

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 423****[CMS-0011-F]****RIN 0938-AN49****Medicare Program; E-Prescribing and the Prescription Drug Program****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule adopts standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). These standards will be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in our incremental approach to adopting final foundation standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

DATES: These regulations are effective on January 1, 2006. The incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Gladys Wheeler, (410) 786-0273.

SUPPLEMENTARY INFORMATION:**I. Background****A. Statutory Basis**

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 the Voluntary Prescription Drug Benefit Program. Included in the provisions at section 1860D-4(e) of the Act is the requirement that the electronic transmission of prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals comply with final uniform standards adopted by the Secretary.

Section 1860D-4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year (CY) 2006, must be developed, adopted, recognized, or modified by the Secretary not later than September 1, 2005. These

were publicized in a Request for Application for the pilot project announced on September 14, 2005 (Available through grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html). Not later than April 1, 2008, the Secretary must promulgate final uniform standards, which must become effective not later than 1 year after the date of their promulgation. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.

On January 28, 2005, we published the Medicare Prescription Drug Benefit final rule (70 FR 4193-4585) that established the Prescription Drug Benefit Program and cost control and quality improvement requirements for prescription drug benefit plans. One of the provisions in that final rule requires Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) Organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006.

Although there is no requirement that providers write prescriptions electronically, providers that prescribe or dispense Part D drugs would be required to comply with any applicable final standards that are in effect when they conduct electronic prescription transactions, or seek or transmit prescription information or certain other related information electronically.

For a complete discussion of the statutory basis for this final rule and the statutory requirements at section 1860D-4 of the Act, please refer to section I. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256-6264). We requested and received comments on the statutory requirement for industry consultation, adequate industry experience for certain standards, and pilot testing, among other things. Those comments and our responses are addressed in section III. of this final rule.

1. Initial Standards Versus Final Standards

In the proposed rule, we discussed the provisions of section 1860D-4(e) of the Act that distinguish initial standards from final standards. Final standards must be adopted by the Secretary based upon the evaluation of pilot testing or without pilot testing if the Secretary determines there is adequate industry experience for the final standards. The

final standards adopted in this rule have not been subject to pilot testing under MMA, due to the determination by the Secretary that there is adequate industry experience with these standards. We refer to them as "foundation standards" because they provide a foundation for e-prescribing implementation. Based on industry consensus and recommendations from the National Committee on Vital and Health Statistics (NCVHS), these standards were likely candidates for establishing a foundation for future standards and interoperability. A more detailed discussion of this distinction is available in the E-Prescribing and Prescription Drug Program proposed rule, published February 4, 2005 proposed rule (70 FR 6259).

2. State Preemption

In section I of the proposed rule, we discussed State preemption and the meaning of the statutory language in section 1860D-4(e)(5) of the Act. A more detailed discussion is available in the proposed rule at 70 FR 6258-6259. We solicited and received comments on our proposed interpretation. Those comments and our responses are addressed in section III. of this final rule.

3. Anti-Kickback Statute Safe Harbor and Stark Exception

In the proposed rule, we indicated that we would be proposing a new electronic prescribing (e-prescribing) exception under the physician self-referral law (also known as the Stark law) and a new e-prescribing safe harbor under the anti-kickback statute. We also indicated that, in the meantime, compliance with existing State and Federal laws is required. We solicited comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or incentives likely to be offered after rulemaking for the Stark exception and anti-kickback statute. For a more detailed discussion of the Stark exceptions and violation of the anti-kickback statute for e-prescribing please refer to 70 FR 6259.

B. The NCVHS Process

In the proposed rule, we discussed HHS's requirement to consider recommendations of the NCVHS according to section 1860D-4(e)(4)(A) of the Act, and the role of the NCVHS in recommending standards relating to the requirements for an electronic prescription drug program, as outlined in section 1860D-4(e)(4)(B) of the Act.

Section 1860D-4(e)(4)(A) of the Act requires the Secretary to develop, adopt,

recognize or modify initial uniform standards relating to the requirements for an electronic prescription drug program, taking into consideration the recommendations from the NCVHS. It requires that in developing the recommendations, the NCVHS consult with the following:

- Standard setting organizations (as defined in section 1171(8) of the Act).
- Practicing physicians.
- Hospitals.
- Pharmacies.
- Practicing Pharmacists.
- Pharmacy Benefit Managers.
- State Boards of Pharmacy.
- State Boards of Medicine.
- Experts on e-prescribing.
- Other appropriate Federal agencies.

In order to fulfill its responsibilities, the NCVHS's Subcommittee on Standards and Security held public hearings on issues related to e-prescribing on March 30 and 31, 2004; May 25, 26, and 27, 2004; July 28, 29, and 30, 2004; and August 17, 18, and 19, 2004. These hearings included testimony from e-prescribing networks, providers, software vendors, and industry experts on patient safety, drug knowledge data bases, and standards currently in use by the industry. Industry experts involved in e-prescribing studies and initiatives also presented information on the progress and findings of these studies. Following the hearings by the NCVHS Subcommittee on Standards and Security, the Subcommittee developed observations and associated recommended actions and presented them to the full NCVHS Committee for consideration. On September 2, 2004, the NCVHS sent a letter to the Secretary containing the observations and associated recommended actions for an electronic prescription drug program. The document included recommendations for the foundation standards that we are adopting and other long-term recommendations regarding pilot testing of other standards. For specific details, refer to the letter available at <http://www.ncvhs.hhs.gov/040902lt2.htm>.

For a more complete discussion of the NCVHS Process for e-prescribing standards, please refer to the proposed rule (70 FR 6259–6260).

C. Standards Design Criteria

In the proposed rule, we discussed the design criteria for electronic prescription drug program standards specified in section 1860D–4(e)(3)(C) of the Act. The design criteria for electronic prescription drug program standards require that—

- The standards be designed so that, to the extent practicable, they do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists;
- The standards be compatible with standards established under Part C of Title XI, standards established under section 1860D–4(b)(2)(B)(i) of the Act, and with general health information technology standards; and
- The standards be designed so that they permit the electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration (FDA) and the National Library of Medicine (NLM).

D. Current Prescribing Environment

The proposed rule described the processes currently used for writing prescriptions based upon statistical data that is available and information presented in testimony to the NCVHS. For a more detailed discussion of the current process and the reported workflow and administrative inefficiencies that affect costs and quality of care, please refer to section I. of the proposed rule at 70 FR 6260.

E. Current E-Prescribing Environment

In the proposed rule, we discussed the values of e-prescribing in preventing medication errors, statistics concerning certain usage of e-prescribing, and barriers to expanded use of e-prescribing.

The value of e-prescribing in preventing medication errors is that each prescription can be electronically checked at the time of prescribing for dosage, interactions with other medications, and therapeutic duplication. E-prescribing could potentially improve quality, efficiency, and reduce costs by—

- Actively promoting appropriate drug usage, such as following a medication regimen for a specific condition;
- Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
- Speeding up the process of renewing medications; and
- Providing instant connectivity between the health care provider, the pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.

E-prescribing rates vary somewhere between 5 percent and 18 percent for physicians, although usage is slowly

increasing. Some of the barriers to increased usage of e-prescribing by physicians are the costs of buying and installing a system, the training involved, time and workflow impact, lack of reimbursement for costs and resources, and lack of knowledge about the benefits related to quality of care. For more details of this discussion, please refer to the proposed rule (70 FR 6260–6261).

F. Evolution and Implementation of an Electronic Prescription Drug Program

In the proposed rule, we discussed our proposal to adopt foundation standards, which are standards that do not need pilot testing because adequate industry experience already exists for these standards. We also proposed criteria that standards must meet to be considered as having “adequate industry experience.” For a more detailed discussion, please refer to the proposed rule (70 FR 6261). We invited and received public comments on “adequate industry experience”, the roles of Standards Development Organizations (SDOs) and the NCVHS in the adoption of e-prescribing standards, and a process for updating existing standards and adopting new standards. Those comments and our responses are addressed in section III. of this final rule.

G. Electronic Prescription Drug Program

In the proposed rule, we discussed the standards that are required for an electronic prescription drug program as required by section 1860D–4(e)(2) of the Act and the standards that we were proposing. We also discussed which standards would be subject to pilot testing, and which standards would be proposed as future standards. For a more detailed discussion of those standards and the table that summarizes the NCVHS recommendations, please refer to the proposed rule (70 FR 6261–6262). We invited and received public comments on the proposed standards as well as on standards that are currently being used in the industry. Those comments and our responses to those comments are addressed in section III. of this final rule.

H. Summary of Status of Standards for an Electronic Prescription Drug Program

In the proposed rule, we acknowledged that the foundation standards we proposed did not address all of the functions required under section 1860D–4(e)(2) of the Act. For a more detailed discussion, please refer to section I. of the proposed rule (70 FR 6264). We requested comments on the proposed standards, as well as our

proposed phased implementation for electronic prescription drug program requirements. We also requested comments on considerations for interoperability and industry-adopted standards for electronic health records (EHRs). The comments, on both these issues, and our responses to those comments are addressed in section III. of this final rule.

II. General Overview of the Provisions of the Proposed Rule

As stated earlier, on February 4, 2005, we published the E-Prescribing and the Prescription Drug Program proposed rule (70 FR 6256–6274), which discussed our proposal to adopt the first set of final uniform standards (or foundation standards) for an electronic prescription drug program under the MMA. In the proposed rule, we stated that these proposed foundation standards would not be subject to pilot testing because they meet the criteria for adequate industry experience. These standards included the National Council for Prescription Drug Programs (NCPDP) SCRIPT version 5.0 for transactions for new prescriptions, prescription renewals, cancellations, changes between prescribers and dispensers, ancillary messages and administrative transactions; the Accredited Standards Committee (ASC) X12N 270/271, version 4010 and version 4010 A1, for eligibility queries between prescribers and Part D sponsors; and the NCPDP Telecommunications Standard, version 5.1, and the NCPDP Batch Standard Batch Implementation Guide version 1.1 supporting the telecommunications standard implementation guide for eligibility inquiries between dispensers and Part D sponsors.

Also, in the proposed rule, we discussed the need for formulary and medication history standards, and that we were not aware of any standards for these transactions that clearly met the criteria for adequate industry experience. Standards for formulary and medication history will be tested in the 2006 pilot project.

In the proposed rule, we proposed to broaden the scope of 42 CFR Part 423, Subpart D for requirements that relate to electronic prescription drug programs for prescribers, dispensers, and Part D sponsors. We also proposed a number of definitions that are pertinent to the e-prescribing process. We also proposed a compliance date of January 1, 2006 for the foundation standards.

III. Analysis of, and Responses to, Public Comments on the Proposed Rule

We received approximately 84 timely items of correspondence containing

multiple comments on the proposed rule. Some of the major issues we received comments on included preemption of State laws, the foundation standards, the appropriateness of the implementation date for the foundation standards, and a process for modifying and updating the foundation standards. We also received unsolicited comments, comments not submitted timely, and comments outside the scope of the proposed rule. The relevant and timely comments within the scope of the proposed rule that we received are discussed in the following sections.

Comments and Responses on Provisions of Proposed Rule

As we state in section II. of this final rule, in the February 4, 2005 proposed rule, we discussed—

- Our proposal to adopt foundation standards for an electronic prescription drug program under the MMA;
- Our proposal to broaden the scope of Subpart D, part 423 of the MMA to set forth requirements relating to electronic prescription drug programs for prescribers, dispensers, and Part D sponsors; and
- Our proposal to adopt a number of definitions that are pertinent to the e-prescribing process.

The comments that we received on those proposed provisions and our responses to those comments are outlined in the following sections.

A. Proposed Modification of the Title to Subpart D in 42 CFR Part 423

In the February 4, 2005 proposed rule, we proposed modifying the title of subpart D in 42 CFR Part 423 to read “Cost Control and Quality Improvement Requirements” and revising the description of the scope at § 423.150(c).

We received no comments on this proposed modification and, therefore, are changing the title of Subpart D of part 423 to read, “Cost Control and Quality Improvement Requirements” in this final rule.

B. Proposed Revision to § 423.150 (Scope)

In the February 4, 2005 proposed rule, we also discussed our proposed revision to the description of the scope at § 423.150(c) to state expressly that this subpart sets forth requirements relating to electronic prescription drug programs for prescribers, dispensers, and Part D sponsors. We did not receive any comments regarding this proposed change and, therefore, we are making this revision in this final rule.

C. Proposed Amendment of § 423.159(a) (Definitions)

In the February 4, 2005 proposed rule, we proposed to amend § 423.159 to add definitions pertinent to the e-prescribing process and to amend the title of the section to be consistent with the term “Electronic Prescription Drug Program” which we proposed to define below. The proposed definitions and the comments we received are as follows:

- **Dispenser Definition Proposal**—In the proposed rule, we defined a “dispenser” as 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 in the course of professional practice.

Comment: Most of the commenters supported our proposed definition of “dispenser,” but some wanted it modified to address explicitly non-dispensing pharmacy activities involved in providing services, such as medication therapy management services required by MMA.

Response: We believe that our definition of “dispenser” adequately encompasses dispensing and non-dispensing activities and that it is not necessary to add language to distinguish pharmacist roles within the scope of an e-prescribing environment. Therefore, in this final rule, we are adopting the proposed definition as final.

- **Electronic Media Definition Proposal**—In the proposed rule, we defined “electronic media” as having the same meaning as this term is defined for purposes of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In 45 CFR 160.103, electronic media means—

- Electronic storage media including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

- Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide open), extranet (using internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being

exchanged did not exist in electronic form before the transmission.

Comment: The majority of commenters supported the proposed definition of “electronic media”. Some of the commenters recommended that the definition be broadened to include secure wireless communications technologies and other technologies implementing current best practices.

Response: We believe that the term “electronic media,” as defined in 45 CFR 160.103, is sufficiently broad to encompass a range of technology advances, including secure wireless technologies. Moreover, our definition is not intended to establish a comprehensive list of, nor intended to identify best practices for, transmission media. Therefore, we do not intend to change our definition to reflect these additions.

Comment: One commenter requested clarification as to whether the term electronic media, for purposes of the proposed rule, includes prescriptions sent by “electronic facsimile” to a pharmacy. The commenter believed that including them in the definition would establish uniformity and would make electronic facsimiles subject to the same standards as other electronic prescription transmissions. In addition, several commenters proposed adding a new definition of “non-EDI message,” which they defined as being a message that leaves or enters a system (including long-term care facilities and/or pharmacies) as an image, either via fax or e-mail, that is not included in the electronic prescribing standards.

Response: The proposed definition of electronic media for an e-prescribing program is the same definition set forth in 45 CFR 160.103 for HIPAA’s transactions and code sets. We have already clarified, by means of HIPAA guidance in a Frequently Asked Question (FAQ) on the CMS Web site (<http://www.cms.hhs.gov/hipaa/hipaa2>), that paper faxes are not considered “electronic media,” while computer-generated faxes constitute use of “electronic media.” As a result, faxes that are generated by one computer and electronically transmitted to another computer (commonly referred to as computer-generated faxes) would be included under the definition of electronic media for e-prescribing that we proposed.

While we have determined that the NCPDP SCRIPT standard meets the test of adequate industry experience in many e-prescribing applications, in light of the comments received, we now recognize that prescribers using computer-generated faxes to transmit prescriptions to a dispenser’s fax

machine that prints a hard copy of the original computer-generated fax merits separate consideration. Because this computer-generated transmission started as an electronic version, it would constitute a transmission using electronic media as defined in the proposed rule, and, as a result, would be required to comply with adopted e-prescribing standards.

In some cases, the prescriber’s software can generate SCRIPT transactions, but the ability is “turned off” because electronic communication with the pharmacy has not yet been established. In other cases, the prescriber uses software (such as a word processing program) that creates and faxes the prescription document, but does not have true e-prescribing capabilities.

In the first case, the prescriber is already conducting e-prescribing, and should do so after the compliance date using the foundation standards. We would expect that the prescriber will establish electronic communication and begin to use the SCRIPT standard with little difficulty.

