

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 423**

**[CMS-0011-P]**

**RIN 0938-AN49**

**Medicare Program; E-Prescribing and the Prescription Drug  
Program**

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

**ACTION:** Proposed rule.

**SUMMARY:** This rule proposes to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These proposed standards would 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 uniform 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:** To be assured consideration, comments must be received at one of the addresses provided below, no later

than 5:00 p.m. on [OFR--insert 60 days after the date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, please refer to file code CMS-0011-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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2. By mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-0011-P,  
P.O. Box 8014,  
Baltimore, MD 21244-8014.

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with one of our staff members.  
Room 445-G, Hubert H. Humphrey Building,  
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Washington, DC 20201; or  
7500 Security Boulevard,  
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For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Gladys Wheeler, (410) 786-0273.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS-0011-P] and the specific "issue identifier" that precedes the section on which you choose to comment.

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## **I. BACKGROUND**

**[If you choose to comment on issues in this section, please  
include the caption "BACKGROUND" at the beginning of your  
comments.]**

### 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 prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically comply with final uniform standards adopted by the Secretary under an electronic prescription drug program.

On January 28, 2005, we published the Medicare Prescription Drug Benefit final rule that establishes 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, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription

information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.

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 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is "adequate industry experience." Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.

In the context of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and code sets (TCS) requirements, a covered entity that conducts a covered transaction using electronic media must comply with the applicable transaction standard. Electronic media is defined under HIPAA to include both electronic storage media

and transmission media, including the "internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media." (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards.

Section 1860D-4(e)(1) of the Act states that the final e-prescribing standards will govern "prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically. . . ." We believe the best reading of this language, as well of the intent of the Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans - that is, enrollees of prescription drug plans (PDPs) (including employer-sponsored PDPs); fallback PDPs; Medicare Advantage Prescription Drug plans (MA-PD plans); and private fee for service plans, Medicare cost reimbursement plans, or PACE programs receiving Part D reimbursement. We believe this interpretation realizes the intent of the Congress, which in the Conference Report for

the MMA, stated that e-prescribing standards are standards that apply to information, transmitted "under an electronic prescription drug program conducted by a PDP or MA plan."

(H.R. Conf. Rep. 108-391, 108<sup>th</sup> Cong., 1<sup>st</sup> Sess. at 455 (2003)) This statement contemplates that the e-prescribing standards would apply solely to information regarding Part D enrolled individuals, not simply to information regarding Part D eligible individuals who are not enrolled in a Part D plan. We have attempted to clarify the scope of these standards in the proposed definition of "electronic prescription drug program" in proposed §423.159, and the "General Rules" in proposed §423.160.

The requirements of the statute are as follows:

"(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

"(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS--An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered Part D drug:

"(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

"(ii) Information on the availability of lower cost, therapeutically appropriate

alternatives (if any) for the drug prescribed.

"(B) APPLICATION TO MEDICAL HISTORY INFORMATION.--Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

"(C) LIMITATIONS.--Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(D) TIMING.--To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

Section 1860D-4(e)(4)(B) of the Act also requires the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for standards, in consultation with specific groups of organizations and entities. Section 1860D-4(e)(4)(A) of the Act requires the Secretary to take these recommendations into consideration when developing, adopting, recognizing, or modifying initial uniform standards according to the schedule set forth above. The NCVHS process for developing and providing recommendations to the Secretary is detailed below at section B of this proposed rule.

In order to provide for efficient implementation of the

requirements, section 1860D-4(e)(4)(C) of the Act requires the Secretary to conduct a pilot project to test initial standards developed under section 1860D-4(e)(4)(A) of the Act, prior to issuing the final standards that are promulgated in accordance with section 1860D-4(e)(4)(D) of the Act. Section 1860D-4(e)(4)(C)(ii) of the Act also permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. Under this exception, standards can be proposed and adopted through rulemaking as final standards without pilot testing, and would then become final standards under MMA.

In the preamble of the Medicare Prescription Drug Benefit proposed rule, published in the **Federal Register** August 3, 2004 (69 FR 46632-46863), we solicited comments to help us identify consensus on e-prescribing standards ahead of the statutory timeframe and to help us identify and evaluate whether there is adequate industry experience with those standards. Concurrently, the NCVHS held hearings with various groups of constituencies on e-prescribing standards while identifying and examining standards for possible adoption by the Secretary. We attended each of these hearings as an active participant.

Under the MMA, proposed standards can be adopted as

final standards prior to the dates specified in the statute because section 1860D-4(e)(1) of the Act provides for adoption "as of such date as the Secretary may specify." The statute, moreover, only requires pilot testing for initial standards for which adequate industry experience is lacking and calls for final standards "no later than April 1, 2008." Some comments submitted in response to the Medicare Prescription Drug Benefit proposed rule supported an accelerated timetable based on adequate industry experience with certain standards, while others advocated pilot testing of all standards because they felt adequate industry experience did not exist with any standard. We considered all public comments on this issue submitted in response to the Medicare Prescription Drug Benefit proposed rule, along with the NCVHS observations and associated recommended actions. Despite comments to the contrary, we believe that there is adequate industry experience for certain standards and have proposed those standards in this rule. The rationale for our preliminary conclusion that adequate industry experience exists is discussed later in this preamble. Finally, we believe that we have met the statutory requirement for industry consultation because we actively participated in the NCVHS process, and we requested and received industry comments on adequate industry experience with existing standards through the Medicare Prescription Drug Benefit proposed rule. We are also

requesting comments in this proposed rule. The need for pilot testing of future standards will be determined when additional standards are recommended.

#### 1. Initial Standards Versus Final Standards

It is important to emphasize that in section 1860D-4(e) of the Act there are distinct provisions for initial standards and final standards. Initial standards are standards for an electronic prescription drug program that the Secretary would adopt, develop, recognize, or modify before September 1, 2005, taking into consideration recommendations from the NCVHS. These standards will be subject to pilot testing that would occur during the 2006 calendar year. The results of the pilot project will be evaluated and, based upon those results, final standards would be published not later than April 1, 2008. In order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary will conduct an evaluation of the pilot project, and will submit a report to the Congress on the evaluation, not later than April 1, 2007.

