for small rural hospitals, as this rule may have a significant impact on small rural hospitals that dispense discharge medication and "after hours" emergency medications to patients.

Response: In the November 16, 2007 proposed rule (72 FR 64909), we considered how adoption of these standards might affect small rural hospitals. We determined that drugs dispensed to Medicare beneficiaries by small rural hospitals are, for the most part, drugs dispensed in an inpatient setting and as such, are covered under Medicare Part A. The smaller volume of Medicare Part D drugs that might be dispensed as noted by the commenter did not constitute a major impact to the extent that it that would necessitate a regulatory impact analysis.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately \$127 million. Since only Medicare Part D sponsors are required to support e-prescribing, this 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 \$127 million threshold. We would expect that many Medicare Part D sponsors already support the exchange of formulary, benefits, and medication history, because the standards we are proposing are based on proprietary transactions originally developed by RxHub 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 rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. No State categorically bars e-prescribing. In recent years, many States have more actively legislated in this area. Should a State law be contrary to the Medicare Part D e-prescribing standards, or should it restrict the ability to carry out the Medicare Part D e-prescribing program, section 101 of the MMA established preemption of that State law at section 1860D-4(e)(5) of the Act. It provides the following:

(5) Relation to State Laws. The standards promulgated under this subsection shall supersede 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 Medicare Part D drugs under this part.

For the same reasons given above, we have determined that States would not incur any direct costs as a result of this proposed rule. We believe that, taken as a whole, this final rule would meet these requirements. 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. 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 for the conversion from NCPDP SCRIPT 5.0 to NCPDP SCRIPT 8.1 at § 423.160(b)(2); the adoption of final uniform standards for the electronic communication of prescription and prescription-related information on formulary and benefits, medication history, and prescription fill notification status; and the adoption of NPI for use as a health provider identifier in e-prescribing. The adoption of these standards for use in Medicare Part D e-prescribing will build upon the foundation standards e-prescribing requirements that were published as a final rule on November 7, 2005 (70 FR 67568). That rule contained an impact analysis that addressed the costs associated with implementing the use of those foundation standards, and it also

discussed, in concept, the benefits that will accrue from e-prescribing in general. In the November 7, 2005 final rule (70 FR 67589), we noted that commenters had suggested that the estimated e-prescribing start-up costs for an individual physician to be at least \$1,500 and perhaps in excess of \$2,000. For average e-prescribing software implementation, according to a 2003 Center for Information Technology Leadership (CITL) Report, "The Value of Computerized Provider Order Entry" (<http://www.citl.org/research>), 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 \$25 to \$66 a month (\$300 to \$800 annually). (For further discussion of the start-up costs associated with e-prescribing, see the November 7, 2005 final rule (70 FR 67589)). The impact analysis built upon the foundation rule analysis, and we referred to the foundation rule analysis to assure that costs and benefits were not counted twice.

Comment: One commenter discussed CMS' assumptions regarding the cost of e-prescribing systems for physicians, especially those practices which have five or less physicians, which they categorize as small practices. One commenter suggested that CMS consider scaling the savings to be realized through e-prescribing according to practice size. Another comment was that CMS omitted opportunity costs, and that advanced e-prescribing systems that have more robust features differ significantly from basic systems and are therefore, more costly, which CMS did not take into account. They contend that CMS may have double counted licensing fees that were already included in overall cost figures, and that there are significant technology, training and upgrade costs, as well as significant differences between the cost of a T1 Internet access line in a rural versus urban area which the agency should take into account. As only three of the six initial standards were found to be technologically ready for use, they asked that the adoption of standards should continue to be voluntary for physicians, thus keeping their costs at a minimum. Another commenter also asked that CMS recognize additional

costs related to processing e-prescriptions, and the ongoing expenses incurred by prescribers for hardware/software and other associated costs.

Response: In the impact analysis for the November 16, 2007 proposed rule, we attempted to address the cost and benefit of implementation of the two standards that were proposed for adoption at that time, namely medication history and formulary and benefits, and not that of e-prescribing in general, so as not to double count costs already attributed to the implementation of the foundation standards. In the November 7, 2005 final rule (70 FR 67589), we considered the cost of e-prescribing in general. At that time, all of the commenters suggested estimated start-up costs for an individual physician to be at least \$1,500 and perhaps exceeding \$2,000. This estimate would vary based on market share, covered lives and local market competition. Given that, we proffered a conservative estimate of \$3,000, taking into account variations in products, level of adoption, etc., and industry feedback indicated that vendors often provided free and low cost handheld or similar devices. The Journal of Healthcare Information Management report cited by one commenter took this practice into account, but also noted that physicians reported paying user-based licensing fees ranging from \$80 to \$400 per month. We did not note that this cost was included in the overall cost of e-prescribing as cited in that report, nor at that time did we account for opportunity costs because e-prescribing for Medicare Part D is voluntary for providers and dispensers, and we received no feedback from industry and other interested stakeholders indicating that opportunity costs should be considered.