However, the prescriber in the second case is not actually capable of conducting e-prescribing using the standards being adopted by this rule. That prescriber is merely using word processing software and the computer’s fax capabilities in lieu of faxing paper. Requiring these prescribers to convert to e-prescribing using the foundation standards would likely result in their simply reverting to faxing paper. Consequently, requiring these entities to comply with the NCPDP SCRIPT Standard would force the vast majority of them to revert to paper faxes, and, thus, it would impose a significant burden on those entities presently using computer-generated faxing, and would be counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing. Moreover, we believe prescribers using computer fax capabilities will migrate to e-prescribing in time, possibly at the same time as they implement electronic health record systems. Therefore, we adopt an exemption which exempts those using computer-generated faxes from using the NCPDP SCRIPT Standard for transmitting prescriptions and prescription-related information.

We believe this approach is consistent with the statutory direction that the Secretary has to issue uniform standards with the specific objective of improving efficiencies, including cost savings, in the delivery of care, and designed so that the standards, to the extent practicable, do not impose an undue administrative burden on prescribing

health care professionals and dispensing pharmacies and pharmacists. We interpret these statutory objectives as enabling us to ensure that existing functionalities and workflow are not disrupted for a large number of prescribers and dispensers. We believe this interpretation is appropriate given the burden that adherence to the statutory requirements would create and based on the requests in comments received in response to the proposed e-prescribing rule. As indicated above, we anticipate that many prescribers and dispensers would revert to handwritten paper prescriptions or computer-generated prescriptions that are printed in hard copy and manually faxed to the dispenser. This practice would stand as a significant obstacle to the broader statutory goals of the electronic prescription drug program provisions, as well as limit the ability of Medicare beneficiaries and the Medicare program to benefit from the patient safety and cost savings anticipated from e-prescribing drugs under Part D of Title XVIII of the Act. However, we encourage all prescribers using fax technology to move as quickly as possible to the use of electronic data interchange via the SCRIPT standard.

• *E-prescribing Definition Proposal—* In the proposed rule, we defined “e-prescribing” to mean the transmission, using electronic media, of prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.

Comment: Most commenters supported the proposed “e-prescribing” definition. One commenter recommended that the definition of e-prescribing specifically cite “nursing facility.” Some commenters recommended the definition be amended to distinguish between the direct entry of prescribers and the direct entry of non-prescribers, such as clerical staff. Concerns were expressed that the definition does not include activities related to electronic claims adjudication. One commenter suggested that the definition for e-prescribing also be clarified to include two-way transmissions between the point-of-care (POC) and the dispenser.

Response: We believe that the term “e-prescribing” is broad enough in its scope to effectively encompass multiple transaction processes and participants, which exchange prescription or prescription-related transmissions, whether or not the transmission is conducted directly or through an intermediary. We realize that the business model that is typical in the

Long-Term Care (LTC) environment, where both the prescriber and the facility personnel are customarily involved in the prescribing process, is atypical of e-prescribing in the ambulatory setting. During the pilot project, we are planning to review the business process for e-prescribing in the LTC setting. For further discussion about e-prescribing and LTC and the comments we received, please refer to section F.1. of this final rule.

Electronic claims adjudication and other related administrative functions are outside the scope of e-prescribing as specified in section 1860D-4(e) of the Act. Moreover, a number of transactions standards for these administrative functions have already been adopted in the August 17, 2000 HIPAA Standards for Electronic Transactions and Code Sets Final Rule (HIPAA final rule) (65 FR 50312-50372) and modified in the February 20, 2003 Health Insurance Reform: Modifications to Electronic Data Transactions Standards and Code Sets (68 FR 8381-8399).

- **Electronic Prescription Drug Program Definition Proposal**—In the proposed rule, we defined “electronic prescription drug program” to mean a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

Comment: The commenters generally supported the proposed electronic prescription drug program definition, but recommended the definition be written in more generic terms without the reference to Part D.

Response: Based on these comments and our interpretation of our statutory authority, we have decided to expand the scope of our definition of electronic prescription drug program to include all Part D eligible individuals, whether or not they are enrolled in a Part D plan. This group is identical to the universe of persons who participate in Medicare (Parts A or B or both). We revised the definition for the electronic prescription drug program at § 423.159 to broaden the scope of an electronic prescription drug program to include Part D eligible individuals, not just Part D enrolled individuals. This is consistent with our interpretation of the statute to expand the scope of preemption of State laws to include, at a minimum, all Part D eligible individuals, as described in section E.1. of this final rule. Therefore, we are adopting the revised definition in this final rule.

- **Prescriber Definition Proposal**—In the proposed rule, we defined “prescriber” to mean a physician, dentist, or other person licensed, registered, or otherwise permitted by the

U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Comment: Commenters generally supported the proposed definition. One commenter recommended the definition of prescriber remain as defined in the proposed rule so long as the final definition encompasses providers, including Certified Registered Nurse Anesthetists (CRNAs) and others who are not physician providers, but who are granted prescriptive authority through the State in which he/she practices. One commenter recommended that the definition of “prescriber” specifically require prescriber order entry, including electronic signature by the actual prescriber. Several commenters recommended that the definition of “prescriber” be expanded to include those who prescribe drugs for animal use.

Response: The proposed definition does encompass individuals who are non-physicians, but who are permitted to issue prescriptions for drugs for human use. These non-physician providers could include CRNAs, nurse practitioners, and others. We also believe that it is inappropriate to include specific references to prescribing functions, such as electronic signatures, within this basic definition. We do not believe that there is statutory basis in the MMA to include prescribers of drugs for animal use, as the requirements specified section 1860D-4(e) of the Act, as amended by section 101 of the MMA, expressly provide for e-prescribing for covered Part D drugs for Part D eligible beneficiaries. We are not aware of any authority under which a prescriber of drugs for animal use would be writing prescriptions for part D drugs for Part D eligible beneficiaries, or under which animals were Part D eligible beneficiaries. Therefore, in this final rule, we are adopting the proposed definition as final.

- **Prescription-related information Definition Proposal**—We proposed that “prescription-related information” would mean information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan.

Comment: Several commenters recommended amendments to the proposed definition. One commenter recommended that non-dispensing pharmacists (for example, those providing medication therapy management program services) be identified in the e-prescribing program. Several commenters recommended that the definition be written in more generic terms without the reference to Part D,

which they felt could be addressed in the definition for electronic prescription drug program. According to these commenters, the additional language would capture Medicaid and other plans that would voluntarily implement e-prescribing efforts based on the proposed regulations. One commenter recommended the “prescription-related information” definition be expanded to include drug allergies and personal allergies.

Response: We believe that the proposed definition of “prescription-related information” adequately defines different types of information within the scope of the e-prescribing environment intended by the MMA statute. We also believe that the e-prescribing provisions of section 1860D-4(e) of the Act, as amended by section 101 of the MMA apply to pharmacists, both dispensing and non-dispensing, who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible individuals. The statute broadly includes medication history, eligibility, related health or drug information. Furthermore, we believe that “medication history or related health or drug information” is sufficient to include drug allergies and personal allergies.

Comment: Some commenters suggested expanding the definition of prescription-related information as discussed in our proposed rule, which limits the scope of prescription information regarding eligibility for drug benefits, medication history or related health or drug information to a Part D eligible individual enrolled in a Part D plan. Some commenters proposed expanding the definition to include all Medicare beneficiaries. Other commenters suggested dropping the reference to Part D to expand the definition to all e-prescribing.

Response: As indicated previously in this final rule, based on the comments we received and our interpretation of our statutory authority, we have decided to expand the scope of our definition to include all Part D eligible individuals, whether or not they are enrolled in a Part D plan. Accordingly, we are revising our definition of prescription-related information to mean information regarding eligibility for drug benefits, medication history or related health or drug information for Part D eligible individuals.

D. Revision to § 423.160 (Standards)

1. General Rules

In the February 4, 2005 proposed rule, we proposed that Part D sponsors would

be required to establish and maintain an electronic prescription drug program that complies with the applicable standards in § 423.160(b) when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals enrolled in a Part D Plan.

Although we did not receive specific comments on this general rule for Part D sponsors, we did receive many comments related to its scope. In particular, many commenters wanted to expand the scope of e-prescribing in this final rule to include all Medicare beneficiaries and all payers. As indicated previously in this final rule, based on the comments we received and our interpretation of our statutory authority, we have decided to expand the scope of e-prescribing in this final rule to include all Part D eligible individuals, whether or not they are enrolled in a Part D plan. Accordingly, we are revising our general rule for Part D sponsors to state that Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in § 423.160(b) when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

In the February 4, 2005 proposed rule, we also proposed a general rule for prescribers and dispensers. We proposed that prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in § 423.160(b) when e-prescribing for covered Part D drugs for Part D eligible individuals enrolled in a Part D plan. Although we did not receive specific comments on this general rule for prescribers and dispensers, we did receive many comments related to its scope. In particular, many commenters wanted to expand the scope of e-prescribing in this final rule to all Medicare beneficiaries and beyond the Part D program. As indicated previously in this final rule, based on the comments we received and our interpretation of our statutory authority, we have decided to expand the scope of e-prescribing in this final rule to include all Part D eligible individuals, whether or not they are enrolled in a Part D plan. Accordingly, we are revising our general rule for prescribers and dispensers to state that prescribers and dispensers that transmit, directly or through an

intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

2. Standards

As stated in the February 4, 2005 proposed rule, the Secretary had tentatively concluded that the proposed foundation standards are not subject to pilot testing because adequate industry experience with those proposed foundation standards already exists. We received numerous comments on the proposed foundation standards. Those comments and our responses are discussed below.

a. Prescription Proposal

In the proposed rule, we proposed to adopt, as a foundation standard, the transactions and administrative messages included in the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 5, Release 0 (except for the Prescription Fill Status Notification Transaction), to provide for communication of a prescription or prescription-related information between prescribers and dispensers.

Comment: Many commenters supported the adoption of NCPDP SCRIPT as a foundation standard in 2006. NCPDP SCRIPT is the current industry standard for electronically transmitting prescription information from the prescriber to the dispenser.

Although the majority of commenters supported adoption of the NCPDP SCRIPT Standard, some commenters suggested that the foundation standards be included in the pilot project and some recommended a delay in implementation until pilot testing was completed.

Response: We agree that the following transactions of the NCPDP SCRIPT should be one of the foundation standards:

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

We are adopting this standard for these specified transactions to be effective on January 1, 2006. We also plan to include it in the pilot project in

order to ensure interoperability with the standards being pilot tested.

b. Eligibility Proposal (ASC X12N 270/271 Transaction Version 4010, 4010A1)

In the February 4, 2005 proposed rule, we proposed to adopt, as part of the proposed foundation standards, the ASC X12N 270/271 Transaction Version 4010, 4010A1 (the 270/271 standards) for conducting eligibility and benefits inquiries between prescribers and Part D sponsors.

Comment: The majority of commenters supported the adoption of the ASC X12N 270/271 transaction standard for eligibility inquiries where appropriate. Commenters agreed that the version adopted should be consistent with the version adopted under HIPAA.

A number of commenters suggested pilot testing this standard and delaying implementation of the 270/271 standards to evaluate and test the impact of this transaction on the e-prescribing environment. Comments that supported adoption of the 270/271 standards also stressed the need to provide complete responses on the 271 response.

A few of the commenters opposed adoption of the 270/271 standards because they believe it currently does not accommodate enough of the kinds of information that would be necessary to complete the transaction, such as patient enrollment information that may be required for Part D beneficiaries.

Response: We agree that the 270/271 standards should be one of the foundation standards and we are adopting it in this final rule to be effective on January 1, 2006. We considered the potential shortcomings of the 270/271 standards that a few commenters identified, such as the standards not being sufficiently robust for returning pharmacy-related eligibility information. However, the majority of commenters indicated that the 270/271 standards are adequate and have been successfully implemented in e-prescribing programs. In addition, the 270/271 standards are HIPAA standards and are already in widespread industry use, including in e-prescribing programs. We also will work with Part D plans to assure appropriate implementation of the 270/271 standards.

c. Eligibility Proposal (NCPDP Telecommunication Standard, Version 5.1)

In the February 4, 2005 proposed rule, we also proposed to adopt the NCPDP Telecommunication Standard, version 5.1, for conducting eligibility

transactions between dispensers and Part D sponsors.

Comment: Many commenters agreed that the NCPDP Telecommunications Standard, Version 5.1 should be adopted as a foundation standard. Some stipulated that this version should be adopted as a foundation standard as long as newer versions may be utilized. Other commenters suggested that the implementation of this standard be made voluntary until pilot tested. A few commenters alleged that the standard is not in widespread use within the e-prescribing industry.

Response: The majority of commenters supported the adoption of the NCPDP Telecommunications Standard, Version 5.1, as a foundation standard because it had been successfully implemented in e-prescribing programs. We agree that the standard should be one of the foundation standards, and we are adopting it in this final rule to be effective on January 1, 2006. In addition, the NCPDP Telecommunications Standard v 5.1 is a HIPAA standard that must be used for the relevant electronic transactions and already has adequate industry experience. The use of later versions will be addressed with the comments on version updating and maintenance.

3. Formulary and Medication History

In the February 4, 2005 proposed rule, we discussed how the adoption of formulary representation and medication history would enhance e-prescribing capabilities under Part D by making it possible for the prescriber to obtain information on the patient's benefits, including the formulary status of drugs that the physician is considering prescribing, as well as information on medications the patient is already taking, including those prescribed by other providers. We also discussed the potential for cost savings and quality improvements that could result from the use of formulary and medication history standards. Proprietary file transfer protocols developed by RxHub are currently being used to communicate this information in many e-prescribing programs. The RxHub protocols have been submitted to NCPDP for accreditation, and this process is ongoing. We did not specifically propose adoption of these formats as foundation standards because they did not meet the accreditation criteria. However, we proposed characteristics for formulary and medication history standards, and noted that, if those characteristics were met and there was adequate industry experience with them, we would

consider adopting foundation standards for formulary and medication history.

In the interim, the RxHub protocols have taken different routes in terms of accreditation. The medication history protocol is no longer a discrete standard; rather, it was incorporated into the latest version of NCPDP SCRIPT (v. 8.0) as a transaction. This is in NCPDP's formal review process. The formulary and benefits protocol is a discrete standard and is also undergoing NCPDP formal review and ANSI accreditation.

Comment: Commenters generally opposed adoption of the RxHub protocols, even if they became accredited standards. The commenters recommended that those standards be pilot tested. A few commenters supported adoption of the RxHub protocols. No other foundation standards for these functions were proposed by commenters.

Response: In response to many comments about the need for pilot testing the formulary and benefits standard and concerns about its interoperability with other standards, we will not adopt it as a foundation standard, but will include it in pilot testing. However, the transactions may be used voluntarily in the meantime.

We are not adopting the RxHub medication history protocol as a foundation standard because it is included as a transaction in NCPDP SCRIPT v. 8.0, which does not meet the criterion for adequate industry experience. We plan to include that version of NCPDP SCRIPT, including the medication history functionality, in the pilot project.

E. Comments and Responses on Related Issues

In the proposed rule, we requested comments on various issues related to the e-prescribing process. We received numerous comments on those issues and we discuss those comments and our responses in the following section:

1. State Preemption

The MMA addresses preemption of State laws at section 1860D-4(e)(5) of the Act as follows:

“(5) Relation to State laws. The standards promulgated under this subsection shall 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 the eligibility, benefits, and prescriptions with respect to covered Part D drugs under this part.”

In the February 4, 2005 proposed rule, we proposed to interpret this language as preempting State law provisions that conflict with Federal electronic prescription drug program requirements that are adopted under Part D. This interpretation allows Federal preemption of State laws that are either contrary to the Federal standards or that restrict the ability to carry out (or stand as an obstacle to) the electronic prescription drug program requirements, and that pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs (such as medication history) for Part D enrolled individuals.