Final standards are standards that would be adopted in regulations through the rulemaking process. Compliance with

those final standards will be required when prescription information or certain other related information is electronically transmitted among Part D sponsors (as this term is defined in the Medicare Prescription Drug Benefit final rule) and prescribing health care professionals and dispensing pharmacies and pharmacists as specified at section 1860 D-4(e)(1) of the Act for covered Part D drugs prescribed for Part D enrolled individuals.

Final standards may be adopted by the Secretary as a result of the pilot project. However, if the Secretary, after consultation with affected standard setting organizations and industry users, determines that pilot testing is not required because there is adequate industry experience with the standards, those standards may be adopted as final without pilot testing.

We refer to the final standards proposed in this rule as foundation standards because they would be the first set of final standards adopted for an electronic prescription drug program. As mentioned above and discussed further below, we believe that adequate industry experience exists with respect to the standards proposed in this rule which allows us to propose and adopt these foundation standards as final standards without pilot testing.

## 2. State Preemption

Nearly every State allows for the electronic transmission of prescriptions. In recent years, many States

have more actively legislated in this area. The scope and substance of this State activity, however, varies widely among the States.<sup>1</sup> 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 eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

We propose to interpret this section of the Act as preempting State law provisions that conflict with Federal electronic prescription program drug requirements that are adopted under Part D. We view it as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards, or that restrict the ability to carry out (that is, stand as an obstacle to) the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. Consequently, for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B).

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<sup>1</sup> Catizone, Carmen A. National Association of Boards of Pharmacy. Testimony before the NCVHS, July 29, 2004.

Furthermore, there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted. This interpretation closely reflects the language of the statute, and it is consistent with the presumption against Federal preemption of State law<sup>2</sup> and with the fundamental Federalism principles set forth in section 2 of Executive Order 13132. It is also consistent with the Department of Health and Human Service's (HHS) general position of deferring to State laws regulating the practice of pharmacy and the practice of medicine.

We understand that some industry representatives believe that the Congress intended this preemption provision to be much broader. For instance, some expressed the position that this statutory provision preempts all State laws that would in any way restrict the development of e-prescribing for all providers and payors. This position is based on the belief that the Congress intended to preempt the field of e-prescribing through this provision in the MMA. It would require an interpretation that the word "and" between paragraphs (A) and (B) is disjunctive, that is, that "and" means "or" in this context. Under this interpretation, the operative language would be "restricts the ability to carry out this part" in paragraph (A), which arguably would enable the standards and requirements adopted

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

for the Federal electronic prescription drug program to preempt all State laws and regulations that restrict the Secretary's ability to carry out the goals of an electronic prescription drug program, even if they are not related to covered Part D drugs, or Part D covered individuals. They contend that some States have existing statutory or regulatory barriers that could impede the success of e-prescribing; for example, laws and regulations that were drafted with only paper prescriptions in mind, which may not be well-suited to e-prescribing applications.

This interpretation, however, does not appear to comport with the use of the word "contrary" in the statutory language which generally establishes "conflict preemption." This interpretation would seem to render paragraph (B) virtually meaningless and serve to establish "field preemption".

We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies 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 ask for comment on whether this preemption provision applies to only electronic

prescription transactions or to paper transactions as well.

### 3. Anti-kickback Statute Safe Harbor and Stark Exception

Section 1860D-4(e)(6) of the Act requires the Secretary to promulgate regulations that provide for a "safe harbor" under the anti-kickback statute (section 1128B(b) of the Act) and an "exception" under the physician self-referral statute (section 1877 of the Act) for certain nonmonetary remuneration related to e-prescribing information technology items and services. The statute states that--

"The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128(b) [of the Social Security Act] and an exception to the prohibition under sub-section (a)(1) of section 1877 [of the Social Security Act] with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection--

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1877(h)(4), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals."

We will propose the new Stark exception for electronic prescribing in a separate rulemaking to be published in the near future. The new safe harbor under the anti-kickback

statute will be proposed by the Office of the Inspector General. In the meantime, where relevant, arrangements involving nonmonetary remuneration related to electronic prescription hardware, software, information technology and training must comply with an existing Stark exception (such as the exception for non-monetary compensation, 42 CFR §411.357(k), or the new community-wide health information technology exception, 42 CFR §411.357(u)) and must not violate the anti-kickback statute. They must also comply with similar state laws.

B. The NCVHS Process

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, not later than September 1, 2005, taking into consideration the recommendations from the NCVHS (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k (k)) under subparagraph (B)). In particular, the role of the NCVHS in recommending uniform standards relating to the requirements for an electronic prescription drug program is outlined in section 1860D-4(e)(4)(B)(i) through (x) of the Act. 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 response to the requirements of the Act for electronic prescription drug program standards, the NCVHS increased its number of meetings and held public hearings at which representatives of physicians, pharmacists, and experts on e-prescribing, among others, testified. The NCVHS also consulted with standard-setting organizations and accelerated the process for developing recommendations for the Secretary well in advance of the statutory requirement. At the July 21, 2004 Health Information Technology Summit, we announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins.

To fulfill its responsibilities under the MMA's amendments to the Act, the NCVHS' 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 28-30, 2004; and August 17-19, 2004. These hearings included testimony from e-prescribing networks, providers, software vendors, and industry experts on patient safety, drug knowledge databases, 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 proposing 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/0409021t2.htm>.

In order to develop and provide future recommendations to the Secretary, the NCVHS Subcommittee on Standards and Security plans to hold additional hearings on the state-of-the-art in e-prescribing, including testimony from a broad range of stakeholders. The NCVHS will be developing

recommendations for additional standards for consideration by the Secretary for testing and ultimate adoption through the rulemaking process. Readers interested in the NCVHS' hearing schedule, testimony presented at the hearings, and standards recommendations should consult the NCVHS website at <http://www.ncvhs.hhs.gov>.

#### C. Standards Design Criteria

Section 1860D-4(e)(3)(C) of the Act, specifies that 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

According to 2002 data from the National Center for Health Statistics, Americans made more than 823 million

visits to physicians' offices in 2000 and, according to the National Association of Chain Drug Stores (NACDS), four out of five patients leave a doctor visit with at least one prescription. More than 3 billion prescriptions are written in the United States (U.S.), and prescription medications are used by 65 per cent of the U.S. public in a given year, according to an Agency for Healthcare Research and Quality (AHRQ) 1999 report. Given this volume, even small improvements in quality that are attributable to e-prescribing may translate into significant cost benefits.

