Submitter : **Mr. Michael Simko** **Date: 04/05/2005**

Organization : **Walgreens**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-41-Attach-1.DOC

CMS-0011-P-41-Attach-2.DOC

Walgreens
The Pharmacy America Trusts

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

Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments

Centers for Medicare and Medicaid Services:

The Walgreen Company is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Walgreens was founded in 1901. Walgreens operates more than 4700 stores in 45 states and Puerto Rico. Walgreens Drug Stores fill over 1 million prescriptions daily and account for 14% of all retail pharmacy prescriptions dispensed in the United States. Walgreens has been an active participant in eprescribing for over 10 years. Walgreens submits the following responses regarding the NPRM.

I. Background (F. R. page 6257)

A. Statutory Basis

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.

WALGREEN RESPONSE:

Walgreens agrees with and participated in the formation of the NCPDP response.

Section 1860D-4(e)(4)(C)(ii) of the Act 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. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American

National Standards Institute (ANSI) accredited. There is concern that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

Walgreens supports the naming of standards as draft foundation standards and CMS should encourage adoption on a voluntary basis while these standards go through the ANSI-accredited Standards Development Organization. CMS should not mandate by law these draft foundation standards, until they have been approved. CMS should also not wait until the 2008/2009 dates to adopt these standards.

As pilots go through the testing phase, standards not currently adopted, as foundation standards may need to be changed and amended before final adoption. Because of the level of interoperability being suggested as eprescribing moves forward, Walgreens supports the ongoing evaluation of standards by NCVHS and wants to ensure the equal participation of all entities in the entire eHealth continuum.

Standards need to be dynamic and should be reviewed by an official group for ongoing relevancy, adoptibility, adaptability, and practicality.

2. State Preemption (F.R. page 6259)

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.

WALGREENS RESPONSE:

Walgreens agrees with and participated in the formation of the NCPDP response.

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable, national scheme, physicians and pharmacists will be uncertain as to their obligations with respect to Medicare-covered prescriptions as opposed to other electronic prescriptions which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic e-prescribing software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer (e.g., where multiple coverages exist, which coverage will be the ultimate payer under coordination of benefit rules).

"Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available or cannot make available because the determination of coverage isn't made until the actual script is filled and the claim is adjudicated. Patients with multiple benefit plans and secondary payers may present other problems at the point of care as well, such as which formulary and benefit information,. The rules affecting *how* electronic prescribing is done should not vary based on who the ultimate payer will be.

CMS stated in the preamble to the NPRM "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of State law that will require detailed analysis in all 50 states to determine whether existing State law should be read to mingle with Federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a State requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that State require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?
- Does a Medicare prescription transmitted electronically need to meet State rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable State forbids such intermediaries?
- Can the physician or pharmacist be disciplined under State law where a prescription is sent electronically according to the Federal rule but it is deficient for State law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer), which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of this ambiguity and confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

We believe a single, national set of regulations for electronic prescribing is in the interest of all parties, including the states. The principal concern of states would not likely be that the Federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that State Boards of Pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the State Boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- Transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- Rules relating to formatting of prescriptions and documentation of the prescriber's intent
- Rules relating to authentication of the prescriber and dispenser
- Rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of Federal and State laws affecting all electronic prescriptions.

The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a

broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant State law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as Federal standards are adopted for electronic prescriptions, they preempt any contrary State standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all State rules on those topics with respect to all electronic prescriptions.

As similar situations will exist with other pharmacy chains that have pharmacy operations across states, a single set of regulations governing eprescribing is essential for the interoperability of systems, such as EMR's, RHIO's, and NHIN. Variations across states in eprescribing regulations will be expensive to build, difficult to maintain, and will slow down adoption and implementation of eprescribing.

There should be federal preemption of contrary state regulations regarding eprescribing.

Walgreens agrees with NCPDP's position on Long Term Care Setting:

Regarding Long Term Care Settings:

1. Federal, State and insurance payers require paper verification of services rendered including physicians and other health care provider's non-electronic signatures. In order for e-prescribing to work in the LTC setting, the State and Federal survey processes must accept electronic records and signatures.
2. Due to the numerous changes in the level of care for beneficiaries in the nursing facility the e-prescribing model must be available for all payment types not only Medicare Part D. The LTC setting needs a uniform industry standard for e-prescribing.
3. These proposed rules do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different State specific regulations pertaining to the record keeping of controlled substance prescriptions. These State specific regulations are even more unique for the LTC pharmacies and facilities.

E. Current E-Prescribing Environment (F.R. page 6260)

WALGREEN RESPONSE – Walgreens supports and participated in the formation of NCPDP's response.

NCPDP, at the request of industry participants, has created a new work group for Long Term Care. The scope of this work group is:

> Work Group 14 Long Term Care, in conjunction with the other Work Groups, guides and advises payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation, supports data processing initiatives, and provides design alternatives for standards used within the long term care industry

It is expected that long term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy.

1. In order for e-prescribing to work in the LTC setting the beneficiaries eligibility information must be real time. In the LTC setting, physicians and facility nurses do not know a patient's pharmacy benefits eligibility and coverage. The industry has relied on the LTC pharmacy provider to keep this information. The pharmacy and nursing facility-billing offices communicate patient billing status (inpatient or outpatient) which changes by the skilled level of care determined by the patient's medical conditions.
2. Due to the numerous levels of care changes of a beneficiary on a daily basis within a nursing facility, real time eligibility information must be available to the pharmacy and physician to handle the formulary and prior authorization processes within e-prescribing to meet the coordination of benefits (COB) between Medicare Part A, B and D.
3. Medical records for nursing facility patients are located at the nursing facility, not in the physician's office. This causes difficulty when the patients' information is needed from their medical chart. The information gathering process is often left up to the LTC nurses and pharmacists.
4. For e-prescribing to work efficiently in a LTC setting an electronic health record (EHR) is needed. There is an increased need for process adaptations and communication between these healthcare professionals in LTC to assure nursing facilities meet the required Federal regulation to provide prescribed medications to nursing home residents in a "timely manner".

F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)

We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions and we solicit comments on these criteria...

Walgreens Response:

Please see response to section "***I. Background (F. R. page 6257) A. Statutory Basis***".

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.

WALGREENS RESPONSE:
Walgreens agrees with and participated in the formation of the NCPDP response.

Attached is the NCPDP response. Walgreens supports version management and believes that there should be adequate version control by a recognized standard setting organization. The challenge will be for the critical mass of participants to be functioning on supportable version releases to ensure connectivity and interoperability. There are inherent problems with large version release gaps that may impede support of new fields, message lengths, and relied upon data elements.

Walgreens recognizes the impact strict version control may have on entities that do not own their own code and must rely on outside vendors for programming and support. To that extent - Walgreens believes that there should be sufficient flexibility and adequate start date notices for the implementation of new versions and the sun-setting of older versions.

There exists a need for all SDO's to communicate version changes in various systems with adequate notice to ensure equal participation and interoperability of necessary interfaces between entities.

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing.

With the suggested naming of NCPDP SCRIPT Standard Version 5.0 in this NPRM, the industry will begin looking at this version, if they are not already supporting it. It is anticipated that industry participants will actually look at later versions of NCPDP SCRIPT Standard and implement these, since the modifications are not major, and then be able to support version 5.0 and above. It is also important to not negatively impact the traction of the current e-prescribing environment by naming a version the industry is not able to support timely. NCPDP SCRIPT

An NPRM on versioning methodology that is separate from this current e-prescribing NPRM may be required be for adopting this or a similar methodology. But the overall goal of this methodology would be to avoid the formal rulemaking process when introducing new versions of a standard while still allowing for a fully open process.

Walgreens suggests this process be followed for the NCPDP standards (and potentially other standards) named as part of the MMA or named in the future. The process would be invoked when the industry requests a new version of any of the NCPDP standards named as part of the MMA (excluding standards already named in HIPAA), or a new standard to be named. Walgreens also suggests that HHS consider using this process for advancing HIPAA named standards. The timings suggested above – such as the NCVHS reporting process – would have to be reviewed for feasibility and resource requirements. It may be better; for example, that NCVHS serve as the public announcement vehicle, but that the actual open forum is held by HHS or by the SDO itself.

An alternative step might be to schedule a regular, predictable cycle for holding hearings on submitting or retiring versions of a standard, for example. We welcome the opportunity to work with HHS to hone these concepts further so that they meet the needs of all stakeholders, comply with Federal law, and ultimately result in advancing patient care.

G. Electronic Prescription Drug Program (F.R. page 6261)

WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE:

Within the proposed rules the impact on the Nursing Facility, LTC Pharmacies or Physicians serving Nursing Facilities is not addressed, as related to the MMA.

1. In the LTC setting there is a need to develop technology for a three-way communication between off site physicians, nursing facility medical record and LTC provider pharmacies. Have some incentives for nursing facility staff for training of high turnover nursing staff and access to computers for data entry. Nursing facilities have very few computer workstations and are still using a very manual charting process.
2. Prescription Drug Plans (PDP), LTC pharmacies, physicians and nursing facilities may incur additional costs different than the ambulatory setting since a more complex process of a three-way communication must be developed for an e-prescribing model to be successful in the LTC setting.
3. If the LTC setting is excluded from an e-prescribing process, this could add a strain to the physicians who have ambulatory and nursing facility patients.

(F.R. page 6263)
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.

WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH THE NCPDP RESPONSE.

The NCPDP Provider ID is the current de facto standard pharmacy identifier used for both the NCPDP Telecommunication Standard Version 5.1 and the NCPDP SCRIPT Standard. Both of these standards will support the use of the NPI to identify the dispenser. Industry is only now analyzing the system changes necessary for industry to begin using the NPI for HIPAA named transactions. No analysis has been done to assess the impact of using the NPI as a standard identifier for pharmacies in electronic prescribing. It is not likely that pharmacies will realize any positive financial impact of making this change and doing so may slow voluntary adoption. Therefore, NCPDP believes since the use of the NPI for this purpose has not been proven, its use should not be accelerated.

The NPI and the NPPES were not designed with electronic prescribing in mind. For example, an NPI may be assigned to organizations and subparts, but organizations cannot prescribe, only people. Additionally, some prescribers are not currently required to obtain an NPI under the HIPAA regulations. If the NPI is named as a standard for electronic prescribing, it is imperative that all prescribers including those not sending or receiving HIPAA transactions be required to obtain an NPI. Allowing an alternative identifier for prescribers that do not need to obtain an NPI under HIPAA would only result in the need to support multiple identifiers, which is contrary to administrative simplification.

Because the NPI and the NPPES were not designed with electronic prescribing in mind, industry will need to devise other methods of determining routing instructions for prescribers with multiple practice addresses if used. Industry will also need to determine whether a given NPI is that of a prescriber or an organization. The use of proprietary databases mapping the NPI to routing information and providing other information needed for authentication will be critical to successful messaging. These mechanisms are not currently in place as the numbers currently used by industry support multiple practice addresses and only enumerate prescribers.

The NPI is not meant to replace the DEA number or the Taxpayer Identifying Number that were established for purposes other than the purpose of the NPI and careful consideration must be given to using the NPI for this new purpose.

NCPDP suggests that (1) both the NPI and the NCPDP HCIdea® prescriber identifier be utilized in pilot programs to determine the applicability of each of the identifiers, that (2) a standard identifier for prescribers be named only after there is adequate industry experience in the use of the named identifier and that if the NPI is the named standard, (3) acceptable business practices are available for distribution of the NPI file to the industry. Until that time, we suggest the e-prescribing industry continue to use existing identifiers that support business purposes that the NPI currently does not support, such as transaction routing to specific locations.

(F.R. page 6263)
NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® 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.

WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE.

There is adequate industry experience in using the NCPDP Provider Identifier Number for identifying dispensers. NCPDP recommends that this identifier should be supported until such time as the NPI has proven to be a successful identifier for electronic prescribing. To require the use of the NPI to identify dispensers for electronic prescribing prior to successful pilot testing would be a disservice to e-prescribing and may slow voluntary adoption.

In identifying prescribers, NCPDP suggests that both the NPI and NCPDP HCIdea® are included in pilot tests and that the standard identifier best suited for electronic prescribing is selected for that purpose. If not selected as the standard prescriber identifier for e-prescribing, the HCIdea® Database may prove to be useful as a bridge for dispensers between the DEA, the NPI, and other identifiers currently used for prescriber identification. This bridge or cross walk between the NCPDP HCIdea®, the NPI, the DEA and other possible identifiers such as State license number and UPIN number m ay support healthcare organizations in populating their prescriber files with the proper NPI for each prescriber, linking one prescriber to multiple practice addresses and routing SCRIPT messages to the proper practice address (which can not be done with the NPI alone).