This is an important issue because there is wide variation among the State laws regarding the extent to which electronic prescribing can be done, what information e-prescriptions must contain, how that information is worded and represented, and whether and how this information can be received into or transmitted from that State. As a result, Part D sponsors may face significant operational barriers and costs in implementing their e-prescribing programs.

We invited public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant contrary State statutes that commenters believe should be preempted, beyond those that would be preempted under our proposed interpretation. We specifically asked for comment on whether this preemption provision pertains only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also asked for comment on whether this preemption provision pertains to only electronic prescription transactions or to paper transactions as well. The comments that we received in response to our requests and our response to those comments are as follows:

Comment: Some commenters agreed that the MMA's preemption provision would pertain only to electronic prescriptions for Part D enrolled Medicare beneficiaries for drugs covered under Part D, as set forth in our proposed rule. However, many other commenters argued for a broader interpretation of the statute. Some commenters suggested preempting State laws concerning e-prescribing for all drugs that are prescribed for all Medicare beneficiaries. The commenters believed that the narrower interpretation would be unworkable because it would create one set of rules for Part D enrolled beneficiaries and another set for other Medicare

beneficiaries. Since prescribers may not know at the point-of-care whether a Medicare beneficiary is enrolled in Part D, or whether the drug being prescribed would be covered under Part D, they would not know whether State law applied, or was preempted.

Response: Based on these comments, we agree that the preemption provision can be read more broadly than proposed in the February 4, 2005 proposed rule. The scope of preemption includes all Part D-eligible individuals, whether or not they are enrolled in a Part D plan. This group is identical to the universe of persons who participate in Medicare (Parts A or B or both). Since Medicare A or B status is virtually always known or immediately ascertainable by a prescriber, this interpretation will minimize both confusion and mistakes. This is particularly important because the patients themselves may not always know whether they are enrolled in Part D (beneficiaries often know the plan name, but not their enrollment status), but will have a Medicare card and number if they are enrolled in Parts A or B.

The preemption provision and other language in the e-prescribing statute give the Federal government the ability to preempt those State laws that “restrict the ability to carry out this part” and “pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to part D drugs under this part” (section 1860D–4(e)(5) of the Act). This language permits preemption to pertain to more than Part D enrolled individuals. Therefore, we are interpreting section 1860D–4(e)(5) of the Act to preempt all contrary State laws that are applicable to a prescription that is transmitted electronically not only for those individuals who are enrolled in Part D, but for all Part D eligible individuals.

As to our proposal to limit preemption to “covered Part D drugs,” we agree with commenters that it will not always be possible for a prescriber to know, in advance, which category a particular drug falls. Indeed, some drugs, such as immunosuppressive drugs, may be reimbursed under either Part D or Part B depending not only on which coverage the patient has, but also on whether the transplant occurred before or after turning age 65. We do not believe that the States have any plausible interest in applying different rules in these situations, or that prescribers should face such uncertainty. Accordingly, we interpret the MMA preemption provision as preempting State laws that restrict the Department of Health and Human

Services’ (DHHS) ability to carry out electronic prescribing, as specified at section 1860D–4(e) of the Act, and pertain to the electronic prescribing, for Part D eligible individuals, of drugs that may be covered by Part D in at least some circumstances, whether or not that particular prescription is covered under Part D in those specific circumstances.

We have codified the statutory preemption provision found at section 1860D–4(e) of the Act in this final rule. This addition, found at § 423.160(a)(4), is essentially identical to the statutory language.

Comment: Some commenters proposed an even broader interpretation, arguing that preemption should pertain to all e-prescribing, not just to e-prescribing in the Medicare context. They stated that limiting preemption to Medicare would create a “Medicare silo” with significantly different rules than for other payers, which would be costly for PBMs, plans, and pharmacies to address and administer. Those commenters believe that one set of rules for all payers would facilitate the adoption of e-prescribing outside the Medicare program. They contend that some States have existing statutory or regulatory barriers that could impede the success of e-prescribing. For example, some State laws were drafted with only paper prescriptions in mind and, thus, may not be well-suited to e-prescribing applications.

Response: We agree that broadening our interpretation of State preemption to include all Medicare beneficiaries and drugs that may be covered by Part D, in at least some circumstances, whether or not that particular prescription is covered under Part D, is consistent with our statutory authority. It also would reduce confusion for prescribers and, therefore, would likely encourage expanded use of e-prescribing and the adopted standards. Therefore, we interpret the MMA’s State preemption provision to preempt State laws that are contrary to the e-prescribing standards or restricts the ability to carry out this part for drugs that may be covered under Part D, in at least some circumstances, whether or not that particular prescription is covered under Part D, and that are e-prescribed for any Part D eligible beneficiaries. We also urge States to enact legislation consistent with and complementary to the goals of the MMA’s e-prescribing provisions and to remove existing barriers to e-prescribing.

Comment: Several commenters proposed that the preemption should be applied to any State laws that could be considered a barrier to e-prescribing.

Some commenters noted that this interpretation would be consistent with their view of the Congress’ intent to enable e-prescribing. The commenters suggested preempting a variety of laws, such as those that—

- Prohibit or fail to allow for e-prescribing;
- Establish requirements or standards for e-prescribing content and formats that are inconsistent with current e-prescribing practices in other jurisdictions; and
- Prevent e-prescribing across State lines.

One commenter stressed that State laws also can afford patient safety and quality of care protections and that preempting those laws could adversely affect patient safety and quality.

Response: While these commenters suggested categories of laws that might be preempted, few specific examples emerged. Under our interpretation of the statutory preemption provision, State laws that restrict the ability of entities to electronically prescribe covered Part D drugs for Part D eligible individuals in accordance with the Federal provisions would be preempted. While we agree that some State laws preempted under our interpretation of the statute may have had health or safety objectives, the statutory test is whether those laws are contrary to the standards we adopt or restrict the ability to carry out e-prescribing under Part D, and also pertain to the electronic transmission of prescription-related information. We also note that for a law to “pertain” to e-prescribing, it need not specifically single out e-prescribing. Our strategy is to define a general preemption rule in this final rule and identify several specific categories of laws that would be preempted. Preemption of these State laws is necessary because they restrict the ability of entities to electronically prescribe covered Part D drugs for Part D eligible individuals. Further, this preemption is necessary at a minimum in order for Part D sponsors and the providers and pharmacies that choose to e-prescribe covered Part D drugs for Part D eligible individuals to conduct e-prescribing beginning on January 1, 2006. Of course, under the statutory provisions, preemption of State laws that are contrary to these standards, or otherwise restrict the ability to carry out e-prescribing, will be effective upon the effective date of this regulation.

We also anticipate that, as problems are identified with particular State laws or practices, some States will enact laws to address specific patient safety or confidentiality concerns that will not be contrary to, or restrict the ability to

carry out, the requirements of this final rule. We encourage 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 urge States to enact legislation consistent with and complementary to the goals of the MMA's e-prescribing provisions. This includes removing existing barriers to e-prescribing. We believe that, under this approach, we can achieve national uniformity in e-prescribing standards and practices, while preserving the maximum reasonable autonomy for State-specific practices that do not consequentially hamper e-prescribing. If other State laws also stand as an obstacle to Congress's goal of implementing uniform e-prescribing standards that are to be used in electronic prescribing of Part D covered drugs for Part D eligible individuals, we can reevaluate the scope of preemption that is warranted when we adopt additional standards or in future rulemaking.

At this time, we have identified several categories of State laws that are preempted, in whole or in part, upon the effective date of this final rule. These categories are intended to be examples and do not constitute an exhaustive list. However, they are illustrative of the examples identified through NCVHS testimony and comments received in response to our proposed rule; our application of the MMA's preemption provisions to those State laws are based on our interpretation of the statute, in which State laws would be preempted if they restrict the ability of entities to electronically prescribe covered Part D drugs for Part D eligible individuals in accordance with Federal provisions. It is important to note that those State laws are preempted to the extent that they pertain to covered Part D drugs that are electronically prescribed for Part D eligible individuals. A State law, whether or not it includes an e-prescribing standard, can be preempted if it is contrary to the adopted standards or restricts the ability to carry out Part D standards, and pertains to electronic transmission of prescription-related information. Those categories of State laws are as follows:

- State laws that expressly prohibit electronic prescribing.
- State laws that prohibit the transmission of electronic prescriptions through intermediaries, such as networks and switches or PBMs, or that prohibit access to such prescriptions by plans or their agents or other duly authorized third parties.

- State laws that require certain language to be used, such as dispense as written, to indicate whether generic drugs may or may not be substituted, insofar as such language is not consistent with the adopted standard.

- State laws that require handwritten signatures or other handwriting on prescriptions.

We interpret the MMA preemption provision to preempt State laws that prohibit e-prescribing. Such laws would clearly restrict the Department's ability to carry out the e-prescribing program for Part D, and they pertain to the electronic transmission of prescription and prescription-related information for covered Part D drugs. The application of this preemption provision is necessary for e-prescribing to occur for covered Part D drugs for Part D eligible individuals.

We interpret the MMA preemption to preempt laws that prohibit transmission of electronic prescriptions through intermediaries because they would effectively preclude e-prescribing since establishing direct connectivity between each prescriber and each pharmacy is impractical, according to NCVHS testimony and information from other sources. In addition, this is current industry practice, and Part D plans may in many cases use software systems that rely on third party processing e-prescriptions either simultaneously or before they reach pharmacies. Without preemption, this type of law would restrict the ability to carry out e-prescribing for Medicare Part D because prescribers would be unable to e-prescribe covered Part D drugs for Part D eligible individuals.

We interpret the preemption provision to preempt State laws that establish specific generic substitution language to the extent that such a requirement is not consistent with an adopted standard—that is, where an adopted standard does not permit use of specific generic substitution language or where the State requires that the language be placed at a specific location on the prescription. Such requirements would be contrary to adopted standards and restrict the ability of Part D sponsors to conduct e-prescribing in accordance with the adopted standards.

Lastly, we interpret the preemption provision to preempt State laws that require handwritten signatures or other handwriting on prescriptions. Those laws restrict e-prescribing for Part D covered drugs for Part D eligible individuals because they introduce manual requirements and a resulting paper product into the electronic prescribing process, which effectively prevents the prescription from being

transmitted electronically from the prescriber to the pharmacy as required by this final rule. As a result, these State laws restrict the ability of entities to electronically prescribe covered Part D drugs for Part D eligible individuals in accordance with Federal provisions.

Comment: Several commenters suggested that the MMA e-prescribing provision should preempt State laws that affect the security of prescription information and patient privacy.

Response: The security of electronic prescriptions and the protection of electronic prescription information must meet the requirements set forth under HIPAA's administrative simplification provisions for the protection of protected health information (PHI) and electronic protected health information (EPHI) (see 45 CFR Parts 160 and 164) since, so far as we can determine, entities that conduct e-prescribing transactions under this final rule will be covered entities under HIPAA and the information contained in these transactions is PHI and EPHI.

Because HIPAA's privacy requirements are a floor, some States have additional privacy requirements that remain in effect, such as those laws requiring electronic or digital signatures and prescriber authentication, and those restricting the release of medication information for certain sensitive medical diagnoses, such as substance abuse disorders and HIV/AIDS, without patient consent. State privacy laws that are not contrary to the HIPAA Privacy Rule will also be in effect. Because it is not clear that all variations in State privacy laws negatively impact e-prescribing, no preemption determination can be made categorically at this time. Variations in privacy laws within and among States will be assessed in the broader context of EHRs. When specific State privacy laws are identified, we will be able to assess their impact on e-prescribing under this or any other preemption analysis.

Comment: Several commenters requested preemption of State laws affecting electronic transmission of prescriptions for controlled substances. Other commenters urged HHS to work with the Drug Enforcement Administration (DEA) to develop guidance on electronic signature requirements for controlled substances.

Response: HHS and the DEA are working together to address the intersection of the Controlled Substances Act and regulations issued thereunder and rules regarding e-prescribing issued pursuant to the MMA.

Comment: One commenter pointed out that many States require that Medicaid prescriptions must have a prescriber's handwritten statement across the prescription, if a brand name prescription is required when a generic drug is available. Even the wording is dictated.

Response: The MMA transfers payment responsibility for the prescription drugs of dually eligible Medicaid and Medicare enrollees from Medicaid to Medicare. However, some States will provide additional prescription drug coverage for other Part D beneficiaries for drugs that would otherwise be paid out-of-pocket. If any State law or regulation prohibited a brand name drug prescription for prescriptions for these Part D eligible beneficiaries without a "handwritten" statement, the requirement that the statement be handwritten (but not the requirement for a written statement) would be preempted.

2. Anti-Kickback Statute Safe Harbor and Stark Exception

As stated earlier in this preamble, in the proposed rule, we indicated that we would be proposing an e-prescribing exception under the Stark law and an e-prescribing safe harbor under the anti-kickback statute. We also indicated that, in the meantime, compliance with existing provisions is required. We also solicited comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or incentives likely to be offered after rulemaking for a Stark exception and an anti-kickback safe harbor. We received many comments on this issue.

Comment: Commenters requested this regulatory guidance and noted that the lack of it is a barrier to adoption of e-prescribing.

Response: We agree that guidance is needed and two proposed rules have been issued. The Physicians' Referrals to Health Care Entities with which They Have Financial Relationships—E-Prescribing Exceptions proposed rule, which proposed new exceptions to the Stark law for e-prescribing and electronic medical records, published in the **Federal Register** on October 11, 2005. The Medicare and State Health Care Programs; Fraud and Abuse: Safe Harbor for Certain Electronic Prescribing Arrangements under the Anti-Kickback Statute proposed rule, published in the **Federal Register** on October 11, 2005, proposed new safe harbors under the anti-kickback statute for e-prescribing and electronic medical records.

3. Three Criteria for Assessing Adequate Industry Experience

In the February 4, 2005 proposed rule, we discussed adopting the following three criteria for assessing adequate industry experience:

- Approval by an ANSI-accredited SDO to assure consideration of industry requirements.
- Implementations among multiple partners to assure interoperability.
- Recognition by key stakeholders to assure industry recognition of a single standard.

Comment: One commenter proposed that standards meeting some, but not all, of the criteria be recognized as "draft standards for trial use" (DSTU) on a voluntary basis. Some SDOs use the concept of DSTU to permit interested parties to test new standards prior to their final voting process.

Response: This suggestion presumes a category of standards that would fall outside the structure of the MMA and we, therefore, cannot accommodate it. The MMA does not recognize the concept of DSTUs, and for purposes of standards development and implementation, it characterizes standards as either final (to be implemented) or initial (to be pilot tested). The standards adopted in this final rule are the first set of final standards. In addition, NCPDP's procedures, unlike those of other SDOs, do not recognize DSTUs. However, we encourage the voluntary adoption of e-prescribing standards that are not adopted as final standards.

Comment: Several commenters generally supported the proposed criteria. Many of the commenters specifically favored the requirement for ANSI accreditation, although a few commenters indicated that this requirement was unnecessary and that the remaining two requirements were adequate. Some commenters felt that the criteria were not strong enough to demonstrate widespread utilization throughout the health care industry and thus were not an adequate substitute for pilot testing, particularly in light of the short implementation deadline for the Part D benefit.

Response: Based on the majority of comments we received in response to the proposed rule, we believe the proposed criteria for assessing adequate industry experience are valid, and will assure that foundation standards adopted in this final rule are consistent with them. Therefore, we will continue to use these criteria to assess adequate industry experience for future standards.

4. Medical History

Medical history broadly relates to information about a patient's health care and health status. We did not propose standards for communicating medical history in the February 4, 2005 proposed rule. Section 1860D-4(e)(2)(B) of the Act treats the electronic transmission of medical history differently from the electronic transmission of other information in an electronic prescription drug program in that it explicitly states that the medical history provision shall be effective "on and after such date as the Secretary specifies and after the establishment of appropriate standards."

Comment: A few commenters suggested that POC checking should include allergy/intolerance checking, validation of patient, and confirmation that a prescription is linked to a patient problem list. Moreover, the commenters recommended that an e-prescribing system provide physicians with information needed to discuss drug therapy with the patient at the POC.