Today, physicians and other health care providers make their drug-prescribing decisions using whatever medical, medication, and eligibility information that is known or available to them. Then they give a handwritten prescription to the patient or fax it to the patient's pharmacy of choice. At the pharmacy, tasks are somewhat more automated. Through electronic claims, eligibility, and benefits submission, the dispensing pharmacist may learn about drug interactions, disease management concerns, the need for prior authorization, or lower cost alternatives. The pharmacist may then contact the prescriber by phone for approval of changes, refills, or renewals. This process can be very repetitive and time consuming for both the pharmacist's and the prescriber's office staff. According to some estimates, almost 30 percent of prescriptions require pharmacy call backs, resulting in 900 million

prescription-related telephone calls that are placed annually.<sup>3</sup>

Many witnesses before the NCVHS have stated that the current prescribing process is prone to errors. Prescribers may not have access to the latest drug knowledge. They often do not have a completely accurate medication list or even medical history for their patient, and, as a result, may be unaware of potential drug-drug or drug-disease interactions or duplicate therapies. Pharmacists often have difficulty reading handwritten prescriptions and frequently have little or no information about the patient's condition for which the prescription is written. Contacting the prescriber by phone to clarify what is ordered and to make changes often results in delays for the patient and is time consuming for the prescriber and the pharmacist. There are disconnects between the prescriber and patient in the medication process, and little or no feedback is given to the prescriber on whether a prescription was filled or refilled. These disconnects can lead to preventable adverse drug events (ADEs) that are common and can be serious. According to the Center for Information Technology Leadership, more than 8.8 million ADEs occur each year in ambulatory care, of which over three million are preventable.<sup>4</sup> Medication errors account for one out of 131

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<sup>3</sup>Hutchinson, Kevin, SureScripts. Testimony before the NCVHS Subcommittee on Standards and Security, May 25, 2004.

<sup>4</sup>Center for Information Technology (CITL, a research organization chartered in 2002) <http://www.citl.org>, Wellesley, MA (781-416-9200) 2003 report: "The Value of Computerized Order Entry in Ambulatory Care."

ambulatory deaths.<sup>5</sup> In addition, the current system results in numerous and pervasive administrative and workflow inefficiencies, which affect costs and quality of care.

#### E. Current E-Prescribing Environment

E-prescribing is a complex process that usually involves a number of stakeholders, including prescribers, pharmacists and associated staff, vendors, hospitals and health systems, patients, health plans, and Pharmacy Benefit Managers (PBMs), among others. In a basic e-prescribing system, clinicians review, enter, manage, and sign prescriptions using a computerized system, instead of writing them on paper. The prescription is then electronically transmitted to a pharmacy. Currently, e-prescribing systems are available in a variety of graduated levels of technology with associated benefits for each level. The levels range in sophistication from a basic electronic drug information reference with dosing calculators and formulary information to medication ordering that is automatically linked to an electronic health record.

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,

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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. An article reported that in a large primary care practice in Kokomo, Indiana, of 206 daily prescription-related calls, 97 calls were renewal requests<sup>6</sup>; 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.

The use of e-prescribing shows promise for improving Medicare operations by creating efficiencies in the administration of the Part D drug benefit, by decreasing costs in facilitating patient eligibility checks, promoting generic drug use, and creating timely interface with formularies. This also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

According to industry surveys, usage rates for

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<sup>5</sup> Institute of Medicine, Committee on Quality in Healthcare in America. To Err is Human: Building a Safer Health System.

e-prescribing vary in number and in the level of sophistication of the electronic prescription system used. Somewhere between 5 percent and 18 percent of physicians are estimated to be using e-prescribing of one sort or another, 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.

F. Evolution and Implementation of an Electronic Prescription Drug Program

In this regulation, we propose to adopt foundation standards (that is, standards that do not need to be pilot tested because adequate industry experience with those standards already exists). While the statute includes an exception to the pilot testing requirement for standards with adequate industry experience, it does not define the term. The concept was discussed throughout the NCVHS hearings, as industry participants debated whether specific standards should be recommended as foundation standards. We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the

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Washington, DC, National Academy Press: 1999.

<sup>6</sup> Ennis K, Maus R. Kokomo Family Care: Automating the Clinical Practice. MGM Journal, 2001 (July/August): p. 8-11.

NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:

- The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.

- The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.

- The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.

The Secretary has determined that pilot testing is not required for the standards proposed in this regulation because they meet the criteria for adequate industry experience. The need for pilot testing of future standards

will be determined when additional standards are recommended.

Standards for e-prescribing must not only meet the specific requirements in section 1860D-4(e)(2) of the Act, but must also be compatible with standards adopted under Part C of Title XI (the Administrative Simplification provisions of HIPAA), and technology and general standards adopted under section 1860D-4(b)(2)(B)(i) of the Act. The standards should be vendor neutral and technology independent, and developed by Standards Development Organizations (SDOs) that are accredited by the ANSI.

The standards proposed in this regulation are important foundation standards, but do not represent the full set of standards that will be necessary to implement effectively an electronic prescription drug program. Further, at least one of the standards with which we are proposing to address basic e-prescribing functionality could be refined in the future ultimately to support more advanced functions. For example, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard contains a segment that supports free text patient dosage instruction which could be enhanced to structure the patient instructions.

These proposed foundation standards are a first step toward a more complete set of standards required for an electronic prescription drug program under the MMA. Additional final standards will be identified, pilot tested,

and proposed through separate processes in accordance with the time frames set forth in the statute and will build on these foundation standards.

In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.

#### G. Electronic Prescription Drug Program

Section 1860D-4(e)(2) of the Act specifies that an electronic prescription drug program for covered Part D drugs for Part D enrolled individuals shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the--

- Prescription;
- Information on eligibility and benefits

(including the drugs included in the applicable

formulary, any tiered formulary structure, and any requirements for prior authorization);

- Information on the drug being prescribed or dispensed and other drugs listed on the medication history;

- Information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments;

- Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed; and

- Information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

While it is important to note that, to the extent Part D sponsors, prescribers, and dispensers are covered entities under HIPAA, they must continue to abide by the applicable HIPAA standards, including those for privacy and security. All Part D Plans are covered entities under HIPAA, and we assume that many of the providers participating in Part D will likewise be covered entities. Providers are HIPAA covered entities if they engage in electronic transactions for which there are HIPAA standards. In general terms, under HIPAA, a covered entity is a health plan, a health care clearinghouse, and a health care provider who transmits

any health information in electronic form in connection with a standard transaction. A standard transaction is defined as a transaction that complies with the applicable standards at §162.1101 through §162.1802. Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at §162.1101 through §162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. Complete definitions for HIPAA covered entities and standard transactions are available at 45 CFR 160.103 and 45 CFR 162.103.