Formulary and Medication History Standards (F.R. page 6263)
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:

WALGREENS RESPONSE:

Testimony to NCVHS showed industry experience. Medication History Standard has been brought forth to NCPDP and is being balloted. The Formulary and Benefit Standard has been brought forth to NCPDP and upon approval, will be taken to ballot. As with any standard, if business needs are brought forward, they will be discussed and taken through the approval process.

(F.R. page 6263)
We propose the following critical characteristics for formulary and benefit data standards:
WALGREENS RESPONSE: SEE ABOVE
See above.
(F.R. page 6263)
We WALGREENS RESPONSE: SEE ABOVE
See above.

Drug Information (F.R. Page 6264)
We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.

WALGREENS RESPONSE:

Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. Access to referential electronic drug information should be part of the overall physician practice management system and access to this type of information should not hinder the exchange of e-prescribing data. The availability and type of drug information made available to the prescriber should be determined by the prescriber's practice setting and individual needs.

H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)

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).*

WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF NCPDP'S RESPONSE.

WALGREENS supports these foundation standards. WALGREENS recommends that the minimum standard be the version named and that other higher versions, if backward compatible, are also acceptable, except where HIPAA supercedes this Final Rule. Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***", where it is recommended that consideration for changes be given to HIPAA-named transactions.

The completed NCVHS Standards Worksheet indicated several gaps in the ASC X12N 270/271 Eligibility Inquiry and Response Standard. The near term solution proposed

> *"Where there are gaps in the information that needs to be transmitted in the 271 response (such as the need for formulary or benefit identifiers) the transaction does have a free form message segment that could outline the details that cannot currently be codified."*

Until the long-term solution is adopted under HIPAA, NCPDP requests the ASC X12N 270/271 Workgroup publish a document that outlines the details on how to use the free form message. The benefit of the document is a consistent implementation of the free form message.

(F.R. Page 6264)

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.

WALGREENS RESPONSE:

There is no benefit to impeding the momentum driving the adoption of e-prescribing nor the development and implementation of standards for e-prescribing. E-prescribing and EHRs can exist both in an integrative and independent fashion. EHR is very broad and may be implemented in different timeframes and may be driven by different business and clinical needs. E-prescribing is available today and is being used in many clinical settings. As functionality is available, it should be incorporated into the whole continuum of care; but do not postpone implementation of the parts that are available today.

The simultaneous growth and emergence of both systems can occur at various stages independent of each other. There should be no "halt" in eprescribing development. HER is not yet "well defined" and will probably emerge more slowly than eprescribing connectivity.

II. Provisions of the Proposed Regulation (F.R. Page 6264)

B. Proposed Definitions (F.R. Page 6265)

- *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 or a Part D eligible individual enrolled in a Part D plan.*

WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.

Walgreens supports the definition of e-prescribing. E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information.

Non-EDI Messages (e.g., Faxes or Emails)

Messages that leave or enter the system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions.

Walgreens supports the definition of electronic media.

Walgreens recommends the definition of Prescriber be expanded to authorized prescribers of drugs for human or animal use.

C. Proposed Requirements for Part D Plans (F.R. Page 6265)

(F.R. Page 6265)

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.

WALGREENS RESPONSE:

Standards should be used when transmitting outside of the enterprise and the inter-connection of separate systems.

E. Proposed Standards (F.R. Page 6265)

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.

WALGREENS RESPONSE:

Walgreens trading partners using these transactions, especially in the 2006 pilots. Walgreens supports this approach

(F.R. Page 6265)

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

WALGREENS RESPONSE:

Walgreens supports these transactions being adopted.

(F.R. Page 6266)

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.

WALGREENS RESPONSE: Walgreens agrees with and participated in the formation of NCPDP's response.

There is a difference between "adopt" and "require". NCPDP prefers CMS adopt these different transactions, but not require them unless the business need or the technology solution is demonstrated. For example, if a provider is connected via the internet/leased line/frame relay, they may not need to support GETMSG mailboxing functions. Why require it when they do not need it?

There is industry experience with STATUS and ERROR. The STATUS and ERROR messages are used today, and these are part of the "real-time" request and response environment of transaction processing. The STATUS and ERROR messages perform transactional functionality; this is different than the housekeeping transactions.

The GETMSG and PASCHG are housekeeping functions. There is adequate industry experience with GETMSG and PASCHG, for those entities needing the functionality.

GETMSG and PASCHG are in a sense internal messages: they flow only between a provider and his mailboxing service (e.g., aggregator), not from one provider to another. Thus, an aggregator may never see GETMSGs from prescribers or an aggregator may never see GETMSGs from pharmacies (depending on the relationship of the technology between the aggregator and the provider). In some instances where a partner does not have a static IP address and "listening capabilities" the GETMSG and PASCHG are being used.

VERIFY is a return receipt function. VERIFY is only used when someone needs it (much like requesting return receipt at USPS; not all mail needs return receipt). The VERIFY message may be used by the end users and sometimes by network partners. There is industry experience using VERIFY, although it should not be a required function as it is not a business function transaction, but rather a special case transaction.

2. Eligibility (F.R. Page 6266)

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...

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. First, these standards adhere to EDI for EDIFACT and ASC standards.

WALGREENS RESPONSE:

The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

A clarification. The NCPDP Telecommunication Standard is EDI and was named in HIPAA. It does not adhere to EDIFACT or ASC standards. The NCPDP Telecommunication Standard was named in HIPAA for eligibility between pharmacies and payers. The pharmacy industry will be using the Telecommunication Standard for eligibility checking under MMA, especially in determining coordination of benefits information.

E-prescribing should not be hindered by the length of time that modifications are adopted in HIPAA named transactions.

(F.R. Page 6267)
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.*

WALGREENS RESPONSE:

Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

(F.R. Page 6267)
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.

WALGREENS RESPONSE:
Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

IV. Regulatory Impact Analysis (F.R. Page 6268)

We invite public comment on our expectations for prescriber participation.

WALGREENS RESPONSE:
Please see NCPDP's response at section "***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)
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.

WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.

The NPI is not in use today and the impact on pharmacies of adopting the NPI as an identifier for the electronic Prescriber may not be positive. Prescribers are defined as people and NPIs are to be assigned to places as well as people. The NPPES was not designed with e-prescribing in mind. Some Prescribers do not submit HIPAA transactions and will not have NPIs. The impact could well be negative if the NPI is not piloted and electronic prescriptions are received by pharmacies from places.

It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new standards and new versions of the standards must be predictable and timely (i.e., sensitive to current industry adoption capabilities)

so as not to negatively impact the movement of the industry as it addresses new business functions and needs.

E. Impact on Patients (F.R. Page 6271)

WALGREENS RESPONSE:

We agree that the adoption of electronic prescribing will have a net positive impact on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance.

G. Impact on Small Businesses (F.R. Page 6271)

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.

WALGREENS RESPONSE:

Participants of NCPDP noted that small businesses, independent pharmacies; small prescriber environments are already using SCRIPT. We are not aware of other studies and agree that more studies will need to be funded to assess and evaluate the overall impact on each of the participant entities. These would be valuable to the industry as a whole.

H. Effects on States and Federalism Statement (F.R. Page 6272)

WALGREENS RESPONSE:

Please see response at section "***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)***".

I. Conclusions and Alternatives Considered (F.R. Page 6272)

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.

WALGREENS RESPONSE:

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard. Please see comments in Section *"G. Electronic Prescription Drug Program (F.R. page 6261)."* Walgreens believes that the NCPDP HCIdea prescriber identifier, which enumerates prescribers and not places, should be piloted as an alternative to the NPI for e-prescribing applications if needed. Careful consideration needs to avoid undue burden on pharmacy systems and prescribers in implementing too complex a message routing format.

(F.R. Page 6273)

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.

WALGREENS RESPONSE:

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard, and the Formulary and Benefit Standard.

PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard.

Conclusion:

Walgreens supports an eprescribing system – including EMR's that allows rapid adoption by all participating entities utilizing proven industry standards such as NCPDP Script. While foundation standards can be initially implemented, attention must be paid to adapting standards in a structured way that is fair to all participants in a practical timeframe without slowing down the adoption of eprescribing and EMR implementation.

Walgreens believes in the preemption in contrary State pharmacy regulations concerning eprescribing. These will only hinder adoption and slow the process of gaining the patient safety and improvement of care benefits EMR's and eprescribing will bring.

Thank-you

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Walgreens
The Pharmacy America Trusts

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

Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments

Centers for Medicare and Medicaid Services:

The Walgreen Company is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Walgreens was founded in 1901. Walgreens operates more than 4700 stores in 45 states and Puerto Rico. Walgreens Drug Stores fili over 1 million prescriptions daily and account for 14% of all retail pharmacy prescriptions dispensed in the United States. Walgreens has been an active participant in eprescribing for over 10 years. Walgreens submits the following responses regarding the NPRM.

I. Background (F. R. page 6257)

A. Statutory Basis

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.

WALGREEN RESPONSE:

Walgreens agrees with and participated in the formation of the NCPDP response.

Section 1860D-4(e)(4)(C)(ii) of the Act 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. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American

National Standards Institute (ANSI) accredited. There is concern that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

Walgreens supports the naming of standards as draft foundation standards and CMS should encourage adoption on a voluntary basis while these standards go through the ANSI-accredited Standards Development Organization. CMS should not mandate by law these draft foundation standards, until they have been approved. CMS should also not wait until the 2008/2009 dates to adopt these standards.

As pilots go through the testing phase, standards not currently adopted, as foundation standards may need to be changed and amended before final adoption. Because of the level of interoperability being suggested as eprescribing moves forward, Walgreens supports the ongoing evaluation of standards by NCVHS and wants to ensure the equal participation of all entities in the entire eHealth continuum.

Standards need to be dynamic and should be reviewed by an official group for ongoing relevancy, adoptibility, adaptability, and practicality.

2. State Preemption (F.R. page 6259)

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.

WALGREENS RESPONSE:

Walgreens agrees with and participated in the formation of the NCPDP response.

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable, national scheme, physicians and pharmacists will be uncertain as to their obligations with respect to Medicare-covered prescriptions as opposed to other electronic prescriptions which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic e-prescribing software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer (e.g., where multiple coverages exist, which coverage will be the ultimate payer under coordination of benefit rules).

"Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available or cannot make available because the determination of coverage isn't made until the actual script is filled and the claim is adjudicated. Patients with multiple benefit plans and secondary payers may present other problems at the point of care as well, such as which formulary and benefit information,. The rules affecting *how* electronic prescribing is done should not vary based on who the ultimate payer will be.

CMS stated in the preamble to the NPRM "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of State law that will require detailed analysis in all 50 states to determine whether existing State law should be read to mingle with Federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a State requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that State require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?
- Does a Medicare prescription transmitted electronically need to meet State rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable State forbids such intermediaries?
- Can the physician or pharmacist be disciplined under State law where a prescription is sent electronically according to the Federal rule but it is deficient for State law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer), which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of this ambiguity and confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

We believe a single, national set of regulations for electronic prescribing is in the interest of all parties, including the states. The principal concern of states would not likely be that the Federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that State Boards of Pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the State Boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- Transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- Rules relating to formatting of prescriptions and documentation of the prescriber's intent
- Rules relating to authentication of the prescriber and dispenser
- Rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of Federal and State laws affecting all electronic prescriptions.

The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a

broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant State law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as Federal standards are adopted for electronic prescriptions, they preempt any contrary State standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all State rules on those topics with respect to all electronic prescriptions.

As similar situations will exist with other pharmacy chains that have pharmacy operations across states, a single set of regulations governing eprescribing is essential for the interoperability of systems, such as EMR's, RHIO's, and NHIN. Variations across states in eprescribing regulations will be expensive to build, difficult to maintain, and will slow down adoption and implementation of eprescribing.

There should be federal preemption of contrary state regulations regarding eprescribing.

Walgreens agrees with NCPDP's position on Long Term Care Setting:

Regarding Long Term Care Settings:

1. Federal, State and insurance payers require paper verification of services rendered including physicians and other health care provider's non-electronic signatures. In order for e-prescribing to work in the LTC setting, the State and Federal survey processes must accept electronic records and signatures.
2. Due to the numerous changes in the level of care for beneficiaries in the nursing facility the e-prescribing model must be available for all payment types not only Medicare Part D. The LTC setting needs a uniform industry standard for e-prescribing.
3. These proposed rules do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different State specific regulations pertaining to the record keeping of controlled substance prescriptions. These State specific regulations are even more unique for the LTC pharmacies and facilities.

E. Current E-Prescribing Environment (F.R. page 6260)

WALGREEN RESPONSE – Walgreens supports and participated in the formation of NCPDP's response.

NCPDP, at the request of industry participants, has created a new work group for Long Term Care. The scope of this work group is:

> Work Group 14 Long Term Care, in conjunction with the other Work Groups, guides and advises payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation, supports data processing initiatives, and provides design alternatives for standards used within the long term care industry

It is expected that long term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy.