As one commenter noted, The Journal of Healthcare Information Management also reported that in some instances prescribers had to invest in new or updated hardware, such as computer servers, and networking infrastructure to use an e-prescribing system, but again, that the amount varied significantly by product and level of adoption. Since that time, we note that the cost of new or updated hardware in particular has come down dramatically due to increased semi-conductor production, improved computer manufacturing methods and total factor productivity growth.² One commenter said that e-prescribing requires a T1 data transmission line, which may be

² Congressional Budget Office, The Role of Computer Technology in the Growth of Productivity May 2002, <http://www.cbo.gov/>.

true for very large practices, but if the mainstream physician practice constitutes less than five physicians, we believe that e-prescribing can be initiated by many physician practices without the installation of a T1 data transmission line.

We have acknowledged, and continue to acknowledge, that e-prescribing has both initial and ongoing costs associated with it. Those include, and for the most part we have accounted for, some initial loss of productivity, hardware costs, software costs, training, etc., but with widespread e-prescribing, we anticipate that prescribers will eventually absorb these as a cost of doing business, much as they would any purchase of equipment. Additionally, provider costs for e-prescribing are very much contingent on a wide variety of factors, including the size of the practice; whether an e-prescribing system under consideration for purchase is a stand-alone versus integrated into an electronic health record system; the level at which a provider enters into e-prescribing (in other words, entry-level necessitating the purchase of hardware/software, versus integrating into existing hardware/software); whether the provider is located in an urban versus rural area, and the related costs/availability of connectivity; the features, whether basic, intermediate or advanced, of any given e-prescribing package; the number of patients seen per year, and the number of prescriptions written, etc. Physicians in some medical specialties (such as geriatrics or internal medicine) may regularly prescribe a higher volume of prescription drugs per patient due to severity of illness, multiple diagnoses, etc., versus other medical specialties, and thus realize more benefits through more frequent, repeated use. We also acknowledged in the proposed rule that benefits will not be immediately recognized, that benefits will accrue over a multi-year timeframe and that, with more widespread adoption, we anticipate that costs will come down, systems capabilities will be more robust, and the full benefits of e-prescribing will be realized.

We again reiterate that nothing in the proposed rule or this final rule changes the tenet of section 101 of the MMA that e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals is voluntary for prescribers and dispensers. Because adoption of e-prescribing is voluntary under Medicare Part D, we also assume that an individual provider or group practice will perform their own cost/benefit analysis, and will make the decision to invest in e-prescribing if they determine

that their investment will yield a net benefit and positive patient outcome results. Dispensers may incur higher transaction fee costs as a result of the increased volume of electronic prescriptions, and any costs associated with dispenser access to medication history. Again, we anticipate that with this increased volume of e-prescriptions, transaction fees will decrease, and whatever residual transaction and/or access costs associated with medication history remain, eventually will be absorbed into the dispenser's cost of doing business, while benefits continue to accrue.

Comment: One commenter said that there currently is no way to verify that the pharmacy has received an electronically transmitted prescription or renewal, which, since many dispensers do not routinely check their electronic prescription messages or facsimiles, results in an increase of physician office inquiries and call backs from the pharmacy. The commenter noted that this workflow issue was not accounted for in the impact analysis relative to physician costs of e-prescribing.

Response: We have received industry feedback that most physician e-prescribing software packages feature a response mechanism that indicates a successful transmission of the electronic prescription to the pharmacy. In the case of EDI transmissions, we also understand that the failure rate of EDI transmission is less than three tenths of one percent. We assume that the small failure rate of EDI transmission, combined with basic pharmacy workflow adjustments to routinely check on the receipt of electronic prescriptions, that any resulting call backs to physicians' offices would be minimized, and would not represent a significant cost for either the dispenser or provider.

A. Overall Impact

In the November 7, 2007 proposed rule (72 FR 64912) we noted that according to 2006 CMS data, approximately 24 million beneficiaries were enrolled in a Medicare Part D sponsor's plan, either a stand-alone Prescription Drug Plan or a Medicare Advantage Drug Plan. This data has since been revised to approximately 25 million Medicare beneficiaries.³ Another 7 million retirees were enrolled in employer or union-sponsored retiree drug coverage receiving the Retiree Drug

³ CMS, Total Medicare Beneficiaries with Prescription Drug Coverage as of January 2008, 1-31-08, <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>.

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 the e-prescribing of Medicare Part D covered drugs for Medicare Part D eligible individuals 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 e-prescribing populations unless they are manifestly unsuited for the purpose. However, we note again that e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals is voluntary for both prescribers and dispensers under the Medicare Part D e-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. We have worked to avoid imposing an undue administrative burden on prescribing health care professionals, and dispensers. With the exception of the NPI, the standards we are adopting in this final rule, as with the foundation standards adopted previously, are maintained by accredited standards development organizations. The standards for the Medication History, Formulary and Benefits, and Fill Status Notification transactions have been shown through pilot testing to work effectively with the foundation standards.

B. Costs

Because e-prescribing is voluntary for prescribers and dispensers, 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 November 7, 2005 final rule (70 FR 67568) but we do not claim either in this analysis). We assume that as e-prescribing becomes more widespread, workflow adjustments will follow that will result in the full range

of benefits that can potentially be realized through e-prescribing. Also, implementation of the standards that are adopted in this rule will not materially affect the implementation cost that was projected for NCPDP SCRIPT 5.0 in the foundation standards final rule. That is, the cost to implement NCPDP SCRIPT 8.1 under § 423.160(b)(2), the NCPDP SCRIPT 8.1 Medication History Standard, NCPDP Formulary and Benefits 1.0, the National Provider Identifier (NPI) and the NCPDP SCRIPT 8.1 standard for fill status notification (RxFill) are not materially higher than the cost of implementing the NCPDP SCRIPT 5.0 foundation standard alone. These entities could incur additional costs for the purchase of new e-prescribing products that include functions that support the ability to conduct transactions using these e-prescribing standards. They would also incur the benefits of the all of these final standards.