If a provider is not otherwise a covered entity under HIPAA, it would become a covered entity if it conducts an e-prescribing transaction that is also a HIPAA transaction, such as the 270/271 eligibility and response transactions. It should also be noted that disclosures of protected health information (PHI) in connection with an e-prescribing transaction that is not a HIPAA transaction would have to meet the minimum necessary requirements of the Privacy Rule if the entity is a covered entity. The Privacy Rule

excludes from the minimum necessary requirements those disclosures that are required to comply with a HIPAA transaction standard. However, this exclusion would not apply to e-prescribing standards that are not also HIPAA standards, making compliance with minimum necessary a requirement, unless another exception applies.

The MMA requires the Secretary to develop, adopt, recognize or modify initial uniform standards related to the requirements of an electronic prescription drug program taking into consideration any recommendations from the NCVHS. The standards must be designated to enable transmission of basic prescription data to and from prescribers and dispensers, as well as the transmission of information about the patient's drug utilization history, possible drug interactions, the drug plan, and cost information. The design of the standards for an electronic prescription drug program must be consistent with the objectives of improving patient safety, quality of care, efficiencies and cost savings in the delivery of care, and meet the standards design criteria outlined in this section. The standards also must permit the use of appropriate messaging, according to section 1860D-4(e)(2)(d) of the Act, as it relates to the prescribing of drugs and permit patients to designate a dispensing pharmacy.

In its September 2, 2004 letter, the NCVHS provided its

observations and associated recommended actions related to the standards needed for the interoperable electronic exchange of information for most of the categories of information enumerated in section 1860D-4(e)(2) of the Act.

The key NCVHS recommendations concerning these functions and whether they are included in the NPRM are summarized in the table below:

<b>Function</b>	<b>NCVHS Standards Recommendations - HHS Should:</b>	<b>Standard in NPRM</b>
Provider and Dispenser Identifiers	Adopt NPI when it becomes available.	No
Prescription (Clinical drug)	Include in the 2006 pilot tests the RxNorm terminology in the NCPDP SCRIPT Standard.	No
Drug order for new, renewals, cancellations, and change orders	Recognize, as a foundation standard, the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers.	Yes
Drug orders for fill status notification	Should include the fill status notification function of the NCPDP SCRIPT Standard in the 2006 pilot tests.	No
Patient instructions (SIG)	Support NCPDP, HL7, and others (especially including the prescriber community) in addressing SIG (patient instruction) components in their standards.	No
Medication history	Participate in and support rapid development of an NCPDP standard for a medication history message for communication from a payer/PBM to a prescriber.	Standard functionality identified
Formulary and benefit coverage information	Participate in and support the rapid development of an NCPDP standard for formulary and benefit information file transfer.	Standard functionality identified
Eligibility inquiry and response	Recognize, as a foundation standard, the NCPDP Telecommunication Standard and the ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response.	Yes
Prior authorization	Support ASC X12N in their efforts to incorporate functionality for real-time prior authorization messages for drugs in the ASC X12N 278 Health Care Services Review.	No
Drug-drug Interaction	No recommendations advanced. Subject to future NCVHS hearings.	No
Medical History	No recommendations advanced. Subject to future NCVHS hearings.	No
Exchange of medication history, and	No recommendations advanced. Subject to future NCVHS hearings.	No

medical history for e-prescribing program.		
Electronic signature	No recommendations advanced. Subject to future NCVHS hearings.	No

In section II of this proposed rule (Provisions of the Proposed Regulation), we describe the proposed requirements related to the use of the most current version of NCPDP SCRIPT for new prescriptions, prescription renewals, cancellations, changes between prescribers and dispensers, and ancillary messaging and administrative transactions, the NCPDP Telecommunication Standard, and the ASC X12N 270/271 transaction, for transmitting eligibility data between dispensers and Part D sponsors and between prescribers and Part D sponsors, respectively.

The NCVHS also observed that "there are several areas in the foundation standards that do not support all the MMA requirements." As can be seen from the Table above, additional standards will be required to implement many of the functions of an electronic prescription drug program as envisioned by the MMA. Examples of some of the needed standards and associated issues are as follows:

- Provider and Dispenser Identifiers. The MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions. However, the NCVHS found that it was important to address the issue of provider identifiers for various e-prescribing standards it reviewed

and, more generally, for an electronic prescription drug program. We agree. After assessing a number of candidate identifiers, the NCVHS further recommended the use of the National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available.

HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. We believe that it is necessary to have a unique identifier for these transactions. The NPI is the preferred option, because it is a standard that many entities will be required to use under HIPAA. If use of the NPI is required for e-prescribing transactions involving Medicare Part D drugs at the time the benefit is available in January 2006, prescribers, pharmacies, pharmacists, Part D sponsors and potentially other entities would be required to implement the NPI for e-prescribing transactions earlier than the current compliance date for the HIPAA covered transactions.

The NCVHS also urged HHS to accelerate the enumeration of all providers to support transition to the NPI for e-prescribing. We have been planning to enumerate HIPAA covered providers over the course of several years.

Accelerated NPI usage for e-prescribing, therefore, may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. Furthermore, there is a possibility that unforeseen system

or budget concerns could delay provider enumeration, and, therefore, the date by which the NPI would be available for use in e-prescribing under Medicare Part D.

We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.

NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCId<sup>®</sup> for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.

- Formulary and Medication History Standards.

Adoption of standards for formulary representation and medication history would clearly enhance e-prescribing

capabilities under Part D. Such standards would make 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. Significant quality improvement and cost savings could result from the use of formulary and medication history standards.

The NCVHS noted that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange. In response to industry testimony, RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be considered for adoption as an ANSI-accredited standard. NCVHS considered ANSI accreditation to be a criterion in their recommendations process, and HHS proposes to adopt this as a criterion for determining adequate industry experience.

The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocol as a basis, and indicated its belief that this appeared possible in time to adopt the standard as a foundation standard.

We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. We would consider adopting an NCPDP standard for formulary and medication history that are based on the RxHub protocol.