1. In order for e-prescribing to work in the LTC setting the beneficiaries eligibility information must be real time. In the LTC setting, physicians and facility nurses do not know a patient's pharmacy benefits eligibility and coverage. The industry has relied on the LTC pharmacy provider to keep this information. The pharmacy and nursing facility-billing offices communicate patient billing status (inpatient or outpatient) which changes by the skilled level of care determined by the patient's medical conditions.
2. Due to the numerous levels of care changes of a beneficiary on a daily basis within a nursing facility, real time eligibility information must be available to the pharmacy and physician to handle the formulary and prior authorization processes within e-prescribing to meet the coordination of benefits (COB) between Medicare Part A, B and D.
3. Medical records for nursing facility patients are located at the nursing facility, not in the physician's office. This causes difficulty when the patients' information is needed from their medical chart. The information gathering process is often left up to the LTC nurses and pharmacists.
4. For e-prescribing to work efficiently in a LTC setting an electronic health record (EHR) is needed. There is an increased need for process adaptations and communication between these healthcare professionals in LTC to assure nursing facilities meet the required Federal regulation to provide prescribed medications to nursing home residents in a "timely manner".

F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)

We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions and we solicit comments on these criteria...

Walgreens Response:

Please see response to section "***I. Background (F. R. page 6257) A. Statutory Basis***".

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.

WALGREENS RESPONSE:
Walgreens agrees with and participated in the formation of the NCPDP response.

Attached is the NCPDP response. Walgreens supports version management and believes that there should be adequate version control by a recognized standard setting organization. The challenge will be for the critical mass of participants to be functioning on supportable version releases to ensure connectivity and interoperability. There are inherent problems with large version release gaps that may impede support of new fields, message lengths, and relied upon data elements.

Walgreens recognizes the impact strict version control may have on entities that do not own their own code and must rely on outside vendors for programming and support. To that extent - Walgreens believes that there should be sufficient flexibility and adequate start date notices for the implementation of new versions and the sun-setting of older versions.

There exists a need for all SDO's to communicate version changes in various systems with adequate notice to ensure equal participation and interoperability of necessary interfaces between entities.

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing.

With the suggested naming of NCPDP SCRIPT Standard Version 5.0 in this NPRM, the industry will begin looking at this version, if they are not already supporting it. It is anticipated that industry participants will actually look at later versions of NCPDP SCRIPT Standard and implement these, since the modifications are not major, and then be able to support version 5.0 and above. It is also important to not negatively impact the traction of the current e-prescribing environment by naming a version the industry is not able to support timely. NCPDP SCRIPT

An NPRM on versioning methodology that is separate from this current e-prescribing NPRM may be required be for adopting this or a similar methodology. But the overall goal of this methodology would be to avoid the formal rulemaking process when introducing new versions of a standard while still allowing for a fully open process.

Walgreens suggests this process be followed for the NCPDP standards (and potentially other standards) named as part of the MMA or named in the future. The process would be invoked when the industry requests a new version of any of the NCPDP standards named as part of the MMA (excluding standards already named in HIPAA), or a new standard to be named. Walgreens also suggests that HHS consider using this process for advancing HIPAA named standards. The timings suggested above – such as the NCVHS reporting process – would have to be reviewed for feasibility and resource requirements. It may be better; for example, that NCVHS serve as the public announcement vehicle, but that the actual open forum is held by HHS or by the SDO itself.

An alternative step might be to schedule a regular, predictable cycle for holding hearings on submitting or retiring versions of a standard, for example. We welcome the opportunity to work with HHS to hone these concepts further so that they meet the needs of all stakeholders, comply with Federal law, and ultimately result in advancing patient care.

G. Electronic Prescription Drug Program (F.R. page 6261)

WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE:

Within the proposed rules the impact on the Nursing Facility, LTC Pharmacies or Physicians serving Nursing Facilities is not addressed, as related to the MMA.

1. In the LTC setting there is a need to develop technology for a three-way communication between off site physicians, nursing facility medical record and LTC provider pharmacies. Have some incentives for nursing facility staff for training of high turnover nursing staff and access to computers for data entry. Nursing facilities have very few computer workstations and are still using a very manual charting process.
2. Prescription Drug Plans (PDP), LTC pharmacies, physicians and nursing facilities may incur additional costs different than the ambulatory setting since a more complex process of a three-way communication must be developed for an e-prescribing model to be successful in the LTC setting.
3. If the LTC setting is excluded from an e-prescribing process, this could add a strain to the physicians who have ambulatory and nursing facility patients.

(F.R. page 6263)
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.

WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH THE NCPDP RESPONSE.

The NCPDP Provider ID is the current de facto standard pharmacy identifier used for both the NCPDP Telecommunication Standard Version 5.1 and the NCPDP SCRIPT Standard. Both of these standards will support the use of the NPI to identify the dispenser. Industry is only now analyzing the system changes necessary for industry to begin using the NPI for HIPAA named transactions. No analysis has been done to assess the impact of using the NPI as a standard identifier for pharmacies in electronic prescribing. It is not likely that pharmacies will realize any positive financial impact of making this change and doing so may slow voluntary adoption. Therefore, NCPDP believes since the use of the NPI for this purpose has not been proven, its use should not be accelerated.

The NPI and the NPPES were not designed with electronic prescribing in mind. For example, an NPI may be assigned to organizations and subparts, but organizations cannot prescribe, only people. Additionally, some prescribers are not currently required to obtain an NPI under the HIPAA regulations. If the NPI is named as a standard for electronic prescribing, it is imperative that all prescribers including those not sending or receiving HIPAA transactions be required to obtain an NPI. Allowing an alternative identifier for prescribers that do not need to obtain an NPI under HIPAA would only result in the need to support multiple identifiers, which is contrary to administrative simplification.

Because the NPI and the NPPES were not designed with electronic prescribing in mind, industry will need to devise other methods of determining routing instructions for prescribers with multiple practice addresses if used. Industry will also need to determine whether a given NPI is that of a prescriber or an organization. The use of proprietary databases mapping the NPI to routing information and providing other information needed for authentication will be critical to successful messaging. These mechanisms are not currently in place as the numbers currently used by industry support multiple practice addresses and only enumerate prescribers.

The NPI is not meant to replace the DEA number or the Taxpayer Identifying Number that were established for purposes other than the purpose of the NPI and careful consideration must be given to using the NPI for this new purpose.

NCPDP suggests that (1) both the NPI and the NCPDP HCIdea® prescriber identifier be utilized in pilot programs to determine the applicability of each of the identifiers, that (2) a standard identifier for prescribers be named only after there is adequate industry experience in the use of the named identifier and that if the NPI is the named standard, (3) acceptable business practices are available for distribution of the NPI file to the industry. Until that time, we suggest the e-prescribing industry continue to use existing identifiers that support business purposes that the NPI currently does not support, such as transaction routing to specific locations.

(F.R. page 6263)
NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® 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.

WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE.

There is adequate industry experience in using the NCPDP Provider Identifier Number for identifying dispensers. NCPDP recommends that this identifier should be supported until such time as the NPI has proven to be a successful identifier for electronic prescribing. To require the use of the NPI to identify dispensers for electronic prescribing prior to successful pilot testing would be a disservice to e-prescribing and may slow voluntary adoption.

In identifying prescribers, NCPDP suggests that both the NPI and NCPDP HCIdea® are included in pilot tests and that the standard identifier best suited for electronic prescribing is selected for that purpose. If not selected as the standard prescriber identifier for e-prescribing, the HCIdea® Database may prove to be useful as a bridge for dispensers between the DEA, the NPI, and other identifiers currently used for prescriber identification. This bridge or cross walk between the NCPDP HCIdea®, the NPI, the DEA and other possible identifiers such as State license number and UPIN number m ay support healthcare organizations in populating their prescriber files with the proper NPI for each prescriber, linking one prescriber to multiple practice addresses and routing SCRIPT messages to the proper practice address (which can not be done with the NPI alone).

Formulary and Medication History Standards (F.R. page 6263)
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:

WALGREENS RESPONSE:

Testimony to NCVHS showed industry experience. Medication History Standard has been brought forth to NCPDP and is being balloted. The Formulary and Benefit Standard has been brought forth to NCPDP and upon approval, will be taken to ballot. As with any standard, if business needs are brought forward, they will be discussed and taken through the approval process.

(F.R. page 6263)
We propose the following critical characteristics for formulary and benefit data standards:
WALGREENS RESPONSE: SEE ABOVE
See above.
(F.R. page 6263)
We WALGREENS RESPONSE: SEE ABOVE
See above.

WALGREENS RESPONSE:

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard, and the Formulary and Benefit Standard.

PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard.

Conclusion:

Walgreens supports an eprescribing system – including EMR's that allows rapid adoption by all participating entities utilizing proven industry standards such as NCPDP Script. While foundation standards can be initially implemented, attention must be paid to adapting standards in a structured way that is fair to all participants in a practical timeframe without slowing down the adoption of eprescribing and EMR implementation.

Walgreens believes in the preemption in contrary State pharmacy regulations concerning eprescribing. These will only hinder adoption and slow the process of gaining the patient safety and improvement of care benefits EMR's and eprescribing will bring.

Thank-you

Michael J. Simko, R.Ph.
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Submitter : Mr. Steve Tucker

Date: 04/05/2005

Organization : PacifiCare Health Systems

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Dr. Gary Stein **Date:** 04/05/2005

Organization : American Society of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-43-Attach-1.DOC

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0011–P
P.O. Box 8010
Baltimore, MD 21244–1850

American Society of
Health-System Pharmacists®
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Bethesda, Maryland 20814
301-657-3000
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Re: CMS-0011-P, Medicare Program; E-Prescribing and the Prescription Drug Program

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) February 4, 2005, proposed rule that would adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. In addition, our Section of Pharmacy Practice Managers has an Advisory Group on Computerized Prescriber Order Entry (CPOE) and Informatics, whose members have provided input for the following comments.

The standards that CMS proposes would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA. Our members have the following concerns about how these standards will be applied. Because of these concerns, particularly the lack of an consideration to pilot test the e-prescribing program, ASHP believes that implementation of final e-prescribing standards should be delayed beyond the proposed January 2006 date.

I. Background

Medication History

A patient's medical history is without a full history of filled and ordered prescriptions. Prescription Drug Plans (PDPs) need to recognize the importance of this complete patient profile, and should provide their network pharmacies with incentives to update their patient profiles for new prescriptions, whether or not they are covered by the PDP.

Currently, Pharmacy Benefit Managers (PBMs) have some limited data on a patient's medication history, but it is not complete. PBM medication history is often only available for those medications that are covered by a patient's plan – a moving and changing set of medications. Information on other medications, not covered by a PDP or PBM that a

patient is taking is essential to making e-prescribing work effectively. A listing of drugs that have been prescribed or claimed across multiple encounter types (inpatient, outpatient, urgent care, emergency care, etc.) and throughout the continuum of care should be required, including over-the-counter, herbal, and nutritional substances. This information is of the utmost value in the context of prescribing and reconciling medications on hospital admission and discharge.

Another concern is that the proposal does not specifically include pharmacists as having access to a patient's medical history." CMS recognizes that there are "disconnects between the prescriber and patient in the medication process," but does not seem to recognize that this disconnect can have serious consequences unless the pharmacist is also involved in the process. Disconnects or fragmentation within the prescribing process leads to fragmented care and adverse drug events. By utilizing electronic systems, the sharing of information in a patient's medical history and the ability to efficiently transfer care between health care providers will allow for improved continuity of care.

Standards

Although the currently adopted National Council for Prescription Drug Programs (NCPDP) standards are workable for transmitting billing information, they were not developed to provide clinical care and communicate effectively amongst all providers and across the continuum of care. The process of developing e-prescribing standards should utilize existing medication event/sentinel event root cause analysis data and other medication error reduction initiatives to examine important failures identified during the prescribing process. Many clinical practice quality groups have done important work analyzing the causes of medication errors, and CMS should utilize this information in the process to evolve adopted and additional standards.

National Provider Identifier (NPI)

From an e-prescribing perspective, the rapid implementation of an NPI is vital for appropriate follow-up and transfers to downstream care providers. These providers would include pharmacists who provide the medication therapy management program (MTMP) services mandated by the MMA, which CMS called "a cornerstone of the Medicare Prescription Drug Benefit" in the agency's January 28 final regulations for the Part D benefit. The concept of an NPI should be pilot tested early in order to better understand

its ramifications, its interrelationship with the HIPAA-mandated NPI and its acceptance by providers.

II. Provisions

Definitions

The proposed regulation defines "E-prescribing" as "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." Throughout the proposal, CMS refers to pharmacists as "dispensers." "Dispenser" is defined as "a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice."