Response: Because we currently are not aware of any medical history standards, we are, therefore, not adopting any at this time. However, we welcome industry suggestions for those standards that we might consider at a future time.

5. RxNorm

RxNorm is a standardized nomenclature for clinical drugs that is produced by the National Library of Medicine. While RxNorm was not explicitly discussed in the February 4, 2005 proposed rule, it was referenced in the table of potential standards contained in section G. of that proposed rule (70 FR 6262) because the NCVHS recommended that the 2006 pilot project include the RxNorm terminology. Efforts to map RxNorm to other terminologies are currently underway.

Comment: While many commenters recognized the potential advantages of RxNorm, they recommended pilot testing the RxNorm terminology because it is not established as a recognized industry standard and needs to be tested in a variety of practice settings. Several commenters recommended accelerating the RxNorm project. One commenter reported that two commercial database vendors are concerned that RxNorm may be incomplete. They suggested that RxNorm's content be validated for completeness and to assure that the code set accurately conveys the drug that the prescriber intends to prescribe, and that a translation table between

RxNorm and the commercial database publishers be developed.

Response: We plan to include RxNorm in the 2006 pilot project to determine its interaction with commercial data bases and certain drug labeling initiatives, to determine whether it translates to the National Drug Code (NDC) for new prescriptions, renewals and changes; and to test RxNorm's completeness and interoperability in the e-prescribing environment.

6. Provider Identifier

In the February 4, 2005 proposed rule, we discussed the salient issues regarding provider identifiers for the Medicare e-prescribing program. NCVHS recommended the use of the National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers once it becomes available. CMS began issuing NPIs on May 23, 2005. However, the use of the NPI in HIPAA standard transactions is not required by regulation until May 23, 2007 (May 23, 2008 for small health plans). We indicated that we were considering requiring the use of the NPI in an electronic prescription drug program as of January 1, 2006, well in advance of the HIPAA regulatory requirements. We noted that accelerating NPI usage for e-prescribing may not be possible, as we may not have the capacity to issue NPIs to all providers involved in the e-prescribing program by January 1, 2006. We also solicited comments on the availability of alternative identifiers that could be adopted as a standard.

Comment: Most of the commenters agreed that the NPI should eventually be the standard provider identifier for use in e-prescribing transactions. There also were some commenters who felt that the NPI needed to establish a proven track record, and should be included in the 2006 pilot project.

Response: We agree that the NPI should be the standard identifier for e-prescribing. It already is a HIPAA standard identifier that must be used in standard transactions, which means that covered entities (including Medicare, Medicaid, private insurers, clearinghouses, and other covered entities) must accept and use NPIs for covered HIPAA transactions by May 23, 2007, and May 23, 2008 for small health plans. Because the NPI is a new identifier and has not been used in the e-prescribing context, we will include it in the 2006 pilot project to determine how it works with e-prescribing standards that will be assessed. This also will allow for provider testing and phase-in.

Comment: The majority of commenters said that the NPI should not be required for use until the May 2007 (or May 2008 for small health plans) HIPAA regulatory compliance dates. They indicated that there is a need for sufficient time for all providers to obtain NPIs since enumeration began on May 23, 2005. They stated that the industry has been preparing for the 2007 (and 2008 for small health plans) compliance dates, and any change to those dates will cause major disruption.

Response: We agree that a transition period is needed. CMS will transition to the NPI when compliance for most covered entities is mandated in May 2007 (May 2008 for small health plans). The NPI will not be required for use in e-prescribing transactions until the May 2007 date (May 2008 for small health plans). As a result, we will not adopt a specific standard identifier for prescribers or pharmacies conducting e-prescribing for Medicare beneficiaries prior to the NPI dates. The NPI will be tested in the 2006 pilot project.

Comment: Commenters had a variety of suggestions for alternative identifiers that could be used in Medicare e-prescribing on an interim basis. These included the NCPDP provider number, the HCIdesa number, Medicare provider identifiers, the DEA number, and proprietary numbers. However, not one of these identifiers is assigned to all pharmacies and prescribers in the United States.

Response: Until May 2007, entities that want to e-prescribe for Medicare beneficiaries may use other identifiers as specified by CMS in program instructions. Details are in CMS' "Instructions: Requirements for Submitting Prescription Drug Event Data" (June 24, 2005) available at <http://www.cms.hhs.gov/pdps/revisedinstr062305.pdf>.

7. Prior Authorization

Prior authorization is the protocol used between a prescriber and payer to determine, in advance, if a particular treatment medication, procedure, service, or device will be covered. Numerous drugs, supplies, and medical services are only covered for certain conditions or under special circumstances, and require coverage authorization by a health plan prior to administration.

Because we are not aware of a prior authorization standard that incorporates real-time prior authorization functionality with messages for drugs, we did not propose adopting a prior authorization foundation standard.

However, in the February 4, 2005 proposed rule, the table that

summarized the NCVHS recommendations indicated that we should support the ASC X12N efforts to incorporate real-time prior authorization functionality in the ASC X12N 278 Health Care Services Review transaction (70 FR 6262).

Comment: All of the comments that we received on this subject supported pilot testing a proposed formulary and benefit standard that includes some measure of electronic prior authorization support. Also, the commenters suggested that electronic prior authorization information should include specific clinical requirements or rules, so that the prescriber would know what information was needed prior to submitting an authorization request. A number of the comments stressed the importance of a prior authorization standard to an electronic prescribing system for improving workflows and ensuring appropriate drug utilization.

Response: We agree with the comments that supported adoption of a prior authorization standard. We also are aware of further development of the ASC X12N 278 Health Care Services Review Transaction and will be pilot testing it for e-prescribing prior authorization in 2006. We will not adopt a standard for prior authorization transactions at this time.

8. Fill Status Notification

While fill status notification was not discussed at length in the proposed rule, it was mentioned in the discussion of the NCPDP SCRIPT standard (70 FR 6265–6266). In addition, because the NCVHS recommended that it be included in the 2006 pilot project, fill status notification was referenced in the table in section I.G. of the proposed rule (70 FR 6262).

Comment: A commenter expressed their disappointment that we decided not to include the NCPDP SCRIPT fill status notification transaction in the 2006 pilot project as this standard has the potential of significantly improving the health of Medicare beneficiaries.

Response: As we mentioned, while we do not think there exists adequate industry experience for this transaction to meet the criteria for a foundation standard, we will be testing the standard in the 2006 pilot project.

9. Pilot Testing

Section 1860D–4(e) of the Act includes an exception to the pilot testing requirement for standards with adequate industry experience.

Comment: Many commenters recommended that all standards be pilot tested to ensure that standards work in multiple environments including

settings where there are three-way transactions. Other reasons cited for pilot testing all standards include the following:

- To determine that an undue burden is not imposed on specific entities.
- To ensure that standards are useful and efficient for the e-prescribing process.
- To ensure that standards function in a manner that enhances the prescribing process.
- To determine if standards are functional and interoperable.

Other commenters warned that if standards are implemented without pilot testing, there will be more electronic errors, less effective prescribing safeguards, or increased system vulnerability and instability. Another commenter added that if the functionalities of the standards are not perfected, frustration could lead to a reduction or cessation of e-prescribing.

Response: We agree that pilot testing all of the standards may provide useful information for the implementation and operation of a multifunctional e-prescribing system. We note that, while we will be including the foundation standards in the pilot project, we do not consider them to be initial standards to be tested. We are including them solely to ensure their interoperability with the various other standards, including both the initial standards and other foundation standards. Moreover, because of interoperability concerns, the pilot project will include both new and emerging standards, as well as established standards for additional functionalities that are not in widespread use. If the standards testing is unsuccessful, we will work with the industry to correct any outstanding issues.

10. Version Updating and Maintenance

In the February 4, 2005 proposed rule, we proposed to adopt specific versions of the foundation standards. However, we also proposed that if standards are updated and newer versions are developed, HHS would evaluate the changes and consider how and when to adopt new updates to the standards. HHS anticipates, as appropriate, updating adopted standards through the incorporation by reference update process, which provides for publishing an amendment to the Code of Federal Regulations (CFR).

When updating a standard, we will look at a variety of factors to consider how the update should occur. If the Department intends to impose new requirements on the public, we would go through notice and comment rulemaking. If, on the other hand, the

updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment under an Administrative Procedure Act exception to the requirement for notice and comment rulemaking. In the latter case, we would likely adopt the version that was previously adopted as well as the new version. This would mean that compliance with either version for a covered transaction would constitute compliance with the standard.

When determining whether to waive notice and comment and whether to incorporate by reference multiple existing versions, we would consider the significance of any corrections or revisions to the standard as well as whether the newer version is "backward compatible" with the previously adopted version. Backward compatible means that the newer version would retain, at a minimum, the full functionality of the version previously adopted in regulation, and would permit the successful completion of the applicable transaction with entities that continue to use the previous version.

We noted, however, that if an e-prescribing transaction standard had also been adopted under the 45 CFR parts 160 through 162, the updating process for the e-prescribing transaction standard would have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard. In the proposed rule, we also sought comment on whether we should simply reference the relevant HIPAA standards so that the e-prescribing standards would be updated automatically in concert with any HIPAA standard modification. In addition, we invited public comment on how to establish a process to assess new and modified standards consistent with the Administrative Procedures Act and other applicable legal requirements, and specifically invited comment regarding the role of industry SDOs and the NCVHS. This final rule adopts and incorporates by reference the relevant HIPAA transactions standards (the X12N 270/271 and the NCPDP Telecommunication Standard). In doing so, whenever these HIPAA transactions standards are modified, the parallel e-prescribing standards would likewise be modified through a separate rulemaking.

Comment: Many commenters recommended that the process of maintenance and modification of standards should not be hindered by extensive rulemaking. They cited industry experience with HIPAA, and

pointed out that the update process precludes even voluntary adoption of newer versions, which stifles progress and innovation. They also supported our proposal of permitting voluntary implementation of later versions if they are backward compatible. Some commenters advocated permitting use of older standards for a period of time after new versions are adopted, while a few commenters recommended that all revisions be accomplished through notice and comment rulemaking.

Response: We agree with the majority of commenters who stressed that the process for adopting new versions of standards must keep pace with industry needs. We also recognize the need to maintain an open process for assessing changes to assure that various viewpoints are considered. However, we are bound by law to comply with the Administrative Procedure Act. Therefore, we will establish a review process to determine—

- Whether a standard should be updated with a new version; and
- Whether the update would necessitate notice and comment rulemaking.

Where it is determined that the notice and comment rulemaking is not required, the new version will be adopted by incorporating the new version by reference, through a **Federal Register** notice. In that case, use of either the new version or the older version would be considered compliant. We would subsequently conduct a rulemaking prior to requiring the use of the newer version and retiring the older version on a specific date.

Where notice and comment rulemaking is required, compliance with the new version will be mandated only after notice and comment rulemaking. We anticipate that such a regulation will provide for an implementation period during which either version of the standard may be used. After that period and on a date specified in the subsequent final rule, only use of the new version would be considered compliant.

Comment: Several commenters wanted to know details concerning the process by which new versions would be assessed to determine whether rulemaking would be waived. Some of the commenters suggested that HHS should make this determination, while others stated that the relevant SDOs were best equipped to make this assessment. Still others suggested that NCVHS facilitate this discussion.

Response: Under the Administrative Procedure Act, only the Secretary may make the decision to waive notice and comment rulemaking. Additionally, the

Secretary will ensure that any newer version that incorporates significant changes from the prior version undergoes notice and comment rulemaking before industry compliance is required. However, we acknowledge the need to elicit input from interested parties. Therefore, we will ask the NCVHS to assess new versions of standards as they are developed, obtain input from SDOs and other organizations, and provide recommendations to the Secretary regarding whether the new versions should be adopted. We do not anticipate that the Secretary would waive notice and comment rulemaking in any case where a new version is not backward compatible with the most recent prior adopted version. Additionally, the Secretary would ensure that any newer version that incorporates substantive changes from the prior version undergoes notice and comment rulemaking prior to the industry being required to comply with it. We believe that affected organizations will be adequately protected by this process because adoption of the new version would be voluntary in cases where rulemaking is waived.

Comment: Several commenters requested that we explicitly state that entities that voluntarily adopt later versions of standards that are backward compatible must still accommodate the earlier version without modification. For example, a plan that adopts a later version could not require its trading partners to adopt the later version, and could not require its partners to modify their implementations of the earlier version.

Response: We agree. Since in this situation both versions of the standard would be compliant, trading partners that voluntarily adopt the later version must continue to accept the earlier version without alteration until the older version is officially retired.

Comment: Several commenters wanted to know who should participate in the process of assessing new versions of standards. A number of the commenters suggested collaboration between HHS and the SDOs, while others suggested that the NCVHS also be involved. Another commenter recommended that no update process be specified until we have additional experience with the e-prescribing standards.

Response: We agree with the majority of the commenters that a process must be put into place now. We will, therefore, utilize the process described above, with the NCVHS providing recommendations to the Secretary for decision after obtaining industry input.

We acknowledge that there may be a need for future revisions to the process.

Comment: A number of commenters addressed the fact that several of our proposed foundation standards (the X12N 270/271 and the NCPDP Telecommunication Standard) had already been adopted as standards under HIPAA. They noted that the HIPAA modification process does not currently permit even voluntary adoption of newer versions of the standards without rulemaking. Some commenters advocated extending the ability to voluntarily adopt new versions of the final uniform foundation standards that are also HIPAA standards to provide the maximum benefit from this flexibility. Others recommended that the adoption of new versions be limited to final standards, including the foundation standards, to synchronize use around a single version.

Response: We believe the first approach, which would permit voluntary use of newer versions, would be inconsistent with current HIPAA regulations, and, HIPAA covered entities may use only the versions of the 270/271 and NCPDP

Telecommunications standards that are adopted under 45 CFR Part 162. We are assessing a number of proposals for making the HIPAA standards modification process more flexible.

Comment: A number of commenters recommended developing a predictable cycle for the update process, and other commenters specifically recommended an annual cycle.

Response: We agree that a predictable update cycle would facilitate planning and budgeting for plans and providers. To the extent possible, we will work with the SDOs and NCVHS to establish a timetable for such deliberations.

Comment: While we did not propose a process for maintaining vocabulary and code set standards, commenters specifically favored an open updating process for vocabulary and code set standards similar to the process in place today for HIPAA standard code sets. Under this process, vocabulary and code set maintenance could be accomplished by their maintainers without respect to the version updating process. This process permits flexibility to respond quickly to new concepts.

Response: We did not propose vocabulary and code sets in our proposed rule, nor are we adopting any in this final rule. When we do propose vocabulary and code sets, we will propose a process for their updating and maintenance.

11. Interoperability/EHR

We proposed adopting foundation standards that are ANSI accredited and have adequate industry experience as a means of facilitating interoperability for Electronic Health Records (EHRs). We also asked for comment on how e-prescribing functionality and our incremental approach to implementing e-prescribing relates to a comprehensive EHR system and interoperates across software and hardware products.

Comment: The majority of commenters supported our approach toward achieving interoperability by requiring ANSI accreditation and establishing criteria that demonstrate adequate industry experience. Some of the commenters suggested that we broaden our approach to include various settings, such as long-term care. One commenter did not support our approach because the proposed foundation standards allegedly have not been adequately tested together in a wide range of settings. This commenter also suggested that we conduct a pilot project to assess the overall impact of e-prescribing on Medicare and on other payers and patient populations.

Response: We agree that e-prescribing functionality should be an essential component of a comprehensive EHR system and that it must interoperate across various software and hardware products and various care settings to be effective. Our incremental approach toward adoption of e-prescribing standards, along with the 2006 pilot project, will address interoperability across software and hardware products in a variety of care settings.

Comment: We received several comments concerning timing. The commenters recommended that implementation of e-prescribing and EHR standards occur at various, independent stages without halting current e-prescribing development. Some commenters suggested postponing the establishment and adoption of standards for e-prescribing until a time when there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time.