We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:

- The standards are accredited by an ANSI-accredited standards development organization.
- The standards permit interface with multiple product, router, and point-of-care (POC) vendors.
- The standards provide a uniform means for--  
+Pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via POC systems; and  
+POC vendors to receive a range of formulary and benefit information through these services.

- The standards cover a range of formulary and benefit data, including information on the--

- +Formulary (for example, therapeutic classes and subclasses);

- +Formulary status (for example, drugs that the benefit plan considers to be "on formulary");

- +Preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and

- +Copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another).

We propose the following critical characteristics for medication history standards:

- The standards are accredited by an ANSI-accredited standards development organization.

- The standards permit interface with multiple product, router, and POC vendors.

- The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.

- The standards provide a uniform means for a Part D

plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.

- Drug Information. Section 1860D-4(e)(2) of the Act specifies that an electronic prescription drug program will include information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments. Given that relevant e-prescribing standards must permit electronic exchange of drug labeling and drug listing information maintained by the FDA and the NLM, medication history standards should be compatible with those standards when they are adopted by the Secretary. While drug information standards will not be foundation standards, they will be supported in the future by the structured product label. While standards for providing this type of information on drugs have not yet been considered by the NCVHS and are not yet proposed, we anticipate proposing standards in the future through rulemaking because they are required by MMA and we believe that providing this information is essential to improving the safety and quality of medication management. We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.

- Medical History. Section 1860D-4(e)(2)(B) of the Act specifies that an electronic prescription drug program includes the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed. "Medical history" differs from "medication history." "Medication history" refers to drugs that have been prescribed to the individual, while "medical history" relates more broadly to information about the patient's health care and health status (for example, allergies, laboratory test results, and chronic conditions).

The statute treats the electronic transmission of medical history differently from the electronic transmission of other information in an electronic prescription drug program. Section 1860D-4(e)(2)(B) of the Act specifies that the medical history provision is only effective "on and after such date as the Secretary specifies and after the establishment of appropriate standards." We intend to propose standards for communicating medical history at a future date. The NCVHS has not yet provided recommendations on these standards. This proposed rule does not address data collection and storage in terms of research. We will consider any NCVHS recommendations in our design of the pilot project for 2006.

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

We recognize that the standards we are proposing do not provide all of the functions for which standards are required by section 1860D-4(e)(2) of the Act. At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience; otherwise, pilot testing is required by section 1860D-4(e)(4)(c) of the Act prior to the adoption of a standard as a final standard. We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics

are met, we are proposing to adopt, as foundation standards, the following:

- The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).
- The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).
- The NCPDP 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) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).

We acknowledge that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive Electronic Health Record (EHR) system with decision support functionality and

must be interoperable with other functions of an EHR. The need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as 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, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI-accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.

## **II. Provisions of the Proposed Regulation**

**[If you choose to comment on issues in this section, please include the caption "PROVISIONS" at the beginning of your comments.]**

### **A. Proposed Change to Scope (§423.150)**

Subpart D of part 423 implements provisions of several sections of the Act, including sections 1860D-4(c), 1860D-4(d), 1860D-4(e), 1860D-4(j), and 1860D-21(d)(3), as well as sections 102(b) and 109 of Title I of the MMA. Because section 1860D-4(e) of the Act pertains to standards for electronic prescription drug programs which require compliance by e-prescribing entities other than Part D plans, we propose to explicitly broaden the scope of subpart D. Therefore, we are proposing to modify the title of subpart D to read, "Cost Control and Quality Improvement Requirements," and revise 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.

#### B. Proposed Definitions

We propose to amend §423.159 of the Medicare Prescription Drug Benefit final rule 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 are proposing to define below. The proposed definitions are as follows:

- 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 on prescription in the course of professional practice.

- Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.
- E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.
- Electronic Prescription Drug Program means 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.
- 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 a Part D eligible individual enrolled in a Part D plan.

#### C. Proposed Requirements for Part D Plans

The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with electronic prescription drug program

standards relating to covered Part D drugs, for Part D enrolled individuals once final standards are effective. Effective January 1, 2006, Part D sponsors would be required to have an electronic prescription drug program and would be required to support electronic prescribing, once standards are in place.

Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy. The e-prescribing standards that these "closed" enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards.

It is important to note that the NCVHS recommendation differs from the HIPAA transaction requirements. The preamble for the Transactions Rule (65 FR 50316-50317) discusses transmissions within a corporate entity requires covered entities to use the adopted transaction standards when conducting covered electronic transactions with other

covered entities. The Transactions Rule also expressly states that if a covered entity conducts a covered transaction using electronic media within the same covered entity, it must conduct the transaction as a standard transaction (45 CFR §162.923). Consequently, whether the transaction is conducted within or outside the entity is immaterial with respect to whether compliance with the HIPAA transactions is required.

This issue is relevant to Medicare Part D in situations where an MA-PD plan, for example, is a staff-model HMO using an internal pharmacy. We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, 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.

#### D. Proposed Requirements for Prescribers and Dispensers

Part D sponsors would be required to comply with the applicable proposed standards in new §423.160(b) when electronically transmitting prescriptions and prescription-related information. If prescribers and dispensers electronically transmit prescriptions and prescription-related information, they also would be

required to comply with the applicable proposed standards in proposed §423.160(b). These entities would be required to comply with the standards whether they transmit prescriptions or prescription-related information using electronic media, either directly or through an intermediary, through, for example, an e-prescribing network.

#### E. Proposed Standards

The Secretary has tentatively concluded that the proposed standards discussed below are not subject to pilot testing because adequate industry experience with these proposed standards already exists. Entities with electronic prescription drug programs would be required to comply with the proposed applicable standards no later than January 1, 2006.

##### 1. Prescription

The NCPDP SCRIPT Standard contains a series of business processes, referred to as transactions, which are included in the NCPDP SCRIPT Standard. We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for 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). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.

We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:

- New prescription transaction
- Prescription refill request and response transactions
- Prescription change request and response transactions
- Cancel prescription request and response transactions
- The following ancillary messaging and administrative transactions:

+Get message transaction

+Status response transaction

+Error response transaction

+Verification transaction

+Password change transaction

We have determined that these transactions of the NCPDP SCRIPT Standard meet our proposed criteria for adequate industry experience for the following reasons:

- First, the ANSI recognizes NCPDP as an accredited standards organization. The NCPDP SCRIPT Standard adheres to Electronic Data Interchange (EDI) for Administration Commerce And Transport (EDIFACT) and Accredited Standards Committee (ASC) standards.