The agency needs to recognize the clinical components of pharmacy work, especially since non-dispensing pharmacists may be significantly involved in providing Part D beneficiaries with the medication therapy management program services required by the MMA. These pharmacists should also be integrated into the e-prescribing program, as they will, by necessity, need to have access to a patient's medication history.

In addition, the definition of "Dispensers" should be modified to clarify that the pharmacist is responsible for the dispensing activity, which includes clinical verification, patient education, etc., as opposed to the pharmacy, which is a business entity.

Although incentives are offered to encourage prescribers to conduct e-prescribing, the proposal contains no requirements for electronic signatures. It is likely that physicians will use office staff to enter a patient's prescription information to obtain the financial incentive. This will result in safety issues. To get maximum clinical benefit, the regulations should specifically require prescriber order entry, including electronic signature by the actual prescriber. It should also require mechanisms to verify that only the prescribers are actually entering the data. The definition of "E-prescribing" should be

rewritten to clarify direct entry of prescriptions by prescribers as opposed to clerical staff and that e-prescribing does not include electronic claims adjudication.

Pilot Testing

The CMS proposal states that "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." Despite the National Committee on Vital and Health Statistics (NCVHS) observation that there is adequate industry experience for certain standards, these experiences are industry-driven, and despite some success they may not necessarily be in the best interests of those involved in the medication-use process and, most importantly, the patient.

Although the proposed standards are a good starting point, CMS must also recognize that the agency is setting the stage by stating what is and what is not important to address in the future. By not requiring pilot studies on these proposed standards or the standards developed after reviewing public comments, there will be little evidence on which to base Centers for Medicare & Medicaid Services future standards decisions. The standards being proposed have been used successfully to support reimbursement and manage medication costs and rebate revenues for PBMs. There is no evidence that they have supported better patient care. An example of why such pilot testing is necessary, is the situation in which Cedars-Sinai Medical Center in Los Angeles found itself when it had to suspend implementation of its CPOE system because of problems found while installing the system. According to an article in the *American Journal of Health-System Pharmacy* (Vol. 60, Apr. 1, 2003, pp. 635-42), Rita Shane, the institution's pharmacy director, noted that to be successful, "health systems should conduct extensive testing to identify what changes need to be made before implementing a system and to ensure that staff members clearly understand how to use" new technology.

There are assumptions that the current standards that serve the needs of PBMs and e-prescribing consortiums will provide additional information to support better patient care, but the CMS proposal does not provide a strategy to identify how the results of applying these standards will be measured.

It is vital that pilot projects are developed to represent a variety of practice models, including hospitals with outpatient infusion therapy centers, dialysis centers, oncology clinics, anticoagulation facilities, and dermatology clinics. The pilot projects should also

incorporate all types of prescribing, including IV infusions and Total Parenteral Nutrition.

Other Provision Issues

CMS states in the proposal that "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." The agency should also include allergy/intolerance checking, as well as validation of patient and correct indication if prescription ordering is linked to a patient problem list.

Another concern is that there are no requirements in the CMS proposed standard for the development of reasonable down-time processes when the electronic systems are not functioning.

IV. Impact Analysis

This section of the CMS proposal also recognizes the impact an e-prescribing system will have on pharmacies by reducing the number of telephone calls needed between a pharmacy and a prescriber. It should also include – but does not – the importance of communications between prescribers and pharmacies in order to override prescriptions due to clinical and formulary alerts. This could save a significant number of additional calls.

The CMS proposal references testimony by a representative of SureScripts that 75% of pharmacies in the United States have e-prescribing capability. Elsewhere, CMS states that only 5%-18% of prescribers are using this technology, which means that only the significantly lower percentage of prescriptions are being transmitted electronically. The discrepancy can be explained by the definition CMS proposes for e-prescribing, which would also include electronic prescription adjudication. Because of the SureScripts testimony, CMS assumes that the e-prescribing initiative will have minimal impact on pharmacies. Our members believe that the impact on pharmacies to upgrade systems to support this initiative will be significant.

The proposal states that CMS finds that the "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." ASHP believes that the agency has not considered

discharge prescriptions and the need for hospitals to reconcile medications across care settings.

Conclusion

Despite the NCVHS endorsement of the NCPDP SCRIPT standard for e-prescribing, ASHP believes that until CMS adopts the RxNorm for the medication entity, and until a better understanding of the prescriber and pharmacy work flow/interface in terms of patient information, clinical alerts and decision support is gained through significant pilot testing in a variety of practice settings, implementation of final e-prescribing standards should be delayed beyond the proposed January 2006 date. Implementing standards that are limited in terms of their sophistication and clinical integration will only lead to a different category of medication errors than are currently experienced. Despite improvements in medication-ordering software tools, the integration with pharmacy systems in all types of outpatient pharmacy settings is limited and untested, still requiring pharmacist transcription, interpretation, and assumption of what the prescriber intended.

The NCPDP standard has been widely tested for billing and dispensing information, which represents only a small portion of the information needed for pharmacists and prescribers to interact in a clinical dialogue regarding a patient's drug therapy. By examining and testing the pharmacist/physician user interface in an integrated inpatient CPOE system or model to get a better understanding of what data elements are necessary to allow for seamless interaction between prescribers and pharmacists. This would provide a more realistic approach and allow for greater success in implementing the e-prescribing program.

As a final point, ASHP cannot overemphasize the necessity for CMS to develop good measures for determining the success of e-prescribing. E-prescribing standards must be designed with these measures in mind, or it may be impossible to determine the net impact of e-prescribing. Deciding not to pilot test the standards does not alter the need to have good measures of success. Possible measures would include system response times, clinical warning override rates, profile request volume by activity (e-prescribing/refill authorization/dispensing) and satisfaction surveys of physicians, pharmacists and patients.

As additional information regarding standards for e-prescribing that should be adopted, we have attached the testimony ASHP presented at the July 28, 2004 public hearing held by the NCVHS's Subcommittee on Standards and Security.

For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. We appreciate the opportunity to present comments on this important patient care issue. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Attachment

American Society of Health-System Pharmacists
Presentation at the National Committee on Vital and Health Statistics (NCVHS) July 28, 2004, Public Hearing of the Subcommittee on Standards and Security

Presented by Kevin C. Marvin, R.Ph., M.S.
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Chair, Advisory Group on CPOE and Informatics
Section of Pharmacy Practice Managers
American Society of Health-System Pharmacists

My name is Kevin Marvin, and I am a pharmacist currently employed as Senior Project Manager of Information Services at Fletcher Allen Healthcare (FAHC) in Burlington, Vermont. FAHC, in alliance with the University of Vermont College of Medicine, is the only academic medical center in Vermont. Serving Vermont and northeastern New York, FAHC includes 500 licensed beds, 23 sites, and 50 outreach clinics featuring a medical staff of more than 600 physicians

I am also the Chair of the American Society of Health-System Pharmacists (ASHP) Section of Pharmacy Practice Managers Advisory Group on CPOE and Informatics. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems. The mission of ASHP is to advance and support the professional practice of pharmacists in hospitals and health systems and serve as their collective voice on issues related to medication use and public health. ASHP has a long history of advocating Congress and federal agencies about the importance of safe and efficient medication use processes. I am pleased to provide you with ASHP's views on the development of ePrescribing standards.

Studies have shown that approximately 2% of all new prescriptions contain 1 or more problems requiring pharmacist intervention prior to dispensing (Rupp 1992 and others). Approximately 0.5% of all new prescriptions contain an error with the potential for harm if it reaches a patient. Based on these numbers, approximately 9.8 million prescription errors with the potential to cause patient harm entered community pharmacies in 2003. Not including hospital errors, $177 billion is spent annually on outpatient medication-related problems in the U.S. (Ernst 2001, Johnson 1995)

Medication orders in hospitals have an even greater rate of errors and, therefore, an even greater need for pharmacist intervention.

Pharmacists serve a unique role in patient care, being responsible for the medication use and drug distribution systems. These responsibilities include complying with the requirements of the FDA, State boards of pharmacy, JCAHO, pharmacy benefit plans and safe practice standards. In addition to dispensing and distribution, a large aspect of the pharmacist responsibility is in the transcription, verification, translation, and communication of medication information between components of the medication use process. ASHP supports efforts to standardize the information pathways in the medication use process that:

- Are developed in an open forum with the involvement of all stakeholders
- Do not hinder the ability to safely and efficiently meet the patient's medication therapy needs
- Are developed in an iterative process with appropriate measures to support continuous improvement to the standards
- Developed in consideration of the need to evolve existing systems to meet the standards

Identifiers

There is a need to support universal identifiers of patients. This is especially true apparent when maintaining allergy histories or immunization histories.

Standard methods are also needed to positively verify prescriber identifiers in order to meet FDA and State boards of pharmacy requirements. Other standard identifiers and processes are needed to eliminate the State boards of pharmacy requirements for paper prescriptions for narcotics.

In order to support efficient dose and allergy checking, it is necessary to include patient birth date, height, weight, and certain laboratory results. Minimally, allergy coding should be standardized and stored with the medication profile for retrieval in order to reduce the potential for missed allergy coding.

Messaging Standards

Messaging standards of HL7 and NCPDP script have simplified the transmission of medication order and prescription information between components of the medication use process. We support the continued expansion of these standards to meet the ePrescribing and medication use process needs. It is important that the field-level details of these standards match in order to maximize interconnectivity and cross functionality between systems using these standards.

Coding Standards

Drug Names

ASHP supports standardization of the use of generic medication names. We support the continued development of RxNorm, which is focused on a generic naming structure. Current drug databases store multiple drug names. Generally, the product-level drug name is determined by the manufacturer and does not follow a specific standard. For example, the following products frequently result in confusion:

- Artificial Tears, Tears Artificial, Saline Sensitive Eyes Formulation, Sodium Chloride OP
- Bupropion XL, Bupropion SR, Bupropion tabs
- Combination product naming using generic vs trade names

Besides drug names, other elements that should be standardized include:

- Dosage Forms -- require standardization to support clinical checking.
- Unit of Measure -- standards will allow automated conversion and dosage checking, i.e. digoxin 125 micrograms = 0.125 milligrams.
- Modifiers -- such as latex, flavor, preservatives, and dyes are needed to support product selection and verification.
- Order Instructions/SIGs:

  Components of the SIG include:

  Frequency
  Route
  Administration site
  Indication
  Medication modifiers (with/without food)
  Conditional frequencies (1 hour before procedure)
  Rates of infusion

The historical Latin standard for SIG coding has been identified as unsafe. Some codes are no longer allowed, but standard alternatives have not been identified. Examples of these include QD, QOD, OS, OD, AS and AD. There is currently a great need and opportunity to standardize a new SIG coding structure.

Order routes of administration need to be standardized to support rule-based clinical checking to reduce false positive warnings for drugs that have multiple routes of administration, such as Gentamycin.

When the above SIG information is not coded in a standard fashion, it is very difficult to accomplish:

- Automated dose checking.
- Medication administration reminders and verification.
- Automated translation of patient instructions to a more understandable format such as another language, 5th grade reading level, or audio.

- Historical DUR reporting against free text data.

Free text items reduce the potential to automate downstream components of the medication use process such as medication administration, monitoring, retrospective reporting, and clinical checking. Free text will still be needed to support special needs.

Other Needs

EPrescribing standards need to be structured to support medication process workflow and handoffs. This support includes the many communications between physicians, nurses, and pharmacists. Significant telephone time is spent by pharmacists handling refill and third-party payer issues. Technologies are in place to allow patients to electronically request prescription refills from their pharmacy, but no such processes are available to support the requests from pharmacies to the patient's physician and third-party payer pre-authorizations. Automating these processes will significantly enhance workflows in physician offices and pharmacies.

We cannot forget the medication administration component of the ambulatory medication use process. In the hospital environment, significant errors occur in medication administration even though trained professionals are doing the administration. The standardization of prescription terminology throughout the medication use process will support patient needs. Standardized coding of medication information and instructions will allow for good translation of these instructions into language that is better understood by the patient. Consistent labeling and language will support better understanding of patient medication use. Confusing terminology, such as indications and dosing, can be translated in a standard fashion into language the patient understands.

EPrescribing provides opportunities to automate monitoring of the medication administration side of ambulatory medication use process, including:

- Monitoring of refill activity.
- Monitoring whether new written prescriptions are filled.
- Providing prescription fill and refill information to prescribers.

Standardized administration instructions can be interfaced to:

- Electronic reminders built into dispensing packages.
- Voice reminders (take on empty stomach, medication reason, dose due).