Comment: One commenter stated that our analysis did not take into account the adoption of RxFill, and any associated costs and benefits.

Response: In the November 16, 2007, proposed rule we asked for stakeholder comments on the potential utilization of RxFill in Medicare Part D e-prescribing, but did not propose its adoption. As previously discussed, in the proposed rule we referenced industry feedback that the adoption of RxFill “may cause an unnecessary administrative burden on prescribers and dispensers,” and solicited feedback regarding industry’s views on any potential administrative burden associated with its use. Therefore, no cost/benefit analysis was performed in consideration of the adoption of RxFill as a final uniform standard. As a result of comments received through the notice and comment rulemaking process, and as we discussed above, the industry has now indicated that it believes there will be no administrative burden associated with the adoption of the RxFill standard. Therefore, we will adopt both the NPI, and the RxFill standard for fill status notification transactions for use by providers who see value in utilizing electronic transaction using the adopted standards to support patient medication management and discuss both the costs and benefits here.

Because use of the electronic fill status notification transaction is voluntary, we have no clear indication from the industry as to how many providers potentially will see value in, and use transactions utilizing the adopted e-prescribing standards for this function. The feedback we have received from provider organizations

indicates that they envision that its use will be more prevalent among those providers who wish to track medication adherence for Medicare Part D beneficiaries who have chronic medical conditions, such as diabetes, hypertension, etc., for whom following a medication regimen is imperative. We also note that RxFill is limited to informing the prescriber that the prescription has been filled, not filled, etc., and it is but an initial indicator of a patient’s intention to actually take the prescribed medication. The assumption here is that a patient is more likely to take a medication prescribed for him/her if they know that the prescriber will be monitoring this information, and more likely to take the medication if they have made the effort to go to the pharmacy, purchase and take the prescription drug home.

We also understand from industry feedback that prescription information exchange networks have fill status notification functionality (RxFill) built into their systems but that most physicians currently are not signed up to use it. When a patient picks up a prescription at the pharmacy, they likely sign an electronic signature log. This electronic signature triggers a pharmacy software system update which, in turn, triggers a fill status notification message transaction using the RxFill standard to be sent to the prescriber, if the prescriber has requested receipt of such information. Conversely, when a prescription is not picked up and returned to inventory, this activity also triggers a similar message if the prescriber has requested receipt of such information. Stand alone e-prescribing systems usually send such updates to requesting prescribers overnight; however, there are integrated e-Signature systems which employ real-time notification. Given that most dispensers who are already e-prescribing use an electronic signature pad to verify prescription pick-up by the patient are already gathering this information and need acknowledgement from the prescriber through a “flag” in their e-prescribing software system that they want to receive this information, we do not believe that there will be any significant changes to pharmacy or prescriber workflows once that “flag” is activated, and no cost impact associated with the use of RxFill for those prescribers and dispensers who are currently e-prescribing.

Those dispensers still using paper logs to record patient pick-up of a prescription likely are not e-prescribing and therefore, would not be impacted either from a workflow or economic perspective.

We agree with commenters who stated that neither the medication history nor the formulary and benefits standard would result in additional e-prescribing costs for those already e-prescribing, and apply that rationale to RxFill. As the fill status notification function resides on the NCPDP SCRIPT 8.1 standard alongside the medication history function, we expect that it would also not result in any additional costs being incurred. For those not currently e-prescribing, they would incur the costs and benefits associated with the foundation standards (which we discussed in the final rule at 70 FR 67568), but which we did not claim in our analysis.

One potential benefit anticipated from the use of RxFill are those associated with better medication adherence on the part of patients, and this varies depending on the clinical condition. According to a study entitled, “Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost”,⁴ adherence with medication therapy is generally low—approximately 50 to 65 percent, on average, for common chronic conditions such as hypertension and diabetes. In this study, for diabetes, the average annual incremental drug cost associated with a 20 percent increase in drug utilization was \$177, and the associated disease-related medical cost reduction was \$1,251, for a net savings of \$1,074 per patient, or an average return on investment of 7.1:1. Other studies of a mental health condition such as schizophrenia estimate the cost of non-compliance with medication therapy to be about \$705 million over a 2-year period.⁵ Another study on medication therapy adherence in hypertensive patients showed that interventions aimed at improving compliance with medication regimens increased patient adherence by up to 11 percent, and that when it came to prescription refills, partial compliance with prescription refills identified important clinical consequences of reduced compliance, with gaps in taking medication resulting in an increase in hospitalizations.⁶

⁴Michael C. Sokol, M.D., M.S.; Kimberly A. McGuigan, PhD; Robert R. Vebrugge, PhD. And Robert S. Epstein, M.D., M.S. Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost. *Medical Care*. 2005;43:521–530.