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry. With over 25 years experience in the pharmacy health care industry, NCPDP membership includes representatives from--

- +Chain and independent pharmacies;
- +Consulting companies and pharmacists;
- +Database management organizations;
- +Federal and State agencies;
- +Health insurers;
- +Health maintenance organizations;
- +Mail service pharmacy companies;
- +Pharmaceutical manufacturers;
- +Pharmaceutical services administration organizations;
- +Prescription service organizations;
- +Pharmacy benefit management companies;
- +Professional and trade associations;

- +Telecommunication and systems vendors;
- +Wholesale drug distributors; and
- +Other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

The NCPDP SCRIPT Standard is a voluntary consensus-based standard that was developed by NCPDP, and approved by full ballot voting in accordance with ANSI's procedures for due process, openness and consensus. More specifically, the NCPDP SCRIPT Standard transactions we propose for adoption have been used extensively for messaging between prescribers and retail pharmacies for new prescriptions, prescription refill requests, prescription fill status notifications, and cancellation notifications, as part of the Consolidated Health Informatics (CHI) Initiative. CHI is the health care component of President Bush's eGov Initiatives created under the President's Management Agenda.

- Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent

pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users.

- Third, the NCPDP SCRIPT Standard transactions we propose for adoption are recognized as the industry standard. Over 25 e-prescribing vendors (stand-alone and electronic health record integrated systems) which represent 80 percent of the Nation's covered lives are either using or actively programming to the NCPDP SCRIPT standard.

We do include, as part of the proposed foundation standards, the previously identified ancillary messaging and administrative transactions. These transactions are an integral part of the NCPDP SCRIPT Standard, providing the administrative functions to assure that prescription transactions are accurately exchanged. Industry experience with the adopted HIPAA transactions has shown the need for standard acknowledgement and error reports transactions. During the NVCHS hearings, the only transaction specifically mentioned as lacking industry experience was the Prescription Fill Status Notification Transaction and, thus, it has not been included in this proposed rule. Because

these ancillary messaging and administrative transactions are an integral part of the NCPDP SCRIPT Standard, we believe that the industry has adequate experience with them, so as to be able to forego pilot testing. We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.

## 2. Eligibility

We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors.

The ASC X12N 270/271 transaction standards were adopted in August 2000 as the HIPAA standard for eligibility inquiry and response transactions between dentists, (medical) professionals, and institutions, on one hand, and health plans, or just between health plans.

We have determined that the ASC X12N 270/271 transaction standard meets the criteria for adequate industry experience for the following reasons:

- First, the ASC X12N 270/271 are ANSI-accredited standards.
  - Second, the standards are adopted HIPAA standards.
- Use of the ASC X12N 270/271 transaction for conducting

eligibility and response inquiries between providers and health plans and between two health plans has been required since October 16, 2003, at the latest. In May 1998, when adoption of this standard was proposed through notice and comment rulemaking, the majority of comments received expressed support for adopting this standard.

Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.

We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. We have determined that the NCPDP Telecommunication Standard meets our proposed criteria for adequate industry experience for the following reasons:

- First, these standards adhere to EDI for EDIFACT and ASC standards. As previously stated, NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization, with over 25 years experience in the pharmacy health care industry, and its membership consists of over

1,300 members representing virtually every sector of the pharmacy services industry. These standards are voluntary, consensus-based standards that were developed by NCPDP, and approved by full ballot voting in accordance with ANSI's procedures for due process, openness and consensus.

- Second, these standards are adopted HIPAA standards. In addition to being required standards for eligibility inquiries and responses between retail pharmacy dispensers and health plans, they are also required for submitting retail pharmacy drug claims. According to the NACDS, over 4 billion claims were transmitted in 2003 using NCPDP standards. In May 1998, when adoption of these standards was proposed through notice and comment rulemaking, the majority of comments received expressed support for adoption.

- Third, these standards are recognized as industry standards and are used by 99 percent of the retail pharmacies and 95 percent of all pharmacies in conducting eligibility transactions.

If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the **Federal Register** of an amendment to a

standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent 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. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version 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. In this context, we intend the term "backward compatible" to mean 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 e-prescribing transaction with entities that continue to use the previous version. We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 160

through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

F. Compliance Date

The Secretary proposes January 1, 2006 as the compliance date for these proposed foundation standards. Beginning January 1, 2006, prescribers and dispensers that conduct e-prescribing transactions for which standards are adopted, Part D sponsors would be required to use the standards proposed in this rule for transactions involving prescription or prescription-related information regarding Part D enrolled individuals. Compliance is required whether the entity conducts e-prescribing transactions directly or through an intermediary. The Secretary determined that compliance with these foundation standards should be consistent with and coincide with compliance for the Medicare Prescription Drug Program. In January 2006 when entities begin participation in the Medicare Prescription Drug Program, these proposed standards will be available for them to use in their electronic prescription drug program transactions for Medicare Part D drugs for Part D enrolled individuals.

### III. COLLECTION OF INFORMATION REQUIREMENTS

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

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

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

**§423.160 Standards for an electronic prescribing program.**

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

Therefore, as a third-party disclosure requirement subject to the PRA, 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 enrolled individuals as would be required under §423.160.

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, these entities will be required to comply with the adopted final standards only if they transmit prescription information electronically as discussed in section 1860D-4(e)(1) and (2) of the Act.

Testimony presented to the NCVHS indicated that most health plans/PBMs currently have e-prescribing capability either directly or by contracting with another entity. Therefore, we do not believe that conducting an electronic

prescription drug program would be an additional burden for those plans.

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).

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

If you comment on any of these information collection requirements, please mail copies directly to the following:  
Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs,  
Regulations Development and Issuances Group,  
Attn: John Burke, CMS-0011-P  
Room C5-14-03, 7500 Security Boulevard,  
Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs,

Office of Management and Budget,  
Room 10235, New Executive Office Building,  
Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer,  
CMS-0011-P, [Christopher\\_Martin@omb.eop.gov](mailto:Christopher_Martin@omb.eop.gov). Fax  
(202) 395-6974.

#### IV. Regulatory Impact Analysis

[If you choose to comment on issues in this section, please include the caption "IMPACT ANALYSIS" at the beginning of your comments.]