Need for Content Standards for all Relevant Fields in Medications and Orders

The conversion of a prescription in ePrescribing to a pharmacy product is a complex process. It is common in the current hospital world for a Computerized Prescriber Order Entry (CPOE) system to be implemented that results in the electronic order being printed to paper in the pharmacy and transcribed back into a pharmacy computer system for dispensing. Hospitals with proprietary integrated CPOE/pharmacy systems are the only

ones that have implemented CPOE without some type of manual process to convert the physician order to a pharmacy product. With hospital CPOE systems, physician orders can be pre-built with the pharmacy product pre-selected from the hospital's formulary. This cannot occur with ePrescribing in an open ambulatory environment, where the product selection is determined by a combination of the patient's pharmacy insurance benefit, patient choice, and the inventory of the pharmacy filling the prescription. A typical inpatient pharmacy carries approximately 2500-3000 products in stock. The total number of NDC products available has been mentioned by other testifiers to be approximately 80,000, and significantly more if OTC products are included.

Example of a matching process issue:

- Selection of the right combination of strengths for the dose
  Example 12.5mg Warfarin
  a) 10mg + 2.5mg
  b) (2 x 5mg) + 2.5mg
  c) 2 ½ x 5mg
  d) 5 x 2.5mg

If ePrescribing standards do not consider the translation of medication entity to product detail we will still have an error-prone transcription process. We need to develop standards that avoid this unacceptable solution.

Prescription Order Data Integrity and Control

Standards are needed to support the integrity of the original written prescription. The systems should assure that pharmacists are not modifying the intent of the prescription and are selecting the appropriate product to match the medication entity prescribed. Therefore, the data elements carried in the original ePrescription should carry forward to the final prescription filled. Additional data elements will be coded based on the product selected. This is necessary to:

- Support the rule-based clinical checks that work the same for Physicians and Pharmacists.
- Support rule-based product selection.
- Support better physician-pharmacist-patient communication.
- Reduce transcription and translation errors by allowing the patient to be part of the verification chain by seeing the prescription as it was originally written without transcription.

Standards need to provide a hierarchical framework for medication coding from the drug entity level down to the product level (NDC). It is likely that manual transcription will continue to occur until this hierarchical structure is developed.

As prescription information moves through the medication use process, it should be added to but not modified or deleted. This is supported best via hierarchical data structures. Standards are needed to clearly define the source and owners of each data element in an order or prescription. This is necessary to control data integrity. In some cases the ownership can be shared, but the rules need to be clearly defined.

Standards to Support Workflow

Standardized methods are needed to support and enhance communication processes. The system needs to support the communication of decision rationale downstream in the medication use process.

Example: Support the communication of warnings to override rationale by the physician to avoid follow up communication by the pharmacist. Such overrides can occur when the physician selects non-covered or higher cost medications or overrides clinical warnings.

Some expansion of the messaging standard will be needed to better support the handoff of prescriptions from the physician's office to the pharmacy. In addition to prescription information, the passing of medical benefit plan information to the pharmacy will support faster processing of prescriptions by the pharmacy. Also, it will be best if the patient's HIPAA release for the pharmacy is received prior to or during this handoff. Without proper patient approvals, the pharmacy will not be able to access the patient's global medication history and fill the prescription until the patient arrives. This will create unneeded delays for the patient.

In addition, the ePrescribing system should support upstream communication in the medication use process. Such upstream communication includes requests for refill authorization or pharmacist interventions to clarify dosing, routes, etc.

Patient Empowerment

EPrescribing standards need to support patient empowerment. Patients need to be able to select the pharmacy and payment method, as well as influence product selection within the prescriber's intent. Patients also need the ability to review their consolidated medication history information. Standards need to support these goals, as well as provide a mechanism for the patient to verify that the medication received matches the medication ordered.

Standards to Support Measurement

The development of ePrescribing standards is a continuous improvement process that will occur through iterations of design, change, and measurement. Methodologies are needed to measure the safety and efficiency of the system and to provide the evidence to support

continuous improvement of the processes and standards. Such measurement standards should include:

- Time stamps to address response times of automated systems and process steps.
- Methods to document and measure interventions that will support the identification of improvements in:
  - Safety
  - Efficiency
  - Financial Performance

Mechanisms are needed to monitor the measures and, as appropriate, to adjust systems, processes, and standards for improvement.

Recent Directions from JCAHO

On July 20, 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced a new 2005 National Patient Safety Goal:

> Goal: Accurately and completely reconcile medications across the continuum of care.
>
> - During 2005, for full implementation by January 2006, develop a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list.
> - A complete list of the patient's medications is communicated to the next provider of service when it refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization.

This direction from JCAHO will significantly increase the interest in the ePrescribing effort within health systems. It will also include the need to support profile lists of OTC medications, dietary supplements, drug samples, take home medications, and possibly medications administered in clinics and hospitals. Note the requirement for full implementation by January 2006.

It is important to recognize that the ePrescribing standards, although starting as electronic prescribing, will evolve to include all medications. Since these medications will eventually all be included on the same medication profile, they should ultimately share the same standard.

It is possible that the electronic profile functionality of ePrescribing will support this need to reconcile prescriptions. Additional medication profile functions may be needed to complete this support. These functions include:

- Patient access to the profile for verification.
- Documentation that a profile review has occurred by pharmacist, nurse, physician or patient.
- Addition of medications to the profile as documentation only.

Pharmacist Verification of Orders

JCAHO and State boards of pharmacy require that pharmacists review medication orders prior to the medication being dispensed to the patient except in emergencies. In order to support this order verification, pharmacists need complete access to a patient's medication profile, allergy information, problem or diagnosis list, height/weight information, and other applicable laboratory results and clinical data. This requirement for pharmacist verification recognizes that the electronic rule-based clinical checks are not complete and do not support other pharmacist functions, including:

Patient monitoring
Patient education
Local and regional practice differences
Identification of programming or system setup errors

Conclusion

Finally, I would like to emphasize that the development of ePrescribing standards will be an ongoing effort, with iterations of improvement. Pharmacists are important members of the healthcare team to assure that the components of the medication use process meet the requirements of legal and regulatory compliance, payers, and -- most importantly – the best care of patients.

Again I thank the subcommittee for providing this opportunity to present the health system pharmacist's perspective with regards to the development of ePrescribing standards.

ASHP remains available to provide input as these recommendations are developed.

Submitter : Mr. Robert Tennant **Date:** 04/05/2005

Organization : Medical Group Management Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issues

Background

See Attachment

Regulatory Impact Analysis

See attachment

Collection of Information Requirements

See attachment

Provisions of the Proposed Regulation

See attachment

CMS-0011-P-44-Attach-1.DOC

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 5, 2005

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

Re: Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

Dear Administrator McClellan:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the proposed rule on e-prescribing. MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

General Comments

As the federal government and the health care industry move toward adoption of standards for electronic prescribing, the following issues should be considered:

- E-prescribing Standards Should be Flexible and Scalable – From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. The final standards must be both flexible and scalable to encourage adoption by both small and large health care organizations and low- to high-volume prescribing physician specialties. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency and integration with existing practice management software and electronic medical record systems when making an investment.

- E-prescribing Standards Should not Impose Undue Burdens on Providers – In these challenging economic times, with decreasing reimbursement and increasing practice expenses, it is critical that the Centers for Medicare and Medicaid Services (CMS) craft a final rule that does impose undue financial burdens on physician practices. Furthermore, e-prescribing systems should be designed in such a way that clinicians are able to utilize this technology in a time-efficient manner. Clinicians may be discouraged from adopting the technology if it takes them significantly more time to write a prescription electronically than on paper.

- Ensure System Interoperability – In order for an electronic prescribing system in a medical practice to communicate effectively and securely and share patient data with

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other medical practices, hospitals and pharmacies, they all must speak the same "language." E-health standards developed by either the federal government or industry must have the ability to be utilized by multiple stakeholders using a myriad of computer systems. At the same time, "interoperability" should also include the ability for an electronic prescribing system to seamlessly interact with other clinical and administrative systems in the practice.

- Promote the Security and Privacy of Patient Data – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). E-prescribing must maintain these HIPAA standards as part of its core operating features.

- Establish a Quantifiable Return on Investment – For many group practices, the economics of investing in e-prescribing and other health information technology is simply not evident. In an environment of significant scheduled Medicare reimbursement cuts, sharply rising malpractice premiums and ever-increasing practice expenses, many practices are concerned that moving to an electronic information system will not be financially beneficial. MGMA recommends that CMS establish a quantifiable return on investment through survey research and a comprehensive cost/benefit analysis for all sizes of physician practices.

- Incentives for Providers – While medical practices typically absorb the cost of purchasing the health information technology necessary for electronic prescribing many of the benefits accrue to others in the system. MGMA believes there should be a "realigning" of these incentives by promoting appropriate public and commercial reimbursement programs. MGMA has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Additionally, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could also be a stimulus.

- Technology Savings Accounts – The federal government should also explore innovative methods of assisting physician practices to acquire health information technology such as electronic prescribing. Technology Savings Accounts (TSAs) would provide a reduced level of taxation for funds designated for practice health information technology. A TSA would be a special account owned by a group practice where contributions to the account pay for current and future qualified health information technology expenses including electronic prescribing software and hardware. A TSA savings product offers a different way for group practices to pay for their health information technology expenses. TSAs could enable group practices to pay for current expenses and save for future qualified health information technology expenses on a tax-free basis. Unspent account balances would accumulate and accrue interest.

- Stark Regulation Safe Harbor – There are clear legal barriers to the adoption of health technology solutions in medical groups. Anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices. MGMA has advocated for government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation. We congratulate the CMS recent important step in this direction through its creation of a health technology safe harbor in the physician self-referral phase II interim final rule (CMS-1810-IFC; 59 Fed Reg 16054).

- Consultation with the Physician Practice Community – Physician practices must play an integral role the development and deployment of any standardized e-prescribing system. Since the vast majority of all health care is delivered in medical practices, the success or failure of these initiatives will depend heavily upon physician acceptance of this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Patient and Provider Outreach – The successful adoption of e-prescribing will depend, in part, on the ability of the federal government and the industry to encourage both providers and pharmacies to understand and support the system. It is imperative that these two critical stakeholders are well educated as to the systems' capabilities as well as its security and privacy components. In addition, MGMA recommends that CMS work with the appropriate provider and consumer associations as well as the popular media to deliver a consistent message to patients on this important change in the health care system.

- Work with the industry to expand this regulation beyond Medicare Part D – This regulation is expected to enhance patient safety and efficiency for the Medicare Part D program. CMS should expand the use of this standard beyond Medicare and MGMA is hopeful that a successful implementation of this regulation will trigger adoption of these standards by the private sector. MGMA encourages CMS to facilitate this expansion by working with the private sector to exchange data and experiences as well as develop educational materials that will assist stakeholders move forward with e-prescribing.

- Learn from the HIPAA Experience – The protracted nature of HIPAA Transactions and Code Sets implementation process suggests that the federal government's e-health regulatory process must be modified. MGMA calls on the government to stagger implementation dates, thus providing health plans and clearinghouses time to upgrade and test systems before provider implementation takes effect. While piloting is not needed to establish the applicability of the core function standards, piloting of the entire e-prescribing standard should be completed prior to full national implementation in order to identify and correct problems.

Specific Comments on the Notice of Proposed Rule Making

Issue: **State Preemption (70 Federal Register No. 23 Feb. 4, 2005 page 6258)**

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.

Response:

MGMA believes that the proposed rule adopts a very narrow interpretation of federal preemption. The rule appears to limit preemption to only those Part D beneficiaries enrolled at the time the prescription is issued, rather than all Medicare beneficiaries. We also have a concern that Medicare beneficiaries may receive drug coverage from multiple sources. Yet, the rule seems to

limit preemption to only those prescriptions actually covered by Part D. MGMA recommends that CMS adopt an interpretation providing that federal law broadly preempts any state laws that are contrary to or that stand as an obstacle to the objectives of the federal government in creating the e-prescribing standards. We believe that this interpretation is consistent with the settled view of preemption and statutory language. MGMA also suggests to CMS that the preemption standard apply to any prescription issued to any beneficiary eligible for Part D coverage.

Issue: **Current E-prescribing Environment (70 Fed Reg 6260)**

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.

Response:
MGMA believes that e-prescribing will help to deliver relevant patient information and clinical knowledge to the clinician and this will reduce the likelihood of a faulty prescription. In addition, e-prescribing holds the promise of improved administrative efficiencies. Presenting all relevant information to the clinician at the time of prescribing may help streamline the entire prescribing process. Relying solely on downstream inspection to manage quality is inefficient because of the extra work required. By some accounts, the nation's three billion prescriptions generate approximately 150 million clarification phone calls every year. This means that roughly five percent of prescriptions are somehow incompletely specified or unclear, and need to be reworked.