⁵Theida, Patricia, M.A., Beard, Stephen, M.S., Richter, Anke, Ph.D., and Kane, John, M.D. An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia. *Psychiatric Services*. April 2003; 54:508–516.

⁶Steiner, J.F., Prochazka, A.V. The assessment or refill compliance using pharmacy records: methods, validity and applications. *Journal of Clinical Epidemiology*. 1997; 50:105–116.

Researchers generally agree that it is difficult to arrive at a dollar figure that would reflect the outcomes of medication adherence for all clinical conditions, but we believe that, based on studies such as those cited, it is prudent to assume that in the Medicare Part D program, an increase in prescription drug utilization by patients as a result of better medication adherence would be far offset by a larger reduction in the cost of Medicare beneficiary hospitalizations, outpatient procedures and other clinical treatments that might result from non-adherence to medication regimens.

Relative to the NPI, in the proposed rule we discussed that we did not anticipate any significant costs to be associated with the use of the NPI by vendors, prescribers, dispensers or Medicare Part D sponsors for e-prescribing transactions under section 1860D-4(e). Use of the NPI is already required in order to conduct HIPAA-covered 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 easily obtainable, and there is no cost associated with applying for and/or obtaining an NPI. Once received, the NPI is usually entered by the physician initially into their e-prescribing software system, and it is carried thereafter by the system, which automatically populates the NPI field on the NCPDP SCRIPT 8.1 standard. The NPI is in widespread use by HIPAA-covered entities in HIPAA transactions. Although the transactions using the NCPDP SCRIPT standard are not HIPAA transactions, the prescribers and dispensers that conduct such transactions 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 context of transactions using the NCPDP SCRIPT standard.

For e-prescribers whose software products are not able to generate transactions using the NCPDP SCRIPT 8.1 standard, they will not have the capability to use the NCPDP Formulary and Benefits Standard 1.0, the NCPDP SCRIPT 8.1 Medication History transaction, or the NCPDP SCRIPT 8.1 RxFill standard. Costs would be incurred if they were to replace such software with software that generates transactions that comply with the adopted 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 would be accomplished as part of this transition. Prescribers and dispensers already should be using the NPI to conduct retail pharmacy drug claim transactions.

Medicare Part D sponsors will not be significantly affected by the adoption of the NPI because the Medicare Part D sponsors already use the NPI in HIPAA transactions, such as the retail pharmacy drug claim.

Software vendors are already implementing NCPDP SCRIPT 8.1 in their products, NPI is supported by NCPDP SCRIPT 8.1, and we believe that any needed upgrades will be included in routine version upgrades.

Benefits for the use of the NPI in e-prescribing under Medicare Part D have not been quantified by the industry. The NPI provides a standard way for dispensers to identify individual prescribers in an e-prescribing transaction. We anticipate that its use will help dispensers reduce the number of callbacks to a physicians office to verify an e-prescriber's identity, although it is unclear and unsubstantiated from industry feedback as to what percentage of callbacks between the dispenser and the prescriber can be attributed solely to this inquiry.

Comment: One commenter offered that neither the adoption of NCPDP SCRIPT 8.1 nor adoption of the standards for medication history and formulary and benefits would result in significant costs as the majority of the e-prescribing industry is already using these standards. The commenter agreed that the costs for entities that do not now e-prescribe, but will be implementing the e-prescribing technology in the future, would not be substantially increased by the adoption of these standards. Another commenter said although the NCPDP SCRIPT 8.1 Medication History transaction and the NCPDP Formulary Benefit Standard 1.0 are relatively new, it is not accurate for CMS to state that they are not currently deployed for use in the functions that were listed at § 423.160(b)(1).

Response: From industry feedback, we have learned that the medication history and formulary and benefits functions were adopted by some entities nearly two years ago, and there are others in the industry that have been using them for even longer. As such, our conclusion remains the same that adoption of these standards now would result in no new additional costs.

Entities that e-prescribe now using a software product that cannot use the NPI and conduct medication history, formulary and benefits, and fill status

notification standards, and that cannot be upgraded to conduct them (for example, stand-alone Microsoft Word-based prescription writers) will not be required to conduct these transactions (if they choose to conduct these transactions) using the NCPDP SCRIPT standard until April 2009. If they decide to upgrade their entire e-prescribing system to take advantage of the benefits of these new standards, 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 medication history, formulary and benefits, and fill status notification using the three adopted standards would incur no cost or benefit if they decide not to upgrade. 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 utilizing these three standards. This would also apply to entities that e-prescribe now using a product that conducts the three 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.

Entities that e-prescribe now using a product that conducts one or more of the three transactions using nonstandard formats and who continue to use the electronic transactions would have to upgrade their software. They would not enjoy all the benefits of conducting transactions using the three new standards 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. However, 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.

1. Retail Pharmacy

Because e-prescribing is voluntary for dispensers, unless they were to commence e-prescribing, those 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 97 percent of the

nation's retail chain dispensers currently e-prescribe, in contrast to only 27 percent of independent dispensers that e-prescribe.⁷

Transactions using NCPDP Formulary and Benefits 1.0 are carried out between the plan and prescriber and, therefore, dispensers will not incur any cost related to this transaction.