##### A. Overall Impact

We have examined the impacts of this 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) and 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 also, 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 were written in the United States in 2003, with the average cost for a prescription ranging from \$45 to \$67, totaling \$154 billion. 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, available online at <http://www.gpoaccess.gov>) estimates that in calendar year (CY) 2006 as about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan (that is, a PDP or MA-PD). By CY 2010, with growth in the overall Medicare population, estimates indicate that about 35 million Medicare beneficiaries will be receiving this drug coverage. This impact analysis discusses the overall impact of instituting e-prescribing standards under the Medicare Prescription Drug Program. The overall requirements for supporting e-prescribing and providing incentives were discussed in the Medicare Prescription Drug Benefit proposed and final rules. However, the specific standards were not contained in that 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.<sup>7</sup> However, some studies have indicated increased prescriber interest and plans to move to e-prescribing. We anticipate that the use of the standards proposed in this rule, and the fact that we are proposing that these standards be available for 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 our sense of the likely expert consensus, we think it likely that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five 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. We invite public comment on our expectations for prescriber participation.

According to the Center for Information Technology Leadership (CITL), more than 8.8 million ADE occur each year in ambulatory care. E-prescribing helps to deliver relevant patient information at the time of prescribing.

E-prescribing would allow a critical first level of safety checks to occur when a medication is prescribed (in addition to the patient safety software used at the point-of-service and the retrospective drug utilization reviews that are performed). The CITL estimates that nationwide adoption of e-prescribing would eliminate nearly 2.1 million ADEs per year in the U.S. This would prevent nearly 1.3 million

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<sup>7</sup>Howell, Investors Business Daily, September 15, 2003.

provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs. These improvements would 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, utilization of other health care services, and related costs for certain groups of patients. E-prescribing would 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 Randomised 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 which are designed to improve medication use and

reduce the risk of adverse events, including adverse drug interactions, will be enhanced by e-prescribing. 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 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, the adoption of e-prescribing by prescribers, 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 very substantial.

The ASC X12N 270/271 Transaction and the NCPDP Telecommunication Standard proposed in this rule for e-prescribing transactions, are already adopted standards for HIPAA. Thus, any costs associated with adoption of these transaction standards are already encompassed in the baseline. (The impact of implementing these standards was analyzed and adopted in the Health Insurance Reform: Standards for Electronic Transactions final rule, published on August 17, 2000 in the **Federal Register** (65 FR 50312-50372) 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 proposal. In that rule, we knew that many of the electronic claims standards we were requiring were incompatible with many of those already in use for electronic billing of Medicare claims. In this proposed rule, we know that a substantial number of prescribers and other entities are already using the standards we are proposing. Thus, while the Transactions Rule and this proposed rule share common goals and methods, they have different implementation consequences.

It is important to understand that this proposed rule involves both mandatory and voluntary elements, but that 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 (if any), transitioning to the foundation standards will be mandatory to continue e-prescribing (with the option of returning to paper) 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.

We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis. We plan to publish a more complete impact analysis in the final rule, including an assessment of impacts on the Medicare program, the effect on Part D spending, annual savings to Medicare, costs to plans and providers, and estimated costs and savings for the private sector and other Federal programs.

#### B. Impact on Health Plans/PBMs

The final rule on the Medicare Program Prescription Drug Benefit estimates that 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program. 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 would 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. We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request 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.

The only expense attributable to health plans by this impact analysis are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing. We expect many plans to provide these incentives to prescribers to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. We expect that this will be a transfer of costs from prescribers to health plans, and will neither increase nor decrease the overall impact of implementing an electronic

prescription drug program. We note that such incentives must not and will not violate Federal or State laws prohibiting kickbacks and physician self-referrals. As stated earlier in the preamble, we will publish a proposed rule to create an exception under section 1877 of the Act, commonly called the Stark law, for incentives related to e-prescribing. Also, the Department's Inspector General is considering how best to establish a safe harbor under the Anti-Kickback Statute.

Health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely 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. We request public comments and information on this topic that we can utilize when revising this analysis for the final rule.

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 \$1500 per prescriber. At this time, a number of health plans are developing incentive packages for

prescribers to initiate e-prescribing; however, we do not have figures to indicate the extent of these offerings, and invite public comment on the impact for both prescribers and health plans. Because we cannot estimate at this time the incentives that plans may provide, we do not know how costs will be shared between prescribers and plans. Therefore, at this time we are attributing all of the costs to prescribers, as discussed in the next section.

### C. 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. 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 exists, which 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.

After this proposed rule becomes final, once a prescriber decides to conduct e-prescribing for Part D drugs, for Part D enrolled beneficiaries, the prescriber would be required to comply with the standards being proposed in this regulation. However, we have no reason to believe that the use of these particular proposed standards would 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, we would expect vendors to upgrade those systems at no or

nominal cost as part of their normal version updating process. Moreover, a system that uses uniform standards would enable a prescriber to do business with multiple entities, and reduce costs compared to the alternative of having to deal with multiple conflicting systems. We do, however, request comments on whether there are some transition costs attributable to these standards and whether there are steps that we could take to mitigate those costs.

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 in 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 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, such arrangements

must not violate Federal and State laws prohibiting kickbacks and physician self-referrals). We invite 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 cost savings experienced with e-prescribing will encourage prescriber acceptance.

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 one 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.
- Prior to 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 would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.

As can be seen from this discussion, there are both potential costs and potential benefits for providers that implement e-prescribing. The number of prescriptions that a provider writes is a critical issue for providers in determining whether an e-prescribing system will be cost beneficial to them. Although a cost of approximately \$1500,

amortized over several years, would appear very small in the context of even a solo practitioner's overall practice costs (and certainly far below the threshold of 3 to 5 percent of revenues that we normally use for economic significance determinations under the RFA), it is possible that some providers may be negatively affected. However, the voluntary nature of e-prescribing for prescribers makes this unlikely, since each is free to make its own business decision regarding whether and how to implement e-prescribing. Prescribers that have already implemented e-prescribing are also unlikely to be negatively affected, because the standards we are proposing are currently used by most e-prescribing software products in use.

At this time we 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. We are requesting information on these factors to help us improve our analysis for the final rule. Additional examples of administrative savings from e-prescribing, as well as costs of implementing such systems, would be particularly beneficial.

#### D. 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. The industry has provided information indicating that 75 percent<sup>8</sup> of the 57,208 pharmacies<sup>9</sup> in the U.S. already have e-prescribing capability which suggests that pharmacies already find this a beneficial investment. 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

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<sup>8</sup> Hutchinson, Kevin, SureScripts. Testimony before the NCVHS Subcommittee on Standards and Security, May 25, 2004.