Early experience supports the view that electronic prescribing – by shifting the error-inspection process to the point of prescribing – reduces callback volume and improves efficiency. In fact, most clinics that successfully deploy electronic prescribing applications note a dramatic decrease in prescription clarification calls. Moreover, those callbacks that still occur can usually be processed more efficiently because of the streamlined message-handling capabilities that often come with electronic prescribing, coupled with elimination of the need to pull (and re-file) paper charts every time a pharmacist or patient calls with a question or concern about a prescription. This reduction in chart pulls is one of the unheralded beneficial side effects of electronic prescribing and has major cost-savings implications, particularly for larger practices. Even in small practices, however, there is still significant time lost looking for charts that have not been filed and are in multiple locations around the office, waiting for various processes to be completed.

Issue: **Evolution of Standards (70 Fed Reg 6261)**

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.

Response:

MGMA supports the creation of e-prescribing standards as needed by the private sector through ANSI accredited standards developing organizations, with federal government participation in the standards development process. We urge that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to that experienced with the HIPAA

Transactions and Code Set standards. In addition, MGMA recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and any interested party should be eligible to submit proposals for additions and modifications. A responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain these vocabularies.

Issue: **Criteria to Assess "Adequate Industry Experience" (70 Fed Reg 6261)**

We propose to use the following criteria to assess adequate industry experience (with transaction standards), based on testimony presented to the 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.*

Response:

MGMA agrees with this approach to determine if a standard is deemed to have had "adequate industry experience." We would like to emphasize the importance of the final bullet, that the standard be recognized by key industry stakeholders, as this is critical to ensure that the standard has been used in clinical settings and found to be acceptable. In particular, we encourage CMS to continue its outreach to the provider community to ensure that any futures, standards take into account the requirement of clinicians.

Issue: **Drug orders for fill status notification (70 Fed Reg 6262)**

NCVHS Standards Recommendations – HHS Should :include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. Standard in the NPRM: No.

Response:

MGMA is disappointed that CMS decided not to include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. This standard has the potential of significantly improving the health of Medicare beneficiaries. With some industry sources estimating that up to 40 percent of written prescriptions are never filled by the patient, it is clear that many patient conditions are not easily monitored by physicians.

Failure to refill medications at a pharmacy or renew at the clinician's office in a timely fashion can and does lead to adverse events due to exacerbations of the condition. This is a significant

problem particularly for persons who have difficulty affording their prescriptions. Renewing prescriptions in a timely fashion may not be a high priority, especially for drugs that treat relatively asymptomatic chronic conditions. Lack of patient compliance with prescribed medications can also lead to similar adverse events. With electronic prescribing systems leading to better tracking of a patient's drug regimen, it is possible to know when renewals of regularly scheduled medications are likely to come due, assuming proper patient compliance. Systems can send out reminders to patients and clinicians, advising of an upcoming renewal or refill time and even offering one-click renewal transactions. These reminders should have a positive impact on actual compliance.

It would be easy for elderly Medicare beneficiaries, who may be taking multiple prescription drugs, to miss filling an important prescription. Thus, prescription fill status could be an important device allowing clinicians to better monitor chronic care illness, potentially lowering overall health costs by preventing hospitalizations due to improper drug usage. In addition, fill status would potentially be an important patient safety, patient satisfaction and quality measurement. We are hopeful CMS will consider including this function in later standards.

Issue: **Version Control (70 Fed Reg 6267)**

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.

Response:

MGMA recommends that HHS (i) adopt minimal version levels of the standards; (ii) depend on existing standards developing organization (SDO) enhancement processes for newer versions; and (iii) permits health care organizations to use newer versions provided there is backward compatibility. MGMA recommends that the National Committee on Vital Health Statistics (NCVHS) hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such updates to HHS. If NCVHS considers the change to be substantive, as described on 70 Fed Reg 6267 above, HHS would issue a NPRM within 90 days. If the change is deemed not to be substantive, it would waive notice and comment.

MGMA is concerned about any possible divergence between a HIPAA standard transactions and the same e-prescribing transaction, such as the ASC X12N 270/271 eligibility inquiry. MGMA recommends that procedures be designed to permit the changing needs of HIPAA and e-prescribing to be met but that such modifications to standards do not result in multiple standards. MGMA also recommends consideration of implementation phases rather than requiring all transactions by a single date.

Issue: **National Provider Identifier (70 Fed Reg 6263)**

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 HCIdea® 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.

Response:
MGMA is a strong supporter of administrative simplification and believes that the national provider identifier (NPI) is an important step in streamlining health care transactions. The NPI should be the primary identifier for all prescribers and dispensers utilizing e-prescribing. MGMA recommends that current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

In addition, while MGMA recommends that the required date for use of the NPI in transactions in this NPRM not be sooner than the required date for use of the NPI in HIPAA transactions, we strongly urge CMS to move forward with the NPI enumeration process. E-prescribing will be greatly facilitated with a standard provider identifier. We recommend that CMS work with providers and other stakeholders to develop an NPI implementation plan that results in rapid and successful adoption of this important new standard.

Issue: **Formulary and Medications Standards (70 Fed Reg 6263)**

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:

Response:

In order to facilitate a successful implementation, MGMA recommends that the formulary, benefit and medication history messaging standards should be thoroughly pilot-tested prior to the release of a final rule. Vendors should be factored into the regulations and encouraged to bring products to market that assist physicians in complying with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered, as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide the tools necessary to comply with the electronic prescribing program. Strong government leadership will

be critical to rapid and seamless conversion to the new standard.

MGMA urges that HHS make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of HIPAA. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-agency differences from across the federal government in the Addendum to the Electronic Transactions and Code Sets rule (citation). The additional time to resolve these differences left inadequate time for the various vendors to work with their provider and payer customers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long and not conducive to industry usage.

Issue: **Medication History (70 Fed Reg 6263)**

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.*

Response:

MGMA recommends private sector development and maintenance of standards and modifications and enhancements to standards not be hindered by extensive rule-making processes. We are concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the HIPAA Privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

MGMA is also concerned that the current models for retrieving prescription and medical history is daunting. For example, patients often utilize multiple pharmacies—often making the prescription record at any one site incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

Issue: **Proposed Standards (70 Fed Reg 6264)**

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).*

Response:

MGMA agrees with moving forward with these "foundation" standards. It is clear that the industry has already adopted these standards and that they meet the basic needs of the industry. However, MGMA encourages moving to new standard versions as soon as practical, in particular, moving to the new versions of the ASC X12N 270/271 and 278. MGMA also agrees that these foundation standards do not need to be piloted to determine their applicability to the e-prescribing regulation. However, as noted above, we encourage CMS to initiate a comprehensive pilot of the entire standard prior to implementation.

For future additions to the standard, MGMA recommends pilot projects in order to prove the standards not named as foundation standards will work in multiple provider and pharmacy environments. As well, pilot projects should address workflow issues and establish the business rules in order not to impose undue burden on physicians and pharmacies. MGMA recommends that demonstration pilots show achievable financial models for appropriately funding the acquisition of technology, training and support for electronic prescribing in various clinical settings. Pilot projects may also be required for any standard already demonstrated but being proposed for use in new circumstances.

Issue: **Strategy for Phasing in Implementation of an Electronic Prescription Drug Program (70 Fed Reg 6264)**

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.

Response:

MGMA agrees with this phased in approach to the e-prescribing standards. It is important to have the foundation standards adopted quickly by the industry to ensure that the benefits of e-prescribing are achieved in a timely manner. It is also important to move forward with the additional standards with all deliberate speed, with the caveat that these standards be properly vetted through the appropriate standards organizations and piloted when there is insufficient industry experience. MGMA encourages CMS to institute a comprehensive industry outreach program, focused on the provider community. Each release of a new e-prescribing standard should be prefaced with an educational program to explain the new standard and how it should best be implemented.

Issue: **Eligibility (70 Fed Reg 6266)**

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...

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. First, these standards adhere to EDI for EDIFACT and ASC standards.

Response:

For eligibility inquiry and response, MGMA supports the ASC X12N 270/271 for the patient eligibility and benefits inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA. However, as much as this transaction has the capability of significant return on investment by reducing the cost for both medical practices and health plans to verify patient eligibility, in reality, much of the value of this transaction has not been realized. Medical practices report that health plans are simply responding with a "yes" or "no" when queried. While this is permitted under HIPAA, this minimum level of response necessitates the practice use the telephone to ascertain other eligibility information from the health plan – thus incurring significant costs to their organization and for the health plan.

We are hopeful that a recent industry initiative may assist in providing additional electronic eligibility and benefits information to medical practices. MGMA is working with Council for Affordable Quality Healthcare (CAQH) to improve the quality of 271 eligibility responses from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. The CAQH is seeking to define operating rules that health plans will voluntarily adopt, providing information as to whether the patient is covered and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. MGMA recommends that CMS consider modifying the 270/271 to include these operating rules as required data elements in future versions of the standard.

Issue: **Coordinate Update Process when e-prescribing and HIPAA Standards are the Same (70 Fed Reg 6267)**

We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 16 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.

Response:

MGMA recommends that CMS not approach standards that fall within the purview of both e-prescribing and HIPAA differently. CMS should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

Issue: **Regulatory Impact Analysis (70 Fed Reg 6268)**

We invite public comment on our expectations for prescriber participation.

Response:

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2011. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40 percent less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of e-prescribing's promise of improved efficiency, patient safety and health care quality. MGMA believes that e-prescribing offers significant financial and other benefit potential to providers. However, this observation may not appear compelling to many providers in the financial environment between now and 2011. MGMA recommends that CMS fund the development, analysis and educational documentation making the financial case for providers to implement health information technology.

Issue: **Standards Development Approach (70 Fed Reg 6264)**

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.

Response:

MGMA believes interoperability with many clinical terms is very important. For example, some terms may be used differently in a hospital setting than an ambulatory environment. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality and efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process. Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

Issue: **Regulatory Impact (70 Fed Reg 6269)**

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.

Provider Savings, especially solo and small groups (70 Fed Reg 6270)

We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.

Applying the ROI of larger practices to smaller practices (70 Fed Reg 6270)

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 or potential savings, particularly in solo and small group practices.

Response:

Without conducting a wide-ranging survey, MGMA is not in position to provide a detailed impact analysis of these proposed regulations on different types of participants. It is critical, however, that CMS develop a comprehensive and accurate report of the full costs and savings in order to fully understand the impact that this regulation will have on the industry. In particular, MGMA encourages CMS to conduct this important analysis as soon as possible as the results will not only help to guide the policy development process but may also help to facilitate the provider community's acceptance of this technology. It appears as though only a small percentage of practices are currently utilizing e-prescribing, though a significant number are expecting to move to this technology over the next 24 months. MGMA, however, is positioned and willing to develop and analyze surveys for CMS, as well as educational documentation, analysis and financial models, and pilot and testing projects.

Issue: **Application of e-prescribing rules to Part B drugs** (70 Fed Reg 6273)

Proposed definition 42 CFR 423.159: "Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs..."

Comment:

The expansion of the Part D benefit to drugs currently covered by the Medicare system remains a complex aspect of the implementation of the Part D program and the Electronic Prescription Drug Program. Many industry groups, including MGMA, assert that this nexus will result in numerous providers who did not consider themselves to be directly affected by Part D to be swept into the program's requirements, including the e-prescribing obligations.

MGMA seeks clarification, how, if at all, providers will be required to incorporate e-prescribing technologies if ordering drugs currently paid under the Part B program or acquired through the proposed Competitive Acquisition Program (CAP). The proposed rule for the CAP (CMS-1325-P; 70 Fed Reg 10746), acknowledges that drugs dispensed by venders would require a physician's order. This order would include a request for the complete treatment of the patient (multiple doses) and includes the (a) date of order; (b) beneficiary name; (c) physician identifying information, name, practice location, group practice information (if applicable) and Medicare enrollment number; (d) drug name; (e) strength; (f) quantity ordered; (g) dose; (h) frequency/instructions; (i) anticipated date of administration; (j) beneficiary Medicare information/health insurance number; (k) Medicare information; (l) shipping address; and (m) additional patient information including date of birth, allergies, height, weight, diagnosis codes, etc. We recommend that CMS ensure that all of these requirements will be able to be performed with the proposed NCPDP SCRIPT standard. It would be very burdensome if providers are required to submit some of the information through an e-prescribing system and other required data sets through a separate system, either electronic- or paper-based.

Furthermore, the proposed CAP would assign individual Medicare prescription numbers to dispensed drugs used in claims adjudication and payment. CMS should ensure that the NCPDP SCRIPT standard has the ability capture this specific number for Medicare processing.

Lastly, it remains unclear from the proposed CAP regulation, if CAP vendors would be required to use the standards established under the Electronic Prescription Drug Program. It appears that this proposed rule intends to require prescribing physicians and pharmacies/entities of any drug payable under the Medicare program to adhere to the requirements of the Electronic Prescription Drug Program. However, this additional future obligation is not made clear in the CAP regulation, or in the "CAP Vendor Application and Bid Form" or accompanying "CAP Drug Vendor Application Guide" (OMB Approval Pending No. 0938).