While the NCPDP SCRIPT 8.1 Medication History Standard can be used in transactions to support communication between the dispenser and prescriber, its use is, nonetheless, voluntary for both. We assume for purposes of this analysis that the NCPDP SCRIPT 8.1 Medication History Standard will be used in medication history exchange transactions.

Effective May 23, 2008 dispensers are required under HIPAA to use the NPI to conduct retail pharmacy drug claim transactions. Therefore, we associate no additional costs with the use of the NPI in Medicare Part D e-prescribing for retail dispensers.

Comment: One commenter remarked that the cost of migrating to NCPDP SCRIPT 8.1 has already been borne by dispensers and their system vendors, and that there should be no cost associated with adoption of NCPDP Formulary and Benefits 1.0. However, the commenter acknowledged that there may be some costs to dispensers that supply data to support the medication history functionality and these costs are already being borne by participating dispensers.

Response: The benefits of e-prescribing in general, and the specific standards to be adopted through this final rule, are significant, especially in terms of patient safety. As noted in the November 16, 2007 proposed rule (72 FR 64912), depending on their stage of e-prescribing adoption, there may be costs associated with the adoption of these standards for dispensers. These costs are far outweighed by the eventual economies realized by improved workflows and productivity savings within the pharmacy environment; marketplace forces should come into play as e-prescribing volume increases, which will help drive down costs and realize economies of scale.

The adoption of NCPDP SCRIPT 8.1 in place of the NCPDP SCRIPT 5.0 foundation standard for the transactions listed at § 423.160(b)(2) will impact dispensers that conduct e-prescribing. Dispensers will have to ensure that their software can accept prescription transactions using the NCPDP SCRIPT

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 have or are already incorporating NCPDP SCRIPT 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 dispensers, face a different set of costs in implementing information systems for clinical care and financial management. Unlike dispensers, 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.⁸ 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 benefits 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 subscription fees.

For e-prescribers whose software products are not able to generate transactions using the NCPDP SCRIPT 8.1 standards, they will not have the capability to conduct electronic transactions using the NCPDP Formulary and Benefits Standard 1.0 and NCPDP SCRIPT 8.1 Medication History Standard. Costs would be incurred if they were to replace such software with software that can conduct 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.

As the fill status notification function resides on the NCPDP SCRIPT 8.1 standard alongside the medication history function, we expect that it would also not result in any additional costs being incurred. However, we recognize that the use of RxFill may result in workflow changes for the prescriber who must determine what he/she will do with the information provided by the RxFill transaction relative to their clinical practices. For those not currently e-prescribing, they would incur the costs and benefits associated with the foundation standards (which we discussed in the final rule at (70 FR 67568)), but which we did not claim in our analysis.

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

Medicare Part D sponsors will be required to support NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(2), the NCPDP Formulary and Benefits 1.0, and the NCPDP SCRIPT 8.1 Medication History Standard. They will need to assure that their software can receive and conduct transactions utilizing NCPDP Formulary and Benefits 1.0 and the NCPDP SCRIPT 8.1 Medication History Standard, 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 NCPDP SCRIPT 8.1 Medication History Standard. We believe that many Medicare Part D sponsors will have already implemented this functionality because the standards we are proposing are based on proprietary file transfer protocols developed by Rx-Hub that have been included in many e-prescribing products. Medicare Part D sponsors may need to restructure systems to assure

⁷ Surescripts, National Report on E-prescribing, December 2007. <http://www.surescripts.com/report/>.

⁸ E-Prescribing and the Prescription Drug Program final rule, published November 7, 2005 (70 FR 67568).

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 sponsors may need to make additional investments to support these standards.

Because plans typically pay the per transaction network fees for eligibility transactions, which likely includes providing a formulary and benefits response as well as a medication history response, Medicare Part D sponsors will incur increased transaction costs for formulary and benefits 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.⁹

Based on data available at that time, we estimated that approximately 24 million Medicare beneficiaries received Medicare Part D benefits in 2006. (These data have since been revised to approximately 25 million Medicare beneficiaries).¹⁰ This figure reflected those Medicare beneficiaries enrolled in a Medicare Prescription Drug Plan (PDP) or a Medicare Advantage plan with Prescription Drug coverage (MA-PD) or both, for which we have 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 was estimated by CMS at 4.6 percent based on industry feedback (http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_80415465,00.html). So that impact comparisons could be made equally across all years, inflation was removed from the price effects. Conservatively, we calculated the increase in the number of Medicare Part D prescriptions and applied 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 estimated costs for Medicare Part D sponsors of between \$2 million to \$46 million per year.

Medicare Part D 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 anticipated 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 NCPDP Formulary and Benefits 1.0, which would more than offset the transaction costs.

Medicare Part D sponsors would not be affected by the adoption of the NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(2) because these transactions are conducted between prescribers and dispensers, and Medicare Part D sponsors are not involved.

Medicare Part D sponsors would not be significantly affected by the adoption of the NPI as a standard for use in e-prescribing transactions among the Medicare Part D sponsors, prescribers, and dispensers because the Medicare Part D sponsors already use the NPI in HIPAA transactions, such as the retail pharmacy drug claim.

4. Vendors

Vendors of e-prescribing software would incur costs to bring their products into compliance with these requirements. However, we considered 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 believed these costs to be minimal.