Response: We believe that our incremental approach to adopting e-prescribing standards for use in the Medicare Part D benefit will be viewed as an initial step and facilitate the development of EHR standards, thus, promoting interoperability in the short and long terms.

Comment: One commenter recommended that the Federal government use the Integrating the

Healthcare Enterprise (IHE) process. This promotes the coordinated use of established standards, such as DICOM and HL7, to address specific clinical needs.

Response: IHE is an initiative by healthcare professionals and the industry to improve the way computer systems in healthcare share information. IHE promotes the use of established standards to address specific clinical needs in support of optimal patient care. While we do not specifically participate in the IHE and we believe this comment is beyond the scope of the proposed rule, we nonetheless support and participate in projects that foster the coordination of standards across the health care enterprise such as through the SDO process.

12. Closed Enterprise

In the February 4, 2005 proposed rule, we solicited comment on whether Part D plans should be required to use the standards for e-prescribing transactions taking place within their own enterprises, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards. Under the HIPAA transactions rule, it is immaterial whether the transmissions are within a corporate HIPAA covered entity or between two different entities; compliance with the HIPAA transactions standard is required.

Comment: One commenter recommended that both HL7 and NCPDP SCRIPT be allowed for any prescription transactions, with usage based on trading partner agreements. Several commenters recommended that HHS view the exchange of prescription transactions that occur “within the same enterprise” as being outside the scope of the MMA. Another requested that HHS clarify the definition of a “closed enterprise” for purposes of identifying prescription transactions within an enterprise that fall outside the scope of the MMA. One commenter did not believe that closed enterprises should be exempt from following the standards, noting that HIPAA applies to transactions in open and closed environments.

Response: To clarify our use of the term “closed enterprise” in the February 4, 2005 proposed rule, we intended “closed enterprise” to mean a discrete legal entity that may serve as a closed network, such as a staff model HMO, which seeks to conduct e-prescribing

within the confines of the enterprise. To avoid any confusion, we have steered away from using the term “closed enterprise” in this final rule and have stated explicitly that in line with the NCVHS recommendation and comments received, entities may use either HL7 or NCPDP SCRIPT Standard to conduct internal electronic transmittals for the specified NCPDP SCRIPT transactions. For example, there are many entities, such as staff model HMOs, in which all parties to the transaction, including the prescriber and the pharmacy, are employed by, and part of, the same legal entity. The NCVHS recommended that these organizations not be required to convert to the adopted standard (NCPDP SCRIPT) for prescription communications within their enterprise because these closed systems typically utilize HL7 messaging. However, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy) they would be required to use the adopted standards.

We acknowledge the NCVHS recommendation. Thus, MA-PDs and PDPs continue to use HL7 messages for electronic prescriptions sent and received within the same legal entity. This requirement differs from the HIPAA requirement which sets the same standards for internal and external transactions and which will continue to apply to HIPAA transactions, even if the HIPAA transactions are used in e-prescribing. We will require entities to use NCPDP SCRIPT if they electronically send prescriptions for Medicare beneficiaries outside the organization, such as to a non-network pharmacy. Any pharmacy, even if it is part of a larger legal entity must be able to receive electronic prescription transmittals for Medicare beneficiaries via NCPDP SCRIPT from outside the enterprise.

Comment: Another commenter suggested that the February 4, 2005 proposed rule be modified to either allow for the use of both transactions by large institutions, or to allow for the use of an intermediary to translate the HL7 pharmacy order messages to the required NCPDP format that will reach the sponsor or dispenser.

Response: Entities may use HL7 and NCPDP SCRIPT to conduct internal electronic prescription transmittals. We have, therefore, provided an exemption in this final rule for entities to conduct internal transactions using either the NCPDP SCRIPT or HL7, which would otherwise be required to comply with the NCPDP SCRIPT. However, electronic prescriptions sent to pharmacies for Medicare beneficiaries outside the institution or enterprise

network must be converted to NCPDP SCRIPT; a clearinghouse or other intermediary may be used for translation purposes.

13. NCVHS Process

The Secretary is required to develop, adopt, recognize or modify initial uniform standards relating to the requirements for an electronic prescription drug program taking into consideration recommendations, if any, from the NCVHS.

Comment: Several commenters were in favor of the process used by the NCVHS in recommending e-prescribing standards to the Secretary and supported the criteria developed to determine whether a standard demonstrated adequate industry experience. There was general agreement among the commenters that the NCVHS has helped set the path for the e-prescribing environment. Some of the commenters expressed support for the NCVHS process, and the opportunity to participate with the NCVHS and CMS on developing and adopting the standards required for an electronic prescription drug program. A number of commenters suggested that the NCVHS determine if an approved change to a standard is substantive and requires rulemaking. There also were some commenters that recommended that the NCVHS consult with CMS on when rulemaking can be waived for standard updates.

Response: We agree with the commenters on the usefulness of the NCVHS process in recommending e-prescribing standards to the Secretary. The NCVHS will continue to conduct hearings on e-prescribing standards to ensure input and participation with industry stakeholders, and will continue to consult with CMS on the development and updates for e-prescribing standards. We note, however, that the Secretary will determine what is required to comply with the law.

14. Privacy/Security

In the February 4, 2005 proposed rule, we stated that it should be noted that disclosures of protected health information (PHI) in connection with an e-prescribing transaction would have to meet the minimum necessary requirements of the Privacy Rule if the entity is a covered entity (70 FR 6261). We also noted that entities that are covered entities under HIPAA must continue to abide by the applicable HIPAA standards, including those for privacy and security. Although we did not request comments on e-prescribing

privacy and security, we received several comments on the topics.

Comment: Several commenters were concerned about the protection of patient privacy and the confidentiality of patient data, in both the patient care and research settings. The commenters also were concerned about assuring the security of, and authorized access to, transactions among prescribers, pharmacies and health plans. For example, some of the commenters suggested higher levels of security, such as digital and electronic signatures (including public key infrastructure, or PKI).

Response: We agree that privacy and security are important issues related to e-prescribing. Achieving the benefits of e-prescribing requires the prescriber and dispenser to have access to medical history and other patient medical information that may not have been previously available to them. Section 1860D-4(e)(2)(C) of the Act requires that disclosure of patient data in e-prescribing must, at a minimum, comply with HIPAA's privacy and security requirements. Pharmacists generally are responsible under State laws for ensuring the authenticity and validity of prescriptions. Based upon extensive testimony and consultation with industry experts such as the National Institute of Standards and Technology (NIST), the American Society for Testing and Materials (ASTM), and leaders in the financial services industry, the NCVHS did not recommend any standards relating to e-prescribing security at this time. We agree that a standard for the security of prescriptions and related information is essential, but we are not adopting specific standards for security technology at this time because we are not aware of any such standards with adequate industry experience. It is important to note that health plans, prescribers, and dispensers are HIPAA covered entities, that must comply with the HIPAA security standards. Although those standards are flexible and scalable to each entity's situation, they provide comprehensive protections. We will continue to evaluate additional standards, including encryption standards, for consideration as adopted e-prescribing standards.

Comment: One commenter recommended more aggressive educational programs for the public concerning privacy and security.

Response: We agree that public education is important. The HHS Office for Civil Rights (OCR) and CMS will continue their ongoing national educational efforts related to HIPAA's privacy and security requirements,

respectively. (OCR's Web site is <http://www.hhs.gov/ocr/hipaa>. CMS' Web site is <http://www.cms.hhs.gov/hipaa/hipaa2>.)

Comment: One commenter suggested that because of the need to ensure data security and privacy, health plans should be allowed to select their own POC vendors for e-prescribing.

Response: All entities involved in e-prescribing are free to select any technology vendor. However, they should make this decision with consideration of their needs and compliance with internal policies and laws, including those for security and privacy.

15. Compliance Date

In the February 4, 2005 proposed rule, we discussed the Secretary proposing January 1, 2006 as the compliance date for the foundation standards (70 FR 6267). We proposed that, beginning January 1, 2006, Part D sponsors, and prescribers and dispensers that conduct e-prescribing transactions for which standards are adopted, would be required to use the standards adopted in this final rule for transactions involving prescriptions or prescription-related information regarding Part D enrolled individuals. Compliance is required whether the entity conducts e-prescribing transactions directly or through an intermediary.

Comment: Many of the commenters were in support of the January 1, 2006 compliance date. Some commenters suggested that the date be moved. Reasons to delay compliance included concerns that some pharmacies, such as those in rural areas, will be unable to comply by this deadline; doing so may create a competitive advantage for those pharmacies (primarily large chains) that could comply; and the deadline will provide insufficient time for PDPs and MA-PDs to communicate the required contractual requirements to downstream providers as well as complete the necessary contracting activities. A few commenters suggested that delaying the compliance date will increase the use of e-prescribing as the extra time will allow physicians time to acquire the necessary technology as well as obtain financial assistance for doing so.

Response: We will require the January 1, 2006, compliance date for all e-prescribing standards adopted in this final rule. We recognize that because e-prescribing is voluntary for pharmacies, not all will be ready to comply with NCPDP SCRIPT by January 1, 2006. As a result, plans may take more time to work with the pharmacies in their network. While e-prescribing will be a requirement for Part D plans, our goal is

to work with plans to facilitate widespread compliance and avoid the need to impose program sanctions wherever possible.

Comment: Some commenters supported delaying the compliance date because they believe that the NPI will not be ready in time, or on a sufficient scale to achieve wide-spread use by January 1, 2006. The commenters stated that many entities would not be ready for such accelerated implementation because they were working to meet the HIPAA implementation deadline for the NPI of May 2007 (May 2008 for small health plans).

Response: We recognize that the NPI may not be ready for wide-spread industry use by January 1, 2006. The use of the NPI in the e-prescribing context will be pilot tested. However, entities participating in Part D that want to e-prescribe may use the NPI or other identifiers as specified by CMS, such as the NCPDP pharmacy identifier and the State license number for prescribers. Consequently, the availability of the NPI for use by January 1, 2006 will not affect the compliance date for the foundation standards. However, the NPI will be required for use in e-prescribing standards that are also HIPAA transactions as of the May 2007 HIPAA regulatory compliance date (except for small health plans for which the compliance date is May 2008).

F. Additional E-Prescribing Related Topics

We did not solicit comments on the following issues, however, we did receive several comments regarding long-term care pharmacy, and commercial messaging. We respond to those comments in this section.

1. Long Term Care (LTC) Pharmacy

In the February 4, 2005 proposed rule we did not distinguish the flow of information for LTC pharmacies, home infusion pharmacies, or renal dialysis pharmacies from the pharmacies described in the section E of (Current E-Prescribing Environment) of the proposed rule (70 FR 6260).

Comment: Several commenters noted that e-prescribing is rarely conducted in LTC facilities today. They pointed out that while the foundation standards may be said to have adequate industry experience in the ambulatory setting, this is not the case in the LTC setting. They also indicated that the proposed foundation standards do not support the complexities of the prescribing process for patients in LTC facilities. They explained that, while the standard outpatient prescribing process involves a prescriber and a pharmacy,

prescribing in the LTC setting also involves the facility itself and its nursing staff. The patient's chart may be at the LTC facility, but the prescribing physician may not be, and frequently the facility nursing staff transmits the prescription to the pharmacy, annotates the medical record, and dispenses the drug to the patient.

Some of the commenters requested that the foundation standards not be applied to the LTC setting, unless they are first pilot tested in that environment. They specifically suggested that the 2006 pilot project include LTC facilities and that they test the three-way communication between facility, physician and pharmacy.

Response: We agree that the nursing home industry standard practice is not conducive to early application of e-prescribing standards. The foundation standards that have been adequately tested in the ambulatory setting may not be directly transferable to the LTC setting for several reasons. First, there are generally three parties in LTC prescribing: The provider, the nursing facility, and the LTC Pharmacy. The provider generally writes prescriptions on a 1 to 3 month cycle at the facility, or by phone contact with the nursing station on an as needed basis. There is generally no provision in standard practice for direct provider to pharmacy transmission; in fact, such transmission is considered a potential risk if the administering facility staff is out of the communication loop. Second, the facility has the legal responsibility for processing medication orders as written, before pharmacy transmission. There is also a Federal requirement for concurrent and retroactive Drug Regimen Review (DRR) on all residents, which is the responsibility of the nursing home rather than the provider or pharmacist. Finally, less than 30 percent of nursing homes have computer access at the nursing station. The current practice is for written orders to be faxed to the pharmacist as well as transcribed onto the Plan of Care at the nursing station. These intermediate steps would need to be developed separately in an e-prescribing system.

The systems should be made compatible with a three party approach able to accommodate the LTC recording and DRR requirements, as well as changes due to the Part D benefit. Therefore, we do not require Part D plans to support e-prescribing when a facility, such as a LTC facility, is involved in the prescribing process in addition to the prescriber and the dispenser. Moreover, we exempt from the requirement to use the NCPDP

SCRIPT Standard prescription transactions between prescribers and dispensers where a non-prescribing provider is required by law to be a part of the overall transaction process.

We also agree with the commenters who requested that the 2006 pilot project include LTC facilities, and that the three-way prescribing communication between facility, physician, and pharmacy be tested using the standards. We expect to pilot test e-prescribing standards specifically in the LTC environment and welcome participation of LTC facilities.

2. Commercial Messaging

The proposed rule did not address electronic prescribing messaging, which, under the MMA, is aimed at giving providers the appropriate information they need at the POC to make informed decisions for treating Medicare beneficiaries. Section 1860D-4(e)(3)(D) of the Act states that "e-prescribing standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B)."

Comment: Some of the commenters were concerned that standards for appropriate messaging were not included in the proposed rule.

Response: We agree that there needs to be an appropriate balance between providing appropriate information at the POC with messaging that might steer the prescriber to use specific drugs and therapeutics as specified at section 1860D-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, and electronic "detailing" messages from a manufacturer promoting a particular brand or brand-name drug. 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 plans at a future date and, if necessary, propose more specific standards for messaging. We intend to pilot test messaging standards when they are available for testing.

3. Diagnosis Codes

Although we did not propose the use of diagnosis codes in electronic

prescriptions or solicit comments on this subject, we received a number of comments requesting a requirement to report diagnosis codes on standard electronic prescription transactions.

Comment: Some commenters requested the addition of diagnosis codes to the standards required for electronic prescriptions under the electronic prescription drug program. The commenters indicated that this information is helpful for drug utilization review, decision support, formulary compliance, and therapy choices. One commenter believed that requiring a diagnosis on the prescription supports the MMA requirements and objectives and complies with HIPAA.

Response: We agree that diagnosis codes may provide useful information that could assist in improving patient safety and quality of care, and may be helpful in data collection. The diagnosis data field is an optional field in the NCPDP SCRIPT standard and is not in widespread use. Therefore, we are not requiring it for e-prescribing under Part D at this time and it is not part of this final rule.

G. Other Issues

We received a number of unsolicited comments that included recommendations for CMS, and requests for additional functionality.

Comment: Several commenters suggested that we conduct an analysis of formulary compliance, generic utilization, and their impact on patient care, health outcomes, and overall quality of care, and that health plans not be allowed to use financial incentives to influence physician's prescribing habits.

Comment: Several commenters stated that there was no transaction for the alteration of the status of a requested refill.

Comment: Some commenters suggested that CMS provide guidance to pharmacists on how drug product selection instructions may be separately transmitted in electronic prescriptions, an authentication process for end-to-end prescribing, information on whether a prescription was filled, allergy/tolerance checking and validation of patient and prescription, information for the physician to discuss drug therapy with the patient at POC, diagnosis on the prescription, security measures for internet flow of information, testing statistical interoperability, and drug dosage forms, units of measure, modifiers, and SIG with drug names in standards. One commenter also referenced the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirement that

pharmacists review medication orders prior to the medication being dispensed.

Comment: Several commenters offered suggestions for an e-prescribing model such as one built with the patient and prescriber at the center; and a model designed to improve patient care and strengthen the physician-patient relationship, reduce costs, and provide information when it is needed. Also, it was suggested that an e-prescribing model reflect that community pharmacies have significant patient clinical medication information. One commenter suggested that CMS, the NCVHS, the SDOs, and technology vendors collaborate to build an e-prescribing system to support the physician order set for home infusion therapy and be compatible with the X12 837P claim standard.