MGMA appreciates your consideration of these comments. If you have any questions, please contact Robert Tennant in the MGMA Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and CEO

Submitter : **Mr. Steve Tucker** **Date: 04/05/2005**

Organization : **PacifiCare Health Systems**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached.

CMS-0011-P-45-Attach-1.DOC

PacifiCare®

April 5, 2005

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

RE: CMS-0011-P

Dear Sir or Madam:

On behalf of PacifiCare Health Systems, Inc. (PHS), I am responding with comments on the Notice of Proposed Rule Making for the Medicare electronic prescribing program.

PacifiCare is one of the nation's largest consumer and health services organizations, offering groups and individuals, including Medicare beneficiaries, a variety of consumer-driven health care and insurance products. PacifiCare currently serves some 700,000 Medicare beneficiaries enrolled on our Medicare Advantage plan – Secure Horizons – in eight western states. We have been participating in the Medicare risk program since its inception in the mid-1980s. Our wholly owned subsidiary, Prescription Solutions, provides comprehensive pharmacy benefit management services to our Medicare and commercial members as well as members of other external clients, serving over five million lives in total.

We greatly appreciate the opportunity to review these documents and provide commentary. We look forward to working with the Agency to implement the MMA.

If you have any questions, please contact me at (714) 226-3697.

Sincerely,

Steve Tucker,
Vice President
Regulatory Affairs

SMT:jlh

Attachment: Detailed Comments on CMS 0011-P

Medicare Part D Commentary

CMS-0011-P

Medicare Program
E-Prescribing and the Prescription Drug Program

Submitted by
PacifiCare Health Systems
and Prescription Solutions

OVERVIEW:

PacifiCare appreciates the ability to provide comment on the proposed rule for the Medicare Program; E-Prescribing and the Prescription Drug Program published in the Federal Register on February 4th, 2005.

PacifiCare commends the Centers for Medicare & Medicaid Services (CMS) for actively developing and promoting electronic prescribing. We agree that electronic health record frontier holds the promise of reducing medical errors and vastly improving patient safety. We also recognize the work of the National Committee on Vital Health Statistics (NCVHS) and believe the Committee's initial recommendations to the Secretary helped to provide a framework for the e-prescribing environment.

The statute calls for the establishment of pilot programs beginning in 2006 to test the emerging electronic prescribing standards and we strongly support this requirement. PacifiCare was an early supporter of e-prescribing understanding the fundamental and unique benefits that this technology offers. We also acknowledge that for industry wide adoption to be successful, the infrastructure must be appropriately planned and implemented according to the real world environment. Finding the right balance for accelerated adoption of this new platform and ensuring success, in light of enormous modifications taking place with the new Part D benefit, will be a challenge and will require flexibility by CMS while plan sponsors develop each of the necessary component programs for successful implementation of the drug benefit in 2006. We believe that the pilots recommended by the Medicare Modernization Act (MMA) will provide the testing phase necessary to validate assumptions and negate the possible introduction of unanticipated problems. Therefore, it will be critical to allow the pilot programs to be completed prior to introduction of any broad e-prescribing capability. As with any new innovation, especially one steeped in an information technology function, intended solutions need to be confirmed prior to finalizing protocols.

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Compliance Date

The Secretary proposes January 1, 2006 as the compliance date for the proposed foundation standards. We believe that the proposed timeline for the implementation of any e-prescribing standard by January 1, 2006 is operationally unfeasible and national implementation should be delayed.

After attending CMS open door forums on the MMA drug benefit and asking direct questions of CMS staff regarding the proposed e-prescribing compliance date, PacifiCare understands and has relied on the representation that the compliance date would only apply to those companies having e-prescribing programs in place on or after that date. It is also our understanding that there is no requirement that a company create a fully operational e-prescribing capability for the January 1, 2006 date. Indeed, the anticipated pilot programs intended to provide the experience and detail necessary to create the e-prescribing final standards will not have begun until on or after that date.

Additionally, health plans considering Part D participation have begun tasks associated with the annual contracting process. These activities reflect the requirements contained in the final Title I & II regulations and components integral to the Medicare Advantage (MA) and Prescription Drug Plan (PDP) application process. The timeline set forth by CMS for completion of the MA or PDP application requires that plans submit finalized participating pharmacy networks no later than July 15, 2005. In order to meet these strict deadlines, PacifiCare has initiated the overall contracting of the provider networks essential in meeting the Part D *Standards for Convenient Access* requirements.

The extremely aggressive implementation timeline proposed for e-prescribing foundation standards provides insufficient time necessary for encompassing the operational tasks associated with communicating contractual requirements to downstream providers. The activities involved with provider network contracting are resource intensive and time consuming, especially with the advent of a new product offering combined with the size of the regional pharmacy networks. Given that the e-prescribing regulations will not be finalized with adequate time to be incorporated into the current contracting cycle, we urge CMS to include the final provisions in the pilot testing phase.

Initial Standards Versus Final Standards

While the Secretary is permitted under the statute to pre-empt the pilot testing of components if sufficient real-world experience exists, we believe that by and large, e-prescribing is still in the infant stage and that all proposed standards should be tested in the pilot programs prior to nationwide roll-out. We have noted the observations made by the Secretary for the accelerated advancement of this technology as a step towards embracing a full electronic health record.

However, moving too quickly with mandatory standards may compromise overall prescriber participation and diminish the benefits associated with this endeavor.

The true e-prescribing environment is a recent phenomena only being credibly established over the last two to three years. The majority of e-prescribing studies have been conducted under optimal test site conditions and supported with resources to ensure success. Given that less than 10% of doctors currently use electronic prescribing, coupled with the multifaceted issues that impact provider use of new information technologies in the office setting, it is critical that e-prescribing be tested and validated prior to wide-spread implementation.

State Preemption

PacifiCare believes that adoption of unified e-prescribing standards through appropriate and full federal preemption of state laws is essential to overall success of e-prescribing in the health care industry. The Federal government and the States have distinct roles in relation to e-prescribing. While dispensers are ultimately responsible for ensuring the validity and authenticity of prescriptions under state statutes, prescribing requirements are controlled by state boards of pharmacy and the U.S. Department of Justice Drug Enforcement Administration (DEA).

There are state-to-state variations relating to prescribing requirements and the DEA currently requires Schedule II controlled substances to be authorized by the prescriber with a handwritten signature. Additionally, the NPRM notes that "The DEA has not yet made a ruling regarding the requirements for the electronic transmission of prescriptions for controlled substances." To reduce barriers and increase adoption of this new technology, we urge CMS to invoke preemption authority as afforded in the MMA.

Anti-kickback Statute Safe Harbor and Stark Exception Section

Numerous studies have identified economic barriers that retard physician adoption of e-prescribing. Without the support of these resources prescribers will not be incentivized to entertain this new tool, particularly as their organizations embrace various issues presented with the new Part D benefit. The protections afforded by the anti-kickback statute safe harbor are essential to the success of the e-prescribing program and we suggest that that the overall e-prescribing program be delayed, if the new exception for e-prescribing is not timely aligned with the e-prescribing initiative.

Evolution and Implementation of an Electronic Prescription Program

We believe that further articulation of these criteria is necessary and PacifiCare recommends that CMS clarify the subparts of the proposed definition for determining "adequate industry experience".

> • *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.*

PacifiCare recommends that CMS provide the basis for concluding that the "standard has been generally implemented by entities to which the final standard will be applied" including the sampling methodology, survey instruments, and the result authentication mechanism used to reach consensus of the assumptions used in this criterion.

> • *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.*

Pacificare suggests that CMS identify the methodology used to include entities as key industry stakeholders and the oversight process used to ensure that potential conflicts of interest do not pervade these decision making proceedings.

Provider and Dispenser Identifiers

The Secretary of Health and Human Services is required to adopt a national standard identifier (NPI) for health care providers under the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPPA) of 1996. Although providers can begin to apply for an NPI in May 2005, most covered entities are not required to begin using the NPI until May 2007. Currently, physicians are identified by their DEA number. However, physicians who do not prescribe controlled substances may not hold a DEA number. Although the MMA does not expressly require the use of unique identifiers for prescribers or dispensers in e-prescribing, PacifiCare supports the enumeration of health care providers by this method. Some states have objected to the use of physician DEA numbers to identify prescribers for electronic adjudication of prescription claims and use of the NPI would help to eliminate this issue. However, if the NPI is not available for e-prescribing use, we suggest that CMS utilize federal preemption authority over state laws to allow the continued us of other unique prescriber identifiers, such as the DEA number.

Formulary and Medication History Standards

The proposed rule also states that, "the standards should be vendor neutral and technology independent". PacifiCare is concerned about the recommendations by some of the stakeholders in the industry to use RxHUB, a proprietary software program, as a basis for a foundation standard. The adoption of the RxHUB protocol as a foundation standard could potentially stifle competition between existing vendors and discourage new vendors from entering the market. We strongly urge CMS to reconsider the formal endorsement of RxHUB or clarify the involvement of this entity in the standard setting process.

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Eligibility

The Centers for Medicare and Medicaid Services (CMS) has proposed making the ASC X12 278 Healthcare Services Review a standard for use in the MMR Part D when ANSI can incorporate functionality for real-time prior authorization messages for drugs. PacifiCare believes that the

X12 format does not conform to the MMA intent that disclosure of information should "be on an interactive, real time basis" and that CMS should consider using the NCPDP 5.1 telecommunications standard which provides for this real-time interaction.

The ASC X12 278 Healthcare Services Review format is intended for use in a batch process incorporating more than one claim or request. As such, it is not currently usable in the standard real-time (single request) format. The majority of pharmacy claim payers and Pharmacy Benefit Managers (PBMs) are operating in a real-time environment. A requirement to use the ASC X12 178, even if modified for real-time use, would present a significant challenge to the real-time industry. The NCPDP 5.1 telecommunications standard, version 5.1, currently provides the ability to include information and details to support a prior authorization request. The MMA standard should be modified to include the option of using the NCPDP Telecommunication standard, version 5.1, as an option for drug related prior authorization requests.

PacifiCare recommends that until the ASC X12 278 has incorporated real-time functionality, and has been adequately piloted and used in production in the provider and payer communities, it should not be a required standard. Alternately, CMS should allow providers and payers to use the NCPDP 5.1 Telecommunication Standard where applicable until such time as an acceptable industry standard can be defined.

Submitter : Helen Yang **Date:** 04/05/2005

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-46-Attach-1.DOC

PacifiCare

April 5, 2005

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

RE: CMS-0011-P

Dear Sir or Madam:

On behalf of PacifiCare Health Systems, Inc. (PHS), I am responding with comments on the Notice of Proposed Rule Making for the Medicare electronic prescribing program.

PacifiCare is one of the nation's largest consumer and health services organizations, offering groups and individuals, including Medicare beneficiaries, a variety of consumer-driven health care and insurance products. PacifiCare currently serves some 700,000 Medicare beneficiaries enrolled on our Medicare Advantage plan – Secure Horizons – in eight western states. We have been participating in the Medicare risk program since its inception in the mid-1980s. Our wholly owned subsidiary, Prescription Solutions, provides comprehensive pharmacy benefit management services to our Medicare and commercial members as well as members of other external clients, serving over five million lives in total.

We greatly appreciate the opportunity to review these documents and provide commentary. We look forward to working with the Agency to implement the MMA.

If you have any questions, please contact me at (714) 226-3697.

Sincerely,

Steve Tucker,
Vice President
Regulatory Affairs

SMT:jlh

Attachment: Detailed Comments on CMS 0011-P

Medicare Part D Commentary

CMS-0011-P

Medicare Program
E-Prescribing and the Prescription Drug Program

Submitted by
PacifiCare Health Systems
and Prescription Solutions

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Submitter : **Helen Yang** **Date: 04/05/2005**

Organization : **Wyeth Pharmaceuticals**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-47-Attach-1.DOC

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Lucinda E. Long
Vice President
Global Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

April 5, 2005

BY ELECTRONIC SUBMISSION

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

Re: CMS-0011-P (Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256)

Dear Dr. McClellan:

Wyeth Pharmaceuticals welcomes the opportunity to comment on the proposed rule by the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* on February 4, 2005 ("proposed rule") on electronic prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and healthcare products companies with leading products in the areas of women's healthcare, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines.

Section 1860D-4(e) of the MMA establishes a voluntary electronic prescribing (e-prescribing) program and requires the development of national e-prescribing standards. Beginning in 2009, the final e-prescribing standards will be mandatory for Medicare Part D providers who adopt e-prescribing in 2009. Based on recommendations from the National Committee on Vital and Health Statistics (NCVHS), CMS suggests the adoption of foundation standards as the basis for a more complete set of e-prescribing standards in the future.