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 likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.

E. 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; and problems relating to coordination between health care providers and pharmacies. These reductions in errors and improvements in regimens would occur over time as more and more providers use the e-prescribing systems for the Medicare Prescription Drug Benefit.<sup>10</sup> E-prescribing can also drive physicians to appropriate formulary choices, which can save money for the health plans, patients, and

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<sup>9</sup> National Community Pharmacists' Association, press release, June 29, 2004.

health care system.

Nothing in this system creates direct costs for patients. We believe that reductions in patient mortality and morbidity would be a substantial benefit resulting from the adoption of e-prescribing, although we are unable at this time to provide quantitative estimates. Patient health benefits are likely to far exceed the other categories of benefits and direct costs.

#### F. 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. We have no estimates for these types of costs, and invite 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 such as pharmacies and PBMs; 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 invite public comment on the impact of e-prescribing for

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<sup>10</sup>To Err is Human: Building a Safer Health System, Institute of Medicine of the National Academies, 1999, pp. 191-193, <http://www.oim.edu> or <http://www.nap.edu>.

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.

#### G. Impact on Small Businesses

The RFA requires agencies to analyze options for regulatory relief for small businesses when proposed rules may create a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by 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 business based upon 1997 Census data. There are 57,208 retail pharmacy establishments based upon "2004 National Community Pharmacists Association Pfizer Digest." Therefore, we estimate that more than 29,000 pharmacy establishments would be considered small entities. Almost all physicians in private practice (or the practices of which they are members) are small entities because their annual revenues do not meet the Small Business Administration's \$8.5 million

threshold for "small" physician practices. Individuals and States are not included in the definition of a small entity, and this proposed rule has no effect on small governmental jurisdictions.

We believe that this proposed rule would have an impact on a substantial number of small businesses due to the percentage 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 proposed 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 under section 1850D-4(e)(1) of the Act if they electronically transmit prescriptions or other information, with respect to Part D drugs for beneficiaries enrolled in Part D. Finally, we believe that the effects of adoption are economically beneficial to affected entities.

We note that this conclusion differs from the impact of the HIPAA Transactions Rule. The HIPAA Transactions

Rule, although voluntary for health care providers, 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 we are proposing.

Accordingly, we conclude that this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. We welcome comments on this conclusion and additional information on the small business effects of this proposed rule.

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. This proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay. Prescription drugs provided during hospital stays are covered under Medicare as part of Medicare payments to hospitals. Therefore, we are not providing an analysis. We further estimate that this proposed rule would 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 would, therefore, have no net costs imposed upon them by adoption of e-prescribing.

#### H. 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 \$110 million. The private sector would incur costs for hardware and software upgrades, and connectivity for implementation of e-prescribing. However, except for MA and PDP plans, this proposed rule does not include any mandate that would 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 \$110 million annually. Certainly, we would 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 proposed 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 would not incur any direct costs as a result of this proposed rule.

However, as discussed previously in this preamble, and as mandated by section 1860D-4(e) of the Act, we are proposing

to preempt State law. Under the Executive Order, we are required to minimize the extent of preemption, consistent with achieving the objectives of the Federal statute, and to meet certain other conditions. We believe that, taken as a whole, this proposed rule would meet these requirements. We do seek comments from States and other entities on possible problems and on ways to minimize conflicts, consistent with achieving the objectives of the MMA, and will be undertaking outreach to States on these issues.

We have consulted with the National Association of Boards of Pharmacy directly and through participation in NCVHS hearings, and we believe that the approach we 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. We will consult further with States before issuing the final rule. This section, together with the earlier preamble section entitled "State Preemption", constitute the Federalism summary impact statement required under the Executive Order.

#### I. Conclusion and Alternatives Considered

For the reasons given above, we are not preparing analyses under the RFA, section 1102(b) of the Act, or the Unfunded Mandates Reform Act. We have, nevertheless, considered the alternatives discussed below. We welcome comments on ways to lessen any unforeseen burden of our

proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.

Two sets of standards that we are proposing in this rule already are required standards under the Administrative Simplification provisions of HIPAA. The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response and NCPDP Telecommunication Standard are adopted standards and required when conducting standard transactions. We are proposing these standards for e-prescribing because they are already adopted standards for HIPAA transactions and meet some of the requirements specified in Title I, section 1860D-4(e) of the Act, as amended by section 101 of the MMA.

The NCPDP SCRIPT Standard is in widespread use and meets many of the e-prescribing requirements outlined in section 1860D-4(e) of the Act. Also, NCPDP is developing NCPDP SCRIPT transactions to meet other MMA requirements for future consideration or pilot testing. The NCVHS did not recommend any viable alternatives for e-prescribing foundation standards because testimony presented by the industry during the NCVHS hearings strongly supported the NCPDP SCRIPT Standard (available on the web at <http://www.ncvhs.hhs.gov>).

An alternative to adopting these particular standards as final foundation standards for e-prescribing would be to pilot test the recommended standards. The NCVHS did not

recommend pilot testing for these foundation standards because they are already adopted standards with adequate industry experience.

Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.

**List of Subjects 42 CFR Part 423**

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

For reasons set forth in the preamble in this proposed regulation, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Part 423 (to be published on January 28, 2005 and effective on March 22, 2005) 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 title 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 shall have the same meaning as this term is defined 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.

Electronic Prescription Drug Program means 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.

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 a Part D eligible individual enrolled in a Part D plan.

\* \* \* \* \*

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 enrolled in a Part D plan.

(2) 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 enrolled in a Part D plan.

(b) Standards. (1) Prescription. The National Council for Prescription Drug Programs SCRIPT Standard, 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 American 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, 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 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) 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, 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 American 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 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) 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](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 American

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, October 2002, Washington Publishing Company, 004010X092A1 from the Washington Publishing Company, PMB

161, 5284 Randolph Road Rockville, MD, 20852-2116; Telephone (301) 949-9740; and FAX: (301) 949-9742 or

<http://www.wpc-edi.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) 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.ncpdp.org>.

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

Dated: \_\_\_\_\_

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**Mark B. McClellan,**  
Administrator,  
Centers for Medicare & Medicaid  
Services.

Approved: \_\_\_\_\_

\_\_\_\_\_  
**Tommy G. Thompson,**  
Secretary.

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