Comment: Several commenters addressed specific codes for spinal surgery in an ASC setting, reimbursement for specific drugs, and limitations for manipulating a computer keyboard that were out of the scope for the February 4, 2005 proposed rule.

Response: We acknowledge these comments and will take them into consideration in the future as we further develop the electronic prescription drug program. We view e-prescribing as an evolving process and will collaborate with the industry and key stakeholders to enhance and improve the standards for e-prescribing that meet the requirements outlined in the MMA for an electronic prescription drug program.

IV. Provisions of the Final Regulation

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

- In § 423.150(c), we are revising the description of the scope to state expressly that this subpart sets forth requirements relating to electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

- In § 423.159, we are revising the proposed definition for e-prescribing to further define e-prescribing to state that it includes, but is not limited to, two-way transmissions between the point-of-care (POC) and the dispenser. In § 423.159, we are revising our definition of prescription-related information to mean information regarding eligibility for drug benefits, medication history or related health or drug information for Part D eligible individuals.

- In § 423.160(a)(1), we are revising our general rule for Part D sponsors to state that Part D sponsors must establish and maintain an electronic prescription

drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for Part D eligible individuals.

- In § 423.160(a)(2), we are revising our general rule for prescribers and dispensers to state that prescribers and dispensers that transmit directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

- In response to comments received, we decided that an exemption would be appropriate for computer-generated faxes to comply with the adopted NCPDP SCRIPT Standard.

Therefore, in § 423.160(a), we are adding a new paragraph (3)(i) that will permit an exemption for complying with the adopted NCPDP SCRIPT standard for transmitting prescription information between the prescriber's computer and the pharmacy's computers. In paragraph (3)(ii) of this section, we are providing entities with the option of using either HL7 or NCPDP SCRIPT Standard to conduct internal electronic prescription transmittals. In paragraph (3)(iii) of this section, we are including an exemption for complying with the adopted NCPDP SCRIPT Standard when a non-prescribing provider is required by law to be involved in the prescribing process in addition to the prescriber and the dispenser.

- In § 423.160(a), we will add a new paragraph (4) to state that, in accordance with section 1860D-4(e)(5) of the Act, the standards under this section supersede any State law or regulation that is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act and pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

V. Collection of Information Requirements

Section 423.160 of this rule does contain information collection requirements as discussed below:

Section 423.160 Standards for an Electronic Prescribing Program

As the government participates in the development of EDI standards, the question of whether the PRA is implicated has emerged. Part D sponsors

offering qualified prescription drug coverage must support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D eligible individuals as would be required under § 423.160. 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.

However, the requirement that Part D sponsors support electronic prescription drug programs in accordance with standards set forth in this section, as established by the Secretary, does not require that prescriptions be written or transmitted electronically by prescribers or dispensers. After the promulgation of this first set of final standards, PDPs and MA-PDs will be required to comply with these adopted standards as discussed in section 1860D-4(e)(1) and (2) of the Act. E-prescribing is voluntary for prescribers and dispensers; but, if they electronically transmit prescriptions and other prescription-related information, they are required to comply with the standards.

Testimony presented to the NCVHS indicated that many health plans/PBMs currently have e-prescribing capability either directly or by contracting with another entity. While we agree, we note that such capabilities (such as computer-generated faxes) may not be comparable to the functionality that will be required for electronic prescription drug programs under these regulations. Therefore, we do not believe that conducting an electronic prescription drug program would be an additional burden for those plans.

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

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, 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 (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) 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in costs and benefits in any 1 year). Our estimate is that this rulemaking has "economically significant" benefits as measured by the \$100 million standard, and is, therefore, a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

Statistics from the Henry J. Kaiser Family Foundation indicate that more than 3.1 billion retail prescriptions totaling \$154 billion were written in the United States in 2003, with the average cost for a prescription ranging from \$45 to \$67. Individuals who are age 65 years and older average 26 prescriptions per year. The Medicare Prescription Drug Benefit final rule (published in the **Federal Register** on January 28, 2005 (70 FR 4193–4585), available online at <http://www.gpoaccess.gov>) estimates that in CY 2006 about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan. By CY 2010, estimates indicate that about 35 million Medicare beneficiaries will be receiving this drug coverage. (In addition, in CY 2006 approximately 13 million others are Part D eligible, in most cases enrolled in the plans of former employers, and, therefore, will be covered by these rules.) While the Medicare drug benefit participation estimates are subject to uncertainty, changes in the rate or extent of adoption of Part D coverage would not affect the rate of adoption of e-prescribing or the impact of these e-prescribing standards significantly. Virtually all prescribers and pharmacies who serve these beneficiaries now will find that the great majority of their elderly or severely disabled patients are eligible for and enrolled in Part D. To continue to serve any of these patients through Part D plans, and to use e-prescribing, these providers will be subject to these standards.

This impact analysis discusses the overall impact of instituting e-prescribing standards under the Medicare Prescription Drug Program. However, as indicated in the analysis, there are several major factors influencing the adoption of e-prescribing (including existing and future HIPAA rules, these final rules, and forthcoming Stark and anti-

kickback rules) and the attribution of effects among them cannot be accomplished with precision.

The overall requirements for supporting e-prescribing and providing incentives were discussed in the Medicare Prescription Drug Benefit proposed and final rules. However, specific standards were not contained in the Medicare Prescription Drug Benefit proposed rule and the impact analysis in that proposed rule did not analyze those requirements. The adoption of standards for the program will enhance the implementation and provide specific direction for providers, dispensers, plans, and vendors.

According to testimony before the NCVHS and in the written comments in response to the Medicare Prescription Drug Benefit proposed rule (69 FR 46632–46863), between 5 and 18 percent of prescribers are conducting e-prescribing. However, some studies have indicated increased prescriber interest and the likelihood of greater adoption of e-prescribing. We anticipate that the use of the standards in this final rule and the fact that these standards will be available at the time of the January 2006 implementation of the Medicare Prescription Drug Program, will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used. While there are no detailed models predicting specific rates of adoption for this technology, based on prevailing expert opinion, we think it likely that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next 5 years. The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of—

- Publicity surrounding the Medicare Prescription Drug Program;
- More publicity about the benefits of e-prescribing and the experience of prescribers who are participating;
- Increased emphasis on health information technology in general;
- Potential cost savings to providers using e-prescribing; and
- The availability of incentives for participation.

We believe that, as prescribers gain experience with e-prescribing, they will recognize the benefits and share those experiences with colleagues. In the February 4, 2005 proposed rule, we invited public comment on our expectations for prescriber participation. We received the following comments in response to our request:

Comment: Most of the commenters believe that CMS has appropriately estimated or even underestimated the annual rate of participation in electronic prescribing. An e-health management firm stated that "the CMS estimate of 10 percent growth in electronic prescribing per year is reasonable, but only with proper incentives or sponsorships." One of the commenters that is a leading seller of e-prescribing systems stated that "in order to achieve greater than 10 percent annual growth, cost savings from other stakeholders, particularly payers, must be shared with physicians."

A PBM commented that the CMS estimate of prescriber participation is too conservative based on two studies' results. A Pri-Med Research Group study showed 1 in 5 physicians report using electronic prescribing technology now and another 42 percent are planning to adopt it in 2005. A recent Medical Economics survey indicated 1 in 4 physicians plan to purchase an EHR system soon, at least 70 percent of which already include e-prescribing capability.

However, some commenters stated that expectations for provider participation must be seen in the context of increasing practice expenses. These commenters pointed out that CMS actuaries predict five percent reductions in Medicare physician reimbursement each year between 2006–2011. Also, physicians are under pressure to purchase EHR technology rather than e-prescribing stand-alone technology. In many cases EHR software does not yet contain e-prescribing modules, and physicians may be reluctant to invest in incompatible software. Many of the commenters stated that financial incentives and support for physicians and other prescribers who utilize e-prescribing technology should be readily available.

Response: Based on these comments, we see no need to change our estimate of 10 percent annual growth in prescriber participation over the next 5 years. The interoperability between EHR and e-prescribing is particularly important, as mentioned above. We intend to monitor the progress of any future certification process of EHRs and recognize the enhanced value of e-prescribing with the availability of advanced decision support through an EHR. We plan to create incentives for adoption of full EHR through our forthcoming rules on exceptions to the Stark law and safe harbors to the anti-kickback statute.

B. Discussion of E-Prescribing Benefits

According to the Center for Information Technology Leadership (CITL), more than 8.8 million adverse drug events (ADEs) occur each year in ambulatory care. (CITL, *The Value of Computerized Order Entry in Ambulatory Settings*, 2003. A summary is available at http://www.citl.org/research/CITL_ACPOE_Summary.pdf.) E-prescribing helps to deliver relevant patient information at the time of prescribing. The CITL estimates that nationwide adoption of e-prescribing will eliminate nearly 2.1 million ADEs per year in the U.S. This will prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs. These improvements will result in improved care and safety for health plans' members.

There is also evidence suggesting that the use of specific drugs may reduce adverse health events and utilization of other health care services for certain groups of patients. E-prescribing will promote efficient and effective use of drugs by ensuring that prescribers have up-to-date information regarding advances in drug therapies. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients ("Pravastatin in Elderly Individuals at Risk of Vascular Disease (PROSPER): A Randomized Controlled Trial," *Lancet* 2002, 360:9346, 1623–1630).

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management will be enhanced by e-prescribing. All of these are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions. We believe that these improvements, enabled by e-prescribing programs, will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to

detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented. (To Err is Human: Building a Safer Health System, Institute of Medicine of the National Academies, 1999, pp. 191–193, <http://www.iom.edu> or <http://www.nap.edu>).

At this time, we cannot predict how fast (or even if) all of these savings will occur, nor their precise magnitude, as they are dependent on the rate at which we are able to adopt final standards for various aspects/functions of e-prescribing and EHRs, the adoption rate of e-prescribing by prescribers and pharmacies (depending in turn on if savings are realized), the effectiveness and existence of various incentives provided by private vendors/health plans, the quality of the systems implemented for e-prescribing, and the behavioral responses of prescribers, health care practitioners, dispensers, insurers (who help manage treatments), and patients. However, as indicated by the CITL report estimate, the potential is clearly substantial. We received a few comments on our analysis of benefits for e-prescribing which is largely unchanged from the proposed rule.

Comment: One commenter expressed skepticism regarding CITL's and IOM's findings that electronic prescribing can reduce morbidity and mortality rates through reductions in common errors as described.

Response: We appreciate that the predictions as to what can be achieved are necessarily speculative to some degree, and that similar kinds of predictions sometimes are unduly optimistic. However, these data are derived from reputable sources and there is general agreement in the industry about the direction and potential magnitude of these benefits.

C. HIPAA Standards Impact

The ASC X12N 270/271 Transaction and the NCPDP Telecommunication Standard adopted in this final rule, for e-prescribing transactions, are already adopted standards for HIPAA. Thus, any costs associated with the adoption of these transaction standards are already encompassed in the baseline. (The impact of implementing these standards was analyzed and adopted in the HIPAA

final rule and available on the web through <http://www.gpoaccess.gov>).

We note, however, that there is one very important difference between those HIPAA regulations and this final rule. In the HIPAA regulations, we knew that some of the electronic claims standards we were requiring were incompatible with many of those already in use for electronic billing of Medicare claims. We know that some prescribers and other entities are already using the standards we are adopting in this final rule. Thus, while the HIPAA Final Rule and this final rule share common goals and methods, they have different implementation consequences.

This final rule involves both mandatory and voluntary elements, but even the mandatory elements are enabling. For example, the statute might have encouraged e-prescribing by making it a required condition of participation in Medicare, through positive financial incentives, by reducing barriers to adoption, by increasing the value of e-prescribing systems, or through other means. The primary method chosen by the Congress was to increase the value of e-prescribing systems by mandating uniform standards for e-prescribing. Uniform standards reduce barriers to adoption by reducing uncertainty in the marketplace regarding which standards will be the industry standards of the future. These incentives are created without imposing substantial costs. For potential new e-prescribers, whose choice to adopt e-prescribing is voluntary, these standards provide the advantages of uniformity and reduced uncertainty, and, hence, reduce costs or increase benefits of adoption. For those existing entities that currently engage in e-prescribing transactions whose systems are currently incompatible with these standards, transitioning to the foundation standards will be mandatory to continue e-prescribing (with the option of returning to paper or, for internal use, the option of continuing to use HL7 provided that communication with external parties meets the adopted standards and that there is compliance with the HIPAA standards) and will come at some cost, but will also increase value of these systems in the long run as it will enable these entities to communicate with all other e-prescribers. Only for Part D sponsors is use of these standards mandatory, and even then, only to receive or reply to e-prescribing transactions initiated by other entities. In the proposed rule, we requested comments and data on the impact of the proposed standards on prescribers, health plans, and pharmacies based upon our estimates.

We received the following comments on the estimates used to determine the regulatory impact of the proposed rule and input on the data and issues presented in this impact analysis.

Comment: One commenter urged us to clarify the policy for those PDPs that have pharmacies which are not in compliance with e-prescribing standards by the deadline. The suggestion was made to allow a grace period and explain any repercussions.

Response: Our regulations do not require pharmacies to implement e-prescribing. Health plans must have that capability, but use of e-prescribing by both pharmacies and physicians is elective. Accordingly, a grace period is unnecessary.

Comment: One commenter suggested that CMS deal with policy considerations around how e-prescribing technology and standards will relate to Medicare Part B drugs, as well as the Competitive Acquisition Program (CAP).

Response: The MMA only authorized us to impose an e-prescribing requirement on MA plans and free-standing prescription drug plans that pay for Part D drugs. This in no way precludes use of e-prescribing in other Medicare contexts, and likely encourages it, but does not force it. Since there are no separate e-prescribing requirements under Part B or the CAP program, there is no potential inconsistency problem.

D. Impact on Health Plans/PBMs

The Medicare Prescription Drug Benefit final rule (70 FR 4194) estimated that 100 PDP sponsors and 350 MA organizations would submit applications on an annual basis for participation in the Medicare Prescription Drug Program. In fact, a substantially larger number of organizations applied and we approved contracts with 73 PDP sponsors and 416 MA-PD organizations on September 29, 2005.

Testimony presented to the NCVHS (available on the Web at <http://www.ncvhs.hhs.gov>) indicated that, because most health plans/PBMs currently have e-prescribing capability, any additional costs associated with hardware/software connectivity will be minimal. Since the great majority of health plans contract with PBMs for pharmacy benefit administration, we do not consider the fees associated with these contracts to be an additional cost for plans conducting electronic prescription drug programs, although connectivity costs could increase based on volume.

Although we believe that costs incurred by health plans will be minimal, even in those few cases where plans do not currently support e-prescribing directly or through PBM contracts, it is possible that some plans will experience consequential costs that we have not foreseen. In the February 4, 2005 proposed rule, we requested comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also requested comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. We received the following comments in response to our request:

Comment: Most of the commenters on the subject of financial impact agreed that health plans/PBMs stand to gain the most from savings generated by e-prescribing, but most of these commenters believe HHS has underestimated the cost of implementation and management, including the cost to health plans/PBMs. While most health plans/PBMs have e-prescribing capability, start-up costs such as downloading formularies and medication histories, developing and standardizing acceptable medical terminology, as well as ongoing transaction costs, must not be overlooked.

The commenters noted that PBMs may not have the incentive to continue paying for implementation and transaction fees and that other parties in the e-prescribing chain, in the past, have not been paying these fees. The commenters stated that HHS must recognize that costs, or the lack of knowledge of true costs, has been the primary barrier to implementation up to this point. Vendors' costs regarding the HIPAA standards upgrade process were not minimal and many of the commenters do not anticipate e-prescribing updating/systems creation to be negligible.