Comment: A commenter noted that the costs to vendors of migrating to NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(2), as well as adding the NCPDP SCRIPT 8.1 Medication History Standard, the fill status notification standard (RxFill), and the NCPDP Formulary and Benefits 1.0 to their applications, are a normal cost of vendors doing business, and these costs have in large part already been borne by e-prescribing vendors.

Response: We agree with the commenter's contention that minimal additional costs will be incurred by vendors by switching to the NCPDP SCRIPT 8.1 standard, nor by adding the use of the NPI, RxFill, the NCPDP SCRIPT 8.1 Medication History Standard and the NCPDP Formulary and Benefits 1.0 to their applications. Many of them have already incorporated Formulary and Benefits 1.0 into their software products, and have already transitioned to NCPDP SCRIPT 8.1, which houses the RxFill and the Medication History functionality on its platform. As previously discussed in the Cost section of this regulatory impact analysis, software vendors are already implementing NCPDP SCRIPT 8.1 in their products, NPI is supported by NCPDP SCRIPT 8.1, and we believe that any needed upgrades will be included in routine version upgrades. Vendors did not indicate in their comments in response to the proposed rule that the use of the NPI in e-prescribing will create any additional vendor costs, and we assume that any costs that might be incurred, such as testing, would be absorbed by vendors as a cost of doing business.

C. Benefits

In the November 16, 2007 proposed rule (72 FR 64913), we assumed that the benefits of the proposed adoption of standards for formulary and benefits and medication history transactions would take place over a multiyear timeframe. (For discussion of the benefits associated with the adoption of these standards, refer to the discussion in the November 16, 2007 proposed rule (72 FR 64913).)

1. Formulary and Benefits Standard—Generic Drug Usage

We based our assumptions on industry estimates that approximately 5 percent to 18 percent of group practices are e-prescribing today. We anticipated that transactions utilizing NCPDP Formulary and Benefits 1.0 would allow the prescriber to view formulary drugs, alternative preferred drugs in a given class that may offer savings to the patient, or to see in advance what other, less costly drugs within a given drug classification or generic drugs can be substituted for a given brand name prescription drug, resulting in reduced calls to the plan, and fewer callbacks from a pharmacy because a prescribed drug is not on a beneficiary's drug plan formulary.

In the first half of 2006, the ratio of generic versus brand name prescription drugs in the Medicare Part D program was 60 percent versus 40 percent. An

⁹RxHub Announces 2006 e-Prescribing Results and Highlights Milestones for 2007, St. Paul, MN, February 23, 2007, <http://www.rxhub.com>.

¹⁰CMS, Total Medicare Beneficiaries with Prescription Drug Coverage as of January 2008, 1–31–08, <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>.

industry study indicated a 15 percent increase in generic substitution rates for physicians with e-prescribing. However, not all beneficiaries will accept generic prescription drugs and there are some instances in which the brand name prescription drug has proven through physician experience to be the more effective drug. Therefore, we applied a more conservative 7 percent increase in generic prescriptions.

Based on industry data, we assumed the cost of a brand name prescription drug at \$111.02 and the cost of a generic drug at \$32.23.¹¹

While Medicare beneficiaries will be the most direct recipients of the savings realized by the conversion of brand name to generic prescription drugs, the Medicare program also will save money as it will be paying for an increased number of lower cost generic prescriptions versus higher cost, brand-name prescription drugs. We calculated a ten-year cost savings of \$95 million to \$410 million.

Comment: A commenter agreed that while they did not conduct a financial analysis, the benefits identified by CMS in the proposed rule appeared to be reasonable. Another commenter stated that CMS underestimated the benefits that the switch from brand name to generic drugs would generate as a result of prescribers having access to formulary and benefits information at the point of care, and that it would vastly exceed CMS' 7 percent estimate.

Response: We made a good faith effort to estimate both costs and benefits associated with the adoption of these standards using very conservative assumptions on the benefit side, and estimating costs so as to elicit industry and stakeholder comments on the feasibility of our approach. While we believe that the benefits of adoption of these standards could far exceed expectations, we also caution that any one of a number of factors—for example, delays in making real-time formulary and benefits information available to prescribers at the point of care—could hinder the adoption of e-prescribing and the benefits to be realized through, for example, anticipated wider use of generic versus brand name prescription drugs in the Medicare Part D prescription drug program. Given this, we estimated that realistically, a 7 percent increase in the prescribing of generic versus brand name drugs could be achieved through the use of formulary and benefits information.

2. Formulary and Benefits 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 dispensers on formulary questions and generic substitutions. Physician time 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.

CMS estimated the number of physicians in active practice who participated in the Medicare program in 2006 at 1,048,243, and a percentage rise in the number of physicians participating in the Medicare program of .94 percent per year, so we applied that percentage increase to estimate the number of Medicare physicians for 2009 through 2013. We also applied the previous assumption that from 5 to 18 percent of prescribers are e-prescribing today. Per the MGMA survey, we assumed 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 with e-prescribing, responding to refill requests, and resolving pharmacy callbacks were all done more efficiently with e-prescribing than before. However, full implementation would be difficult to achieve, and we used an estimate of 25 percent implementation. Our model calculated that, at that rate of implementation, physicians and staff would realize savings ranging from \$55 million to \$206 million.

b. Dispensers

If each physician and their office staff saved a total of 80 hours a year by using the NCPDP Formulary and Benefits 1.0, and reduced the time spent on the phone with dispensers, we assumed that dispensers would save the equivalent amount of time by not making these calls. Since the MGMA survey assumed a dispenser labor rate of \$60 per hour, our model predicted an annualized cost benefit savings ranging from a low of \$65 million to a high of \$242 million at 25 percent implementation.

Comment: A commenter expressed concern that the administrative savings for dispensers as represented in Table 4 of the proposed rule overestimated the

administrative cost savings for dispensers. They stated that while dispensers are on the phone waiting for a response from a physician on a formulary question, dispensers often perform other work concurrently, and thus devote less time than was estimated for this particular task, which in turn affects the overall estimate of administrative cost-savings benefits to dispensers.

Response: When estimating the benefits accrued to dispensers in Table 4 of the proposed rule, we were conservative in our assumptions so as not to unnecessarily inflate the benefit projections. We used the generally accepted 5 and 18 percent e-prescribing adoption rates versus much higher rates as projected in some widely read industry publications. We relied upon the Medical Group Management Association (MGMA) study of physician and staff time spent on the phone resolving, among other things, formulary and benefits issues, and further reduced our benefit projects down to the 25 percent level.

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

Utilizing the medication history standard in the transmission of medication history information will simplify medication reconciliation through transitions in care and, in so doing, provide consumers with a safer medication delivery system, and greater convenience.

Although outpatient ADEs were difficult to estimate, literature estimated that, as of 2005, there were 530,000 preventable ADEs for Medicare beneficiaries annually. Moreover, the estimated cost per ADE ranged from \$2,000 to upwards of \$6,000 depending on the care setting. We computed the benefits of using the NCPDP SCRIPT 8.1 Medication History Standard based on data regarding ADEs as a percentage of the total Medicare population. Based on CMS Medicare population data, we calculated that of the total Medicare population, ADEs occur in about 1.24 percent of that population each year.

Based on pilot experience, we assumed that the reduction in the risk of ADEs could be attributed mostly to the use of the NCPDP SCRIPT 8.1 Medication History Standard history rather than to e-prescribing in general. The pilot project demonstrated that 50 percent of preventable ADEs could be eliminated if e-prescribing is used, but also recognized that the pilot project may not have accurately represented mainstream experience. Given that, we conservatively assumed that the number

¹¹ <http://www.nacds.org/wmspage.cfm?parm1=5507>. National Association of Chain Drug Stores data.

of ambulatory ADEs associated with Medicare Part D beneficiaries could be reduced by the use of medication history by 25 percent for those patients for whom prescriptions were written electronically; we used the same uptake e-prescribing estimates (5 to 18 percent) as earlier for e-prescribing adoption. We estimated a potential cost savings over 10 years of \$13 million to \$156 million from avoided ADEs.

4. RxFill—Medication Adherence

As previously discussed in the Cost section of this regulatory impact analysis, one potential benefit anticipated from the use of RxFill are those associated with better medication adherence on the part of patients, and this varies depending on the clinical condition. Researchers generally agree that it is difficult to arrive at a dollar figure that would reflect the outcomes of medication adherence for all clinical conditions, but we believe that it is prudent to assume that in the Medicare Part D program, an increase in prescription drug utilization by patients as a result of better medication adherence would be far offset by a larger reduction in the cost of Medicare beneficiary hospitalizations, outpatient procedures and other clinical treatments that might result from non-adherence to medication regimens. See the Cost section of this regulatory impact analysis for more details regarding our benefit assumption for the use of RxFill.

5. National Provider Identifier (NPI)—Reduced Callbacks

We reiterate our previous discussion in the Cost section of this regulatory impact analysis that benefits for the use of the NPI in e-prescribing under Medicare Part D have not been quantified by the industry. We anticipate that its use will help dispensers reduce the number of callbacks to a physicians office to verify an e-prescriber's identity, although it is unclear and unsubstantiated from industry feedback as to what percentage of call backs between the dispenser and the prescriber can be attributed solely to this inquiry.

D. Total Impact

We concluded that the cost of implementing these standards is minimal, with quantifiable benefits reaped by dispensers, prescribers, and beneficiaries. Over five years, we expected that these groups will see average net benefits in a range from \$218.0 million to \$863.9 million from the utilization of formulary and benefits and medication history transactions, and the promulgation of these

standards. As previously discussed, we do not expect that the adoption of RxFill and the use of the NPI in e-prescribing will result in any additional costs. We expect that their use will result in unquantifiable benefits which include the assumption, in the case of RxFill, of better patient medication adherence that will likely result in long-term savings for the Medicare program; and for the NPI, in improved pharmacy workflows via reduced call backs to physician offices to identify individual prescribers.

Comment: A prescription information exchange network agreed that the benefits to all stakeholders of utilizing the NCPDP Formulary and Benefits 1.0 and adopting NCPDP SCRIPT 8.1 for the transactions listed at § 423.160(b)(2) will far exceed the financial costs. In their estimation, the total benefits range of \$218 to \$863.9 million appears to be realistic.