The commenters stated that the cost for a health plan to have e-prescribing capability, that is, the start-up operating cost, was estimated to be \$250,000 by one e-health management firm. This is the cost of connecting to RxHub, the "only viable option for broad-scale connectivity that enables eligibility-based formulary services and Rx claims history at POC."

One commenter concurred with HHS that the impact on health plans/PBMs would be a minimal financial burden, but noted that health plans/PBMs would have to pay for new transaction costs (for example, transactions between prescriber and PBM). The same

commenter expressed skepticism that plans would incur a "substantial financial benefit from just e-prescribing alone." The commenters mentioned savings from formulary and benefits compliance, improved patient outcomes and fewer adverse drug events/hospitalizations, better utilization management and increased use of generics. Additional benefits may include tax incentives to engage in e-prescribing, and/or improvements from implementation of more universal electronic health records systems (EHRs systems).

Full sponsorship of a prescriber by a health plan was estimated to cost at least \$1,500 per physician by several commenters. The cost would vary based on benefit design, market share, covered lives and local market competition. Health plans should see a complete return on investment within 12–18 months after full implementation, according to one commenter. A few commenters did not agree that costs to health plans would be minimal, and stated that systems upgrade requirements may be significant. One commenter stated that the costs associated with adoption are not merely the cost of provider incentives, but also operating costs. There are human, technical and project management resource costs as well. The same commenter recommended implementing a sliding scale for PDP compliance with foundation standards.

An e-health management firm estimated health plan savings from e-prescribing to be 1 to 4 percent over traditional prescribing through formulary and generic drug use improvements and 1 to 3 percent or more through improvements in mail order use.

A commenter discussed the Council for Affordable Quality Healthcare (CAQH) e-prescribing pilot program that began in 2003 and in which 120 area physicians participated. One participating health plan experienced a 35 percent net savings (average savings of \$29.91 per prescription) in drug costs when a formulary warning was given. Savings for other health plans with fewer non-formulary warnings were lower.

Response: We did not intend to suggest that there were no costs to health plans associated with the implementation of e-prescribing. We agree with commenters that there will be a variety of start-up and implementation costs to plans. Some types of costs will be one time (for example, downloading formulary and tiering categories for each drug) subject only to updates, and others will be

recurring and grow with use. Our belief, and one that most of these commenters implicitly or explicitly accept, is that over time plans may save substantially more than the costs they incur.

Moreover, e-prescribing is just one small element in the entire panoply of investments plans are making to participate in the new prescription drug benefit. For example, formulary development and the downloading of formulary and tiering information into several computer systems is necessary for purposes of payment, regardless of whether the prescriptions are made electronically.

We did not accept the comment requesting a sliding scale of adoption for health plans. We are not persuaded that plans face substantial technical or financial barriers to establishing and maintaining the ability to support e-prescribing as would warrant such a delay. Moreover, the larger than expected number of organizations seeking and obtaining MA and PDP contracts indicates that health plans themselves do not see this as a significant impediment.

We agree with commenters that it is likely to cost at least as much as, and perhaps much more than, we originally estimated for prescribers to adopt the new technology. Nonetheless, we continue to expect many plans to provide incentives to prescribers to offset at least some of the prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing.

We expect that incentives to prescribers from Part D sponsors and other health care entities will represent a transfer of costs from prescribers to those entities that offer incentives. These transfers of electronic prescribing items and services should neither increase nor decrease the overall impact of implementing an electronic prescription drug program.

We note that these incentives must not violate either anti-kickback prohibitions or the physician self-referral prohibitions. Section 1860D-4(e)(6) of the Act requires the Secretary to publish regulations that provide for an exception to the Federal self-referral prohibition in section 1877 of the Act and a safe harbor under the Federal anti-kickback statute (section 1128B(b) of the Act) for certain arrangements in which a physician receives necessary non-monetary remuneration that is used solely to receive and transmit electronic prescription drug information.

Both the physician self-referral exception and the anti-kickback safe harbor would protect certain non-monetary remuneration in the form of

hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription drug information. As discussed earlier in this preamble, we published two proposed rules that would implement these provisions and intend to publish final rules as soon as possible. They will both apply to hospitals, group practices, and PDP sponsors and MA organizations.

Health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share potential savings in health care spending through reductions in adverse events and improved compliance. Thus, it is likely that the net effect on plans would be positive rather than negative. Moreover, there is no reason to expect health plans to incur costs without the expectation of a positive return. However, we have no basis at this time for estimating the precise timing or magnitude of either gross or net savings.

E. E-Prescribing Incentives

In the proposed rule, we stated that health plans that have offered incentives to prescribers have estimated the hardware and software costs for implementing an e-prescribing system for a provider to be approximately \$1,500 per prescriber. At this time, a number of health plans are developing incentive packages for prescribers to initiate e-prescribing. We received the following comments on the impact that this regulation will have on both prescribers and the likely costs of those incentives.

Comments: In addition to the commenters previously mentioned, one health plan stated that it had spent \$3 million to equip 700 physicians with hardware and installation, software, and training in their e-prescribing initiative (an average of almost \$4,300 per physician). To boost participation, the health plan is now piloting a program to grant honoraria (between \$600 and \$2,000) to physicians who write electronic prescriptions. The commenter believes that without the financial, hardware/software, and support incentives, the average physicians' practice would incur costs up to \$2,500 per physician to adopt e-prescribing.

Another commenter cited a Massachusetts collaborative project that is partially funding physician adoption of e-prescribing and has reported only about 13 percent of targeted physicians (2,700 of 21,000) have adopted the technology. Wellpoint also offered e-prescribing and physician incentives. Among physicians participating in this initiative, only 12 percent adopted an e-

prescribing system over an offer for a desktop-based practice management system.

Response: These commenters illustrate both the difficulty of changing prescriber behavior and the potentially positive effects of relatively inexpensive incentives. It is clear that training and support, not just equipment and software, are necessary to foster e-prescribing.

F. Impact on Prescribers

Current surveys estimate that between 5 and 18 percent of physicians and other clinicians are using e-prescribing. According to the Agency for Healthcare Research and Quality, MEPS Highlights #11, more than 3 billion prescriptions are written annually. The "2003 CMS Statistics" publication reports the number of physicians in active practice at 888,061. We assume that all of these physicians are considered prescribers. However, the number of practicing physicians is not a direct measure of the volume or scope of potential e-prescribing adoption. According to the 2002 Economic Census, Health Care and Social Assistance industry publication (<http://www.census.gov>), there are about 203,000 physician office establishments. This smaller number reflects the common use of group practices and other arrangements that allow physicians to share caseload, facilities, and costs. For these and other prescribers, the likely focus of a decision to adopt e-prescribing is the office, rather than the individual physician.

Although physicians are encouraged to adopt e-prescribing technology, whether physicians prescribe electronically under the MMA is, nevertheless, voluntary. As previously discussed in this analysis, we expect e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, but the magnitude and timing of savings first will have to be demonstrated to many prescribers to induce them to make the "up front" investment in new systems. Finally, an additional incentive for prescribers to e-prescribe is the improved patient care that e-prescribing brings. Because we cannot determine the effect of these factors on prescribers at this time, we do not know how many prescribers will move to e-prescribing or when they will do so.

As discussed earlier in the preamble of this final rule, once a prescriber decides to conduct e-prescribing for Part D drugs, for Part D eligible beneficiaries, the prescriber will be required to comply with the standards being adopted in this regulation. However, we

have no reason to believe that the use of these particular standards will increase costs for new adopters, compared to what costs otherwise would have been, even for those (and we think they are few) who are currently using systems that may be in some respects incompatible with these standards. The February 4, 2005 proposed rule stated that we expected vendors to upgrade those systems at no or nominal cost as part of their normal version updating process.

Comment: One commenter disputed this claim because, according to the commenter, this was not the case with HIPAA upgrades.

Response: We are not sure what specific experience the commenter is referencing in relation to HIPAA upgrades. More importantly, if existing systems are not upgraded to meet adopted standards at low or nominal expense to current users, then those users will switch to newer systems that do not require costly investments to meet those standards. For example, as we stated in the February 4, 2005 proposed rule, a system that uses uniform standards will enable a prescriber to do business with multiple entities, and reduce costs compared to the alternative of having to deal with multiple incompatible systems.

Comment: Several commenters stated that administrative professionals in medical settings, rather than prescribers themselves, may more readily adopt e-prescribing, particularly as a “stand-alone” tool.

Response: We agree that support staff will often facilitate the adoption of e-prescribing, ease the transition, and manage the system.

Comment: 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 benefit design, market share, covered lives and local market competition.

Response: As previously discussed, the magnitude and timing of potential savings will first have to be demonstrated to many prescribers to induce them to make the “up front investment” in e-prescribing technology. The purpose of this final rule is to adopt standards for electronic drug prescription programs for covered Part D drugs for Part D eligible individuals so that physicians, health plans/PBMs, pharmacies and other stakeholders can plan for widespread adoption of this useful technology in a coordinated and uniform way. As to the cost of system implementation, the comments and information we received varied widely, though generally the

estimated costs cited in these comments were not far above our initial estimates.

For average e-prescribing software implementation, according to a 2003 CITL report, “The Value of Computerized Provider Order Entry”, a basic e-prescribing system costs \$1248 plus \$1690 for annual support, maintenance, infrastructure and licensing costs. The total first year cost averaged approximately \$3000.

The Journal of Healthcare Information Management has published that even though vendors nearly always provide free e-prescribing devices to physicians, physicians reported paying user-based licensing fees ranging from \$80 to \$400 per month. Physicians also reported that they had to invest in new or updated hardware, such as computer servers and networking infrastructure, to operate the e-prescribing system (the amount varied significantly by product).

G. Discussion of E-Prescribing Barriers

One of the barriers to early adoption of e-prescribing by prescribers is the cost of buying and installing a system. Included in the overall costs of buying and installing systems are several factors including—

- Changing the business practices of providers' offices;
- Changing record systems from paper to electronic; and
- Training staff.

Since these costs may be defrayed by the incentives that are being offered, or that may be offered, to prescribers, we expect a steady increase in the number of electronic prescribers. We do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, those arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals). We invited public comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing. We also anticipate that increased communication regarding the safety improvements and potential cost savings experienced with e-prescribing will encourage prescriber acceptance.

As we indicated in the proposed rule, there is anecdotal evidence of direct economic benefits that accrue to prescribers that implement e-prescribing, in addition to the previously discussed health benefits to

patients. The following examples of these benefits have been reported:

- A 53 percent reduction in calls from, and a 62 percent reduction in calls to, the pharmacy.

- Time savings of 1 hour per nurse and 30 minutes per file clerk per day by streamlining medication management processes.

- A large practice in Lexington, Kentucky estimates that e-prescribing saves the group \$48,000 a year in decreased time spent handling prescription renewal requests.

- Before implementation of e-prescribing, a large practice in Kokomo, Indiana with 20 providers and 134,000 annual patient office visits was receiving 370 daily phone calls, 206 of which were related to prescriptions. Of the 206 prescription-related calls, 97 were prescription renewal requests. The remainder consisted of clarification calls from pharmacists or requests for new prescriptions. Staff time to process these calls included 28 hours per day of nurse time and 4 hours per day of physician time. Chart pulls were required in order to process half of the renewal requests. Implementation of an e-prescribing system produced dramatic time savings that permitted reallocation of nursing and chart room staff.

- Potential reductions in malpractice insurance because of improvements in the quality of patient care resulting from better tracking of patients' drug regimen and a reduction of ADEs, which may occur with e-prescribing.

These examples come from large practices, but we expect that most if not all of them will apply equally well to smaller practices. We requested public comments and additional information on actual and potential savings, particularly in solo and small group practices. We received the following comments and information regarding this issue:

Comment: A commenter stated that savings in the e-prescribing pilot conducted by the CAQH were not quantifiable because of the small size of the pilot (127,000 e-prescriptions were generated). However, prescribers did experience reduced call volume and time savings from easier access to medication lists. According to other commenters, McKesson Corporation has achieved similar time savings with partners in Illinois and Iowa. For example, improved clinical information access eliminated the need for chart pulls; 100 percent compliance with prescription requirements leading to reduced call volume regarding formulary questions; and 83 percent improvement in efficiency related to medication refills. While the results

have not been quantified in dollar savings, the initiative has generated a 26 percent increase in nursing time with patients. The Tufts Health Plan Pilot program and Newton-Wellesley Case Study also corroborated physician practice time savings, of approximately 2 hours per day.

Response: These commenters provide additional information confirming that e-prescribing will provide significant savings. Some of the reported savings, such as daily savings measured in hours, would, if replicated, appear to be economically highly significant.

Despite these supportive comments, we still do not have sufficient information on either the costs or benefits for a given type or size of provider to conduct a cost-benefit analysis for that provider type or size.

H. Impact on Pharmacies and Other Dispensers

Testimony from pharmacists and professional pharmacy organizations provided to the NCVHS (available on the Web at <http://www.ncvhs.hhs.gov>) reported the following benefits of e-prescribing for pharmacies:

- Reduced time-consuming phone calls to physicians.
- Improved accuracy and less time for refill authorizations.
- Additional time available for patient contact and services.
- Improved prescription

communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).

- Improved turnaround time for refill authorizations.

We do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing. While we expect to see the efficiencies (discussed at the beginning of this section) at pharmacies with some possible reductions in administrative staff time, we do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program. We note that pharmacies could benefit from the incentives permissible under both the physician self-referral exception and the anti-kickback safe harbor. These exceptions would protect certain non-monetary remuneration in the form of hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription drug information.

The industry has provided information indicating that 75 percent of the approximately 57,000 pharmacies in the U.S. already have e-prescribing

capability which suggests that pharmacies already find this a beneficial investment (75 percent figure from testimony of Kevin Hutchinson of SureScripts before the NCVHS Subcommittee on Standards and Security, May 25, 2004; estimate of number of pharmacies from National Community Pharmacists' Association, press release of June 29, 2004). In this respect, we note that the great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small. For example, as indicated earlier in this preamble, we believe that over 95 percent of pharmacy systems are already compatible with the NCPDP retail pharmacy drug claim standard. Since adoption is voluntary and only undertaken where it is likely to be profitable, we expect any net effects to be positive.

In the February 4, 2005 proposed rule, we did, however, request additional information on pharmacy impacts. We received the following comments and information on pharmacy impacts:

Comment: According to one commenter, e-prescribing will likely save time and money for pharmacies by automating the pre-authorization process between prescribers, third party payers and pharmacies. The commenter stated that it also will reduce calls to physicians and save time for refills. However, the commenter indicated that there also will be costs associated with implementation. There are training expenses associated with supporting inbound e-prescriptions. One commenter who agreed that the net effect on pharmacies will be positive noted that there may actually be a slight negative effect early in the process of implementation due to the learning curve. The number of prescriptions that actually reach pharmacies will likely increase, in part because patients other than Medicare beneficiaries will benefit from e-prescribing. The increase in volume will create additional burden on staff time and the number of prescriptions that are not picked up will likely increase.

According to one commenter (and inconsistent with the information we presented in the proposed rule), most pharmacies, especially small pharmacies, are not networked to exchange data with prescribers electronically. The number of pharmacies actually receiving computer-to-computer prescription transactions is much smaller than CMS estimates. For example, according to this commenter, of 200,000 prescriptions that prescribers using its

system transmit electronically each month, 63 percent must be re-formatted for transmittal to a pharmacy's fax machine. CMS should not underestimate the costs, logistics and training required to migrate to true e-prescribing.

The National Association of Chain Drug Stores (NACDS) stated that there should be incentives for pharmacy adoption of e-prescribing in addition to incentives for prescribers because pharmacies will need to invest in new technology and training as well as pay e-prescribing transaction fees. Another expert organization estimated e-prescribing transaction fees to be between \$0.215 and \$0.35. Therefore, the average community pharmacy may incur costs of between \$4,000 and \$5,000 per year in transaction fees.