Response: Again, efforts were made to estimate both costs and benefits associated with the adoption of the final standards using very conservative assumptions on the benefit side, and conversely, overestimating costs so as to elicit industry and stakeholder comments on the feasibility of our approach. As previously discussed, in addition to the anticipated costs and benefits associated with use of medication history and formulary and benefits, we expect there will be minimal or no cost associated with the use of either the NPI, or RxFill by providers who find value in use of an electronic fill status transaction for purposes of tracking patient adherence to medication therapies. We expect use of the NPI will assist dispensers to identify individual e-prescribing providers, resulting in a reduction of call backs to physician offices. The use of the Fill Status Notification standard by those providers who use an electronic fill status transaction to monitor patient medication adherence will realize benefits such as reduced patient hospitalizations, outpatient procedures, and clinical treatments, and improved patient outcomes.

Comment: One commenter made the observation that actual drug costs will increase due to increased volume related to improved patient compliance, and that CMS should account for this in its discussions of costs and benefits.

Response: We believe that the commenter was referring to the increased drug cost to the Medicare Part D program because the number of prescriptions being picked up at the pharmacy by a Medicare beneficiary might increase with the use of the fill status notification, and not an increase

in the the actual cost of the drug itself. It is true that the Medicare Part D program may incur additional costs if more patients had their prescriptions filled, and in some studies this could account for as much as an 11 percent increase, depending on the clinical condition for which the prescription is being dispensed (for example, diabetes versus hypertension). However, we anticipate that medication adherence could result in lower disease-related medical costs, such as hospitalization, that would benefit the Medicare program. In the study, "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," results showed that, for the four clinical conditions studied, hospitalization rates were significantly lower for patients with high medication adherence, and that drug costs are a relatively small fraction of total healthcare costs. Drug costs have high leverage; in other words, a small increase in drug costs (associated with improved adherence) can produce a much larger reduction in medical costs. This leverage will become even stronger as medications become available, and are prescribed as generic drugs, lowering drug costs even more.¹²

E. Alternatives Considered

For more information on all the alternatives considered, refer to the discussion in the November 16, 2007 proposed rule (72 FR 64916).

As we had successful results from the e-prescribing pilot project, and the value added by the proposed additional standards is substantial, we chose to proceed to a final rule. We considered adopting the prior authorization, Structured and Codified Sig and RxNorm standards for adoption, and elected not to do so until outstanding issues with these standards have been resolved. In the case of the RxFill standard, we considered not adopting it, but based on industry feedback, opted for adoption so that those providers who felt it was of value could benefit from the existence of a standard for use in electronic fill status transactions.

We considered not adopting the NPI as a standard for identifying health care providers in e-prescribing transactions for Medicare Part D covered drugs for Medicare Part D eligible individuals. The fact that large portions of the health care industry are required to use NPI as a HIPAA standard, convinced us that

¹² Michael C. Sokol, M.D., M.S.; Kimberly A. McGuigan, PhD; Robert R. Vebrugge, PhD; and Robert S. Epstein, M.D., M.S. Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost. *Medical Care*. 2005;43:521-530.

adoption at this time was feasible and desirable.

We considered providing for an effective date for these new and updated standards that was less than the maximum amount of time allowed by the MMA. Based on industry feedback, however, we decided to provide the maximum allowed time prior to the effective date of this rule.

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, the Centers for Medicare & Medicaid Services amends 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 revising paragraphs (b) and (c) to read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) Standards. (1) Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section:

(i) Before April 1, 2009 the standards specified in paragraphs (b)(2)(i) and (b)(3) of this section.

(ii) On or after April 1, 2009, the standards specified in paragraphs (b)(2)(ii) and (b)(3) through (b)(6) of this section.

(2) *Prescription.* (i) The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, (Version 5.0) May 12, 2004 (incorporated by reference in paragraph (c)(1)(iv) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (A) Get message transaction.
- (B) Status response transaction.
- (C) Error response transaction.
- (D) New prescription transaction.
- (E) Prescription change request transaction.
- (F) Prescription change response transaction.
- (G) Refill prescription request transaction.
- (H) Refill prescription response transaction.
- (I) Verification transaction.
- (J) Password change transaction.
- (K) Cancel prescription request transaction.
- (L) Cancel prescription response transaction.

(ii) The National Council for the Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (A) Get message transaction.
- (B) Status response transaction.
- (C) Error response transaction.
- (D) New prescription transaction.
- (E) Prescription change request transaction.
- (F) Prescription change response transaction.
- (G) Refill prescription request transaction.
- (H) Refill prescription response transaction.
- (I) Verification transaction.
- (J) Password change transaction.
- (K) Cancel prescription request transaction.
- (L) Cancel prescription response transaction.
- (M) Fill status notification transaction.

(3) *Eligibility.* (i) The Accredited Standards Committee 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 4010, A1, October 2002, Washington Publishing Company, 004010X092A1 (incorporated by reference in paragraph (c)(2)(i) of this section), for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs 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), September 1999, for the NCPDP Data Record in the Detail Data Record (incorporated by reference in paragraph (c)(1)(iii) of this section), for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(4) *Medication history.* The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section) to provide for the communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers.

(5) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(6) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(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

Facsimile (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.

(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 Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunication Standard Implementation Guide, Version 5,

Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record.

(iv) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 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).

(2) Accredited Standards Committee, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (301) 970-4488; and Facsimile: (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: March 14, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 28, 2008.

Michael O. Leavitt,

Secretary.

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