Response: While there are costs associated with e-prescribing technology adoption, it is clear that most pharmacies will benefit. The Tufts Health Plan Pilot Program found that pharmacists were very satisfied with e-prescribing (as defined by their Pilot Program but not "true" e-prescribing as defined under this final rule) and saved almost one hour per day using relatively inefficient fax e-prescribing technology. While the standards being adopted do not accommodate the use of facsimile technology, which involves transmission of graphic image copies rather than fielded data, this relatively primitive modality illustrates potential cost-effectiveness. Broader use of "true" e-prescribing would yield even better results.

I. Impact on Patients

E-prescribing has the potential for improving beneficiary health outcomes. E-prescribing systems enable appropriate drug compliance management and improved medication use, and provide information to prevent adverse drug events. E-prescribing systems can improve patient safety by detecting various kinds of prescribing errors, including duplicate prescriptions; drug-drug, drug-allergy and drug-disease interactions; incorrect dosage strengths prescribed; mis-prescribing, and problems relating to coordination between health care providers and pharmacies (for example, early and late refills). These types of reductions in errors and improvements in regimens will occur increasingly as more and more providers use the e-prescribing systems for the Medicare Prescription Drug Benefit (To Err is Human: Building a Safer Health System, Institute of Medicine of the National Academies, 1999, pp. 191–193, <http://www.oim.edu> <http://www.ioim.edu> or

<http://www.nap.edu>). E-prescribing can also inform physicians on appropriate formulary choices, which can save money for the health plans, patients, and health care system.

Nothing in the e-prescribing system creates direct costs for patients. We believe that reductions in patient mortality and morbidity will be a substantial benefit resulting from the adoption of e-prescribing, although we are unable at this time to provide quantitative estimates. The Department of Defense has an e-prescribing system, Pharmacy Data Transaction Service (PDTs), which uses a centralized repository of prescription and medication information to detect drug interactions (more than 117,000 were found over the last three years). However, this system is integrated with a full patient record.

Comment: All of the commenters on this issue agreed that patients will benefit from e-prescribing. Positive effects include ameliorating care fragmentation; encouraging prescribers to prescribe less expensive drugs so that patients halve their medications less frequently in order to save money; improving accessibility of clinical and personal health history at the POC; eliminating duplicate and negative interaction prescriptions; improving patient compliance by making the process of filling prescriptions easier; and prescriber notification of prescriptions being filled.

Response: We continue to agree that e-prescribing will have a substantial net positive impact on patient care, including improved outcomes, reductions in errors, and the ability for providers to monitor compliance. The previously cited CTIL report estimated in 2003 that e-prescribing will eliminate nearly 2.1 million adverse drug events annually in the U.S. and also projected \$2.7 billion in annual savings with widespread adoption.

Although we did not receive negative comments, we do point out that there are two potentially negative effects of e-prescribing, both of which have been raised at NCVHS meetings. First, like the creation of any computer-based system that includes personal information, e-prescribing creates new privacy risks. The problem is not that private information is not already available to authorized users, but that despite authentication procedures and other safeguards any electronic data base available to authorized users is potentially vulnerable to penetration by unauthorized users who, if they succeed, can potentially gain access to the records of many persons. Relatedly, increases in the number of authorized

users increase the potential for unscrupulous users to sell or otherwise reveal private information. Second, there is the possibility that an e-prescribing system, like any system, can be programmed in ways that result in errors. We think that both potential problems are likely to be infrequent, small in scope, and unlikely to create significant costs.

J. Impact on Others

We see the growth of e-prescribing as business potential for healthcare information technology vendors. Any costs associated with e-prescribing and potential business opportunities could be allocated toward new product development and would likely be recouped. We have no estimates for these types of costs and did not receive public comment from healthcare information technology vendors and others on the impact of e-prescribing.

E-prescribing is in widespread use among some segments of the industry, especially health plans and PBMs and some pharmacies; however, we have not determined the impact and extent of experience for other entities such as pharmaceutical and medical device manufacturers, public health organizations, research and academic institutions, and professional lay organizations. We invited public comment on the impact of e-prescribing for these entities.

The Health Information Network Weekly Update (Volume VI, No. 49, November 15, 2004) stated that e-prescribing is at the top of the list of e-health applications that will see the greatest growth. Thirty-nine percent of participants predict e-prescribing will be the most widely embraced e-health application.

We received the following comments on the impact of e-prescribing on the entities discussed above:

Comment: Commenters stated that the research community and public health professionals could also benefit from new, de-identified data that may become available.

Response: We agree with the commenters. We are already undertaking initiatives to increase reporting on outcomes of new medical devices and drugs that have been approved conditionally or with circumscribed applicability through our coverage decisions. We expect that the records generated in implementing the new Part D drug benefit will provide substantially expanded data bases that, properly analyzed without violating individual patient privacy, will help establish the absolute or comparative effectiveness of pharmaceutical

therapies in curing or alleviating diseases that affect Medicare beneficiaries, and help establish the incidence of adverse or positive side effects.

K. Impact on Small Businesses

The RFA requires agencies to analyze options for regulatory relief for small entities when final rules may create a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses whose revenues fall below specified thresholds, nonprofit organizations of any size, and small governmental jurisdictions (population under 50,000). Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$6 million a year. For purposes of the RFA, approximately 95 percent of pharmacy firms, which account for about 51 percent of pharmacy establishments, are small businesses based upon 1997 Census data. There are approximately 57,000 retail pharmacy establishments based upon the "2004 National Community Pharmacists Association Pfizer Digest." We estimate that about 29,000 pharmacy establishments are considered small businesses, and, therefore, small entities. Almost all physicians in private practice (or the practices of which they are members) are small businesses, and, therefore, small entities because their annual revenues do not meet the Small Business Administration's threshold for "small" physician practices. Individuals and States are not included in the definition of a small entity, and this final rule has no effect on small governmental jurisdictions.

We believe that this final rule will have an impact on a substantial number of small entities due to the large proportion of pharmacies and providers that are small businesses. We recognize that there will be a distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale. However, as indicated earlier in this section, as many as 75 percent of pharmacies already are conducting e-prescribing and 5 to 18 percent of prescribers are using this technology. Clearly, these rates of voluntary adoption indicate that it provides net economic benefits. Furthermore, this final rule recognizes that e-prescribing remains voluntary for entities that are not Part D sponsors. That is, prescribers and dispensers are only required to comply with the standards adopted under section 1860D-4(e)(1) of the Act if they

electronically transmit prescriptions or prescription-related information, with respect to covered Part D drugs for beneficiaries eligible for Part D. Small entity prescribers, therefore, are able to determine whether they incur costs of any kind. Finally, we believe that the effects of adoption are economically beneficial to affected entities.

We note that this conclusion differs from the impact analysis of the HIPAA final rule which was determined to have a significant impact. The basis for that determination was that a significant percentage of providers were already conducting the relevant transactions electronically in nonstandard form. For example, over 80 percent of Medicare claims submitted by physicians were transmitted electronically. Those providers would have been required to switch to the HIPAA standards, which were not in widespread use, creating a burden on a large percentage of affected entities. By contrast, only 5 to 18 percent of prescriptions are conducted electronically, and the small number of providers who are doing so are very likely already using the standards that we are finalizing in this final rule.

Accordingly, we conclude that this final rule will not have a significant economic impact upon a substantial number of small entities, and that neither an Initial nor Final Regulatory Flexibility Analysis is required. In the February 4, 2005 proposed rule, we welcomed comments on this conclusion and additional information on the effects this rule would have on small businesses. We received the following comments and information regarding effects of this regulation on small businesses:

Comment: A number of commenters stated that very small businesses (such as some pharmacy chains, independent pharmacies, and physician offices) will incur disproportionately higher implementation costs than larger entities due to economies of scale. Furthermore, currently, most small pharmacies and physician offices are not currently networked to exchange prescription data electronically (many are only fax-equipped). The cost of implementing and maintaining electronic prescribing technology will be more difficult for small business entities to absorb. Implementation is not truly voluntary in the sense that lack of participation likely means going out of business. Small rural pharmacies, especially, may be less likely to contract with PDPs, thus, creating access issues.

On the other hand, one commenter stated most small physician offices will not be impacted because electronic prescribing is still voluntary. For those

that choose to implement electronic prescribing, their practice will experience a neutral or small impact. Another commenter believes CMS' estimates of prescriber participation are too conservative and cited a Pri-Med Research Group study which found 1 in 5 physicians report using e-prescribing and another 42 percent planned on implementing the technology in 2005. Also, small computing firms and consultants may experience a positive impact in terms of increased demand for their services.

Response: There are three kinds of costs associated with e-prescribing—initial purchase of hardware and software; costs associated with daily use and maintenance, including on-line connectivity; and education and training.

Although e-prescribing is voluntary for physicians and pharmacies, we agree that the cost of implementing and maintaining electronic prescribing technology will be more difficult for small business entities to absorb. However, we believe that those costs could be offset by the grants to physicians that will be made available in 2007, as authorized by section 108 of the MMA. We also believe that our one-year phase-in period for moving from computer-generated prescription facsimiles to true computer-to-computer e-prescribing, as described earlier in section III.1.C. of this final rule, will give small providers and pharmacies the time needed to obtain both funding and acquisition of e-prescribing hardware and software. This also should help these entities better absorb the upfront costs associated with e-prescribing adoption.

In addition, physicians and pharmacies will be able to take advantage of incentives for adoption of e-prescribing technologies from hospitals, plans and other entities, which will be created under an e-prescribing exception under the Stark law and an e-prescribing safe harbor under the anti-kickback statute as discussed earlier in the preamble of this final rule.

Finally, small business entities do not conduct their operations in a vacuum and, as prudent business practice dictates, they should be upgrading their hardware and software on a regular basis. As a result, much of the costs of changing over to new e-prescribing technology should be absorbed as a usual cost of doing business, and may be additionally offset as allowable business-related, tax-deductible expenditures.

A second kind of cost is the cost of daily operations and maintenance,

including internet access. Some small providers and pharmacies already have internet capability for handling bills and claims. As the computerization of payment-related transactions become more and more common, small providers and pharmacies increasingly will acquire internet access. As a result, such costs may be sunk costs with respect to e-prescribing.

Further, the costs of more sophisticated internet access, such as high-speed internet connectivity, are negligible in the context of annual costs and revenues of virtually any health care provider. Even in the most remote rural areas, satellite internet access is available at costs similar to those in the most "connected" urban areas. Internet access through power lines is on the verge of equally widespread and low cost access. For all practical purposes, the cost of wide-band "Wi-Fi" Internet access in a physician office or neighborhood pharmacy is under \$1000 one time investment cost (assuming that a personal computer is not already used for correspondence, billing, or other purposes) and in most cases under \$100. In fact, it is free in some municipalities or designated areas in certain cities. Annual connection costs for broadband access are several hundred dollars.

Finally, in this context, software and training costs for e-prescribing loom larger, but are still small. While a prescriber or pharmacist doing negligible levels of business will incur high costs per prescription at even these cost levels, we do not agree that a solo provider with a medical practice large enough to be a source of livelihood, or small pharmacy, faces consequential cost disadvantages in embarking on e-prescribing. Furthermore, nothing in current or reasonably foreseeable circumstances suggests that a provider or pharmacy unwilling to engage in e-prescribing will be forced out of business in the next decade.

L. Impact on Small Rural Hospitals

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 standards 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 Metropolitan Statistical Area and has fewer than 100 beds. Because prescription drugs are dispensed in hospitals to Medicare outpatients, this final rule will have an effect on small rural hospitals. When hospital pharmacies dispense non-Part B prescription drugs to Medicare

hospital outpatients, if the hospital pharmacy is participating in the patient's Part D plan, the hospital pharmacy will bill under Part D. Since the use of the standards adopted by this final rule is required for Part D plans and is voluntary for prescribers and dispensers, we estimate that this final rule will not have a significant impact on small rural hospitals because the e-prescribing provisions are both voluntary and cost-beneficial for prescribers. In-hospital pharmacy units and staff physicians should face the same benefit/cost calculus as their counterparts, and will, therefore, have no net costs imposed upon them by adoption of e-prescribing.

M. Effects on States and Federalism Statement

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated for annual inflation (the current threshold is about \$120 million). The private sector will incur costs for hardware and software upgrades, and connectivity for implementation of e-prescribing. However, except for MA and PDP plans, this final rule does not include any mandate that will result in this spending because it only deals with the informational standards to be used in voluntarily adopted practices, and, therefore, that spending does not pertain to the thresholds of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Furthermore, we believe that the effects of adoption will be positive, rather than involve net expenditures. Regardless, even using our estimates of significant increases in the use of e-prescribing, we do not believe annual expenditures on installing this capability will reach \$120 million annually. Certainly, we expect the only entities that are required to comply, Part D sponsors (and possibly a few existing e-prescribers), to incur only minimal costs, totaling no more than a small fraction of this threshold.

With respect to States, nothing in this final rule mandates any expenditure by States. While some hospitals and other providers are State-owned, our conclusions with respect to each type of affected entity are not affected by ownership status.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. For the same reasons given above, we have determined that States will not incur any direct costs as a result of this final rule. However, as discussed extensively in this preamble, and as mandated by section 1860D-4(e) of the Act, some State laws will be preempted. Under the Executive Order, we are required to minimize the extent of preemption, consistent with achieving the objectives of the Federal statute, and to meet certain other conditions. We believe that, taken as a whole, this final rule will meet these requirements. We did seek comments from States and other entities on possible problems and on ways to minimize conflicts, consistent with achieving the objectives of the MMA, and will be undertaking outreach to States on these issues.

We have consulted with the National Association of Boards of Pharmacy directly and through participation in NCVHS hearings, and we believe that the approach we suggest as to the scope of preemption discussed earlier in the preamble provide both States and other affected entities the best possible means of addressing preemption issues. This section, together with the earlier preamble section entitled "State Preemption," constitute the Federalism summary impact statement required under the Executive Order.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

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 reasons set forth in the preamble in this final regulation, 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).

Subpart D—Cost Control and Quality Improvement Requirements

■ 2. The heading for subpart D is revised to read as set forth above.

■ 3. In § 423.150, paragraph (c) is revised to read as follows:

§ 423.150 Scope.

* * * * *

(c) Electronic prescription drug programs for prescribers, dispensers, and Part D sponsors.

* * * * *

■ 4. Section 423.159 is amended by revising the heading and adding a new paragraph (a) to read as follows:

§ 423.159 Electronic prescription drug program.

(a) *Definitions.* For purposes of this section, the following definitions apply:

Dispenser means 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 in the course of professional practice.

Electronic media has the same meaning given this term in 45 CFR 160.103.

E-prescribing means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

* * * * *

■ 5. Section 423.160 is added to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable

standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3) *Exemptions.* (i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(ii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

(iii) 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 are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(4) In accordance with section 1860D-4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits,

and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(b) *Standards.* (1) *Prescription.* The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (i) Get message transaction.
- (ii) Status response transaction.
- (iii) Error response transaction.
- (iv) New prescription transaction.
- (v) Prescription change request transaction.
- (vi) Prescription change response transaction.
- (vii) Refill prescription request transaction.
- (viii) Refill prescription response transaction.
- (ix) Verification transaction.
- (x) Password change transaction.
- (xi) Cancel prescription request transaction.
- (xii) Cancel prescription response transaction.

(2) *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, 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, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(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 the 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); the Accredited Standards Committee X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, and 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. You may inspect copies of these materials 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 information on the availability of this material at CMS, call 410-786-0273. For 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. You may obtain a copy of the National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12, 2004, from the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and FAX (480) 767-1042 or <http://www.ncpdp.org>. You may obtain a copy of 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, 004010X092A1, October 2002, from the Washington Publishing Company, 301 West North Bend Way, Suite 107, P.O. Box 15388, North Bend, WA 98045; Telephone (425) 831-4999; and FAX: (425) 831-3233 or <http://www.wpc-edl.com/>. You may obtain a copy of the National Council for Prescription Drug Programs Telecommunication Standard

Guide, 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, from

the National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and FAX (480) 767-1042 or <http://www.ncdpd.org>.

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

Dated: August 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2005.

Michael O. Leavitt,

Secretary.

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