Wyeth commends CMS for its efforts in the proposed e-prescribing rule to improve the quality of care for Medicare beneficiaries. Wyeth believes it is

critical for an e-prescribing system to improve the quality of care and to strengthen the physician-patient relationship. In this spirit, we respectfully offer comments and recommendations to CMS in the following areas:

1) The impact of financial incentives for e-prescribing adoption on both prescribers and Medicare Part D sponsors,
2) The impact of e-prescribing adoption on health outcomes and quality of care,
3) The use of e-prescribing to facilitate enabling automatic prior authorization, and
4) Prescribing information and its presentation format through e-prescribing.

Recommendations

1) **CMS should not allow Part D sponsors that offer financial incentives to physicians for adopting e-prescribing to inappropriately influence physician prescribing behavior or restrict choice of medicines.**

The proposed rule allows Medicare Advantage plans to provide financial incentives to physicians for adopting e-prescribing under the Medicare Part D program in accordance with the established standards. These payments are intended to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. Accordingly, CMS will publish a proposed rule to create an exception under the Stark law for incentives related to e-prescribing. Also, the Office of Inspector General in the Department of Health and Human Services (HHS) will establish a safe harbor under the Anti-Kickback Statute.

As CMS indicated in the propose rule, "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.[1]" While we understand the goal of health plans to achieve positive returns on the costs associated with e-prescribing, Wyeth believes that health plans should not be allowed to use financial incentives to inappropriately influence physician's prescribing habits. The e-prescribing system should protect physician's

[1] Fed. Reg. Vol 70, No. 23, at 6269

prescribing autonomy and support physicians choosing treatment therapies primarily based on clinical judgment rather than cost concerns or financial incentives.

- In the final rule, CMS should ensure that the use of financial incentives do not inappropriately influence physician prescribing behavior or restrict provider choice and decision-making. For example, physicians should not be penalized or discouraged from prescribing clinically appropriate but off-formulary drugs if they deem these drugs to be the most appropriate treatment for their patients.

- CMS should also prohibit plans from incentivizing physicians solely on the basis of their performance in containing costs. For example, plans should not be allowed to set targets for generic prescribing or preferred tier prescribing and reward physicians on the basis of their performance in meeting those targets.

2) **CMS should examine the impact of e-prescribing adoption on health outcomes and overall patient quality of care.**

While e-prescribing is gaining acceptance by health care providers, CMS estimates that only 5 to 18 percent of physicians currently use e-prescribing.[2] The adoption rate is particularly low among solo practitioners, those in rural areas, and certain medical specialties.[3] Given many uncertainties about e-prescribing and possible unintended consequences, we recommend CMS give special considerations to the following areas in developing final e-prescribing standards and making implementation decisions.

- Wyeth believes that the primary drivers for e-prescribing adoption should be the improvement of patient safety and quality of care. However, plans have focused heavily on using e-prescribing to improve formulary compliance, increase generic utilization, and reduce pharmaceutical and administrative costs. We recommend that CMS conduct analyses of e-prescribing's impact on formulary compliance, generic utilization and their impact on patient care, health outcomes and overall quality of care.

[2] Fed. Reg. Vol. 70, No. 23, at 6260
[3] 69 Fed. Reg. at 46672

- In its analyses, CMS should recognize the potential unintended consequences of e-prescribing. For example, if plans are authorized to compensate prescribers who use e-prescribing on the basis of their performance on formulary compliance and/or whether meeting cost containment targets, patient access to medicines may be inappropriately limited by under-prescribing. Under-use of clinically appropriate treatments may not only have a negative impact on health outcomes but also increase the total healthcare costs. Studies have found that appropriate use of pharmaceuticals produces savings from reduced use of medical services as well as from improvements in patients' health, quality of life, longevity, and economic productivity.[4] A study conducted by Dr. Frank R. Lichtenberg concludes that each dollar increase in pharmaceutical spending yields a reduction in hospital expenses of $3.65.[5]

- CMS' analyses should also examine how the use of e-prescribing could maximize potential savings to the Medicare program through improvements in patient safety, quality of care, and health outcomes. These savings could be realized through:
  - reduction in medication errors and adverse events,
  - reduction in total healthcare costs due to appropriate drug utilization (e.g., from adherence to recognized clinical treatment guidelines),
  - improvements in patient medication compliance and persistency,
  - and more efficient communication and prescription transactions among prescribers, dispensers, and plan sponsors, through the use of tools such as automated prior authorization.

3) E-prescribing system should be designed to allow for automated prior authorization at the point of care.

Prior authorization (PA) is a requirement placed on certain drugs to encourage appropriate clinical usage and contain drug expenditures, especially for higher cost medicines (e.g., biologics) or therapeutic categories. NCVHS estimates that 2 percent of prescriptions are subject to PA requirements, and that there is

[4] Meyer, J. *Assessing the Impact of Pharmaceutical Innovation*, 2002
[5] Lichtenberg, F. *Pharmaceutical Innovation, Mortality Reduction, and Economic Growth*, 1999.

a higher rate in the Medicaid program.[6] Prior authorization is now commonly used in prescription drug benefit programs administered by private health plans and Medicaid. According to the Medicare Payment Advisory Commission (MedPAC), it may be used even more frequently in the Medicare Part D program.[7]

The request for a prior authorization for a drug from the prescriber to the payer/Pharmacy Benefits Manager (PBM) is now conducted manually.[8] The manual processes, which may involve coverage denials at the pharmacy counter, phone calls among prescribers, dispensers and plans, and waiting periods for patients—are an administrative burden for patients, pharmacies and prescribers. As a result, medical staff time may be diverted from patient care and education to handling the voluminous paperwork and increased telephone calls from patients.[9] In addition, a manual PA process may require plans to hire extra personnel to handle prior authorization calls.

While PA may provide short-term savings to plans, it may have a negative impact on patient care. Because manual prior authorizations take time to be processed, they can result in unnecessary delays in patient treatment and higher administrative costs. A recent MaineCare study on prior authorization reports that some patients experience dangerous side effects or even a worsening of their medical conditions as they go through the PA process before they are allowed to take an effective medication that is subject to PA.[10] According to the report, consumers find the manual process confusing and frustrating. As a result, instead of trying to navigate the PA process, some patients will simply not get the prescribed medication while others will have to pay the full cost of a drug when told their plans will not cover it at the pharmacy counter.

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[6] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm

[7] MedPAC public meeting, March 10, 2005

[8] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm

[9] *The MaineCare Advisory Committee's Prior Authorization Subcommittee Report and Recommendations on Prior Authorization for Prescription Drugs in the MaineCare and Drugs for the Elderly Programs*, January 19, 2005.

[10] Ibid.

The MaineCare report concludes that aspects of the current PA implementation have adverse consequences directly affecting patient care and medical practices of providers. These consequences may, in turn, result in hidden and unintended costs to the healthcare system.[11] To improve patient care by avoiding unnecessary delays and improving efficiency, Wyeth believes that the e-prescribing system should be designed to help facilitate and fully automate the PA process. In an automated PA system, physicians would be notified at the point of prescribing that a medicine is subject to PA and empowered to enter relevant information that would, if appropriate, provide immediate patient access to the drug.

For example, etanercept is a tumor necrosis factor (TNF) inhibitor indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Many plans impose prior authorization requirements on etanercept before RA patients are provided access to the treatment. Typically, plans request two types of data to process a prior authorization for etanercept: patient diagnosis and previous failed drug therapy(ies). Since the e-prescribing system provides real-time information regarding a patient's eligibility and benefits, including a requirement for PA as well as patient's medication history, physicians should be able to submit a PA request for etanercept through e-prescribing and be informed whether the application is approved at the point of care.

A fully automated PA process will improve patient quality of care, ensure prescribing efficiency and reduce prescribing costs. We believe that the value of an e-prescribing system would be significantly diminished if prescribers must manually submit PA requests. We urge CMS to consider NCVHS' recommendation that HHS should evaluate the economic and quality of care impacts of automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests. [12]

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Wyeth

4) **Standards for the e-prescribing user interface and presentation of drug lists and formularies should ensure that appropriate, accurate and up-to-date information is presented in a comprehensive and neutral format.**

The use of e-prescribing should not inappropriately steer or influence a physician's clinical decision-making or prescribing practices. The content and completeness of the information provided by the system, along with the structure, format, and organization of the formulary and user interface within the e-prescribing technology will undoubtedly impact and influence a provider's prescribing behavior. For example, if the initial e-prescribing interface only provides a list of generic or preferred innovator medicines covered by the plan and requires physicians to scroll through additional pages to access and prescribe alternative therapies, a physician's prescribing choices may be negatively impacted. Patients' access to needed medicines may also be effectively limited. We believe that CMS should be cognizant of these issues and develop standards that will guarantee comprehensiveness and neutrality in the e-prescribing process.

CMS should ensure that future rulemaking on standards for the e-prescribing user interface and presentation of drug lists and formularies address the following issues:

- Physicians should have easy access to the comprehensive list of available drugs and the information should be presented in a single, neutral, and comprehensive format (e.g., alphabetically).

- The user interface should not create barriers to prescribe non-preferred or off-formulary drugs. It also should not limit the ability of physician to prescribe drugs for clinically appropriate off-label uses.

- E-prescribing should not interrupt a physician's workflow—e.g., wading through multiple pages to view drug choices, or pop-up windows with information about formulary or prior authorization.

- The system should provide up-to-date, accurate, and comprehensive information to assist physician communicating with the patient at the point of care, such as information about appropriate drug utilization.

- The system should also provide information needed for timely access by beneficiaries to clinically appropriate treatment, such as accurate and easy-to-understand information about exceptions and appeals.

- The system should be updated on a timely and frequent basis so that real-time information will be presented to ensure patient access to new drugs and drugs with new indications.

Conclusion

Wyeth believes that e-prescribing holds the potential to be used as a tool to reduce prescribing errors, improve patient safety, health outcomes and quality of care, and improve prescribing efficiency. To achieve these goals, e-prescribing should not be used to limit physician prescribing choices, or patient access to clinically appropriate medications. E-prescribing also should not inappropriately influence physicians' decision-making, interfere with physicians' workflow or impede their ability to make appropriate clinical and pharmacological choices.

We appreciate this opportunity to provide CMS with comments and recommendations on e-prescribing standards and the e-prescribing program under the Medicare Part D program. We look forward to working with CMS in future e-prescribing rulemaking and the implementation of the e-prescribing program. If there are any questions about Wyeth comments, please do not hesitate to contact me.

Sincerely,

Lucinda E. Long

Submitter : Mr. Kim Caldwell

Date: 04/05/2005

Organization : DCEP/MDBG/CBC/CMS

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-0011-P-48-Attach-1.DOC

Comments to Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program

PROVISIONS:

F. Compliance Date (pg 6267)

CMS proposes a compliance date of January 1, 2006 for the proposed foundation standards. By requiring Part D Sponsors to "support and comply with electronic prescribing" by January 1, 2006, this would require that all of their contracted pharmacy providers also must support and comply with these standards in that timeline. This timeline is on top of the already passed date for future Part D Sponsors to submit pharmacy access networks. By having conflicting requirements, CMS places the Plan Sponsors in harms way by having attestations bearing the weight of oath on pharmacy networks when the electronic prescribing standards may possibly remove pharmacies from availability to serve status.

We are requesting two things in this area, (1) that CMS change the wording to state that pharmacies willing and able to receive electronic prescriptions by 01-01-2006 comply with the industry approved standards while other pharmacies would be required to comply by a later date (2007 or 2008) if they remain in Part D networks and (2) that CMS comment on what will happen to those pharmacy providers that knowingly cannot comply within these standards and/or do not have the ability to accept electronic prescriptions in this timeframe due to circumstances beyond their control (e.g., cost barriers, technological barriers, etc.). For example, will CMS require that these pharmacies be excluded from contracts with Part-D sponsors if they do not meet the foundation standards by 01/01/06? This would further disadvantage those pharmacies that do not already have e-prescribing capabilities. Alternatively, would CMS allow for a grace period or extended timeline for compliance for pharmacies in these situations?

IMPACT ANALYSIS:

D. Impact on Pharmacies and Other Dispensers (pg 6271)

CMS comments that they do not expect to see "a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing." We disagree. There are three key areas for significant impact on pharmacies and other dispensers. First, electronic prescribing creates an environment in which prescriptions for many different patient types will benefit including those on Medicaid. Medicaid laws as followed in the states require that prescriptions must have a prescriber's *handwritten*

statement across the face of the prescription if a branded prescription is required when a generic is available. Even the wording is dictated. Without this possibility, pharmacies and pharmacists are at significant financial risk when their state pharmacy rules require no substitution if the physician indicates such yet the Medicaid language and audit procedures punish the pharmacists for dispensing the required brand without the prerequisite wording – a catch-22. State pre-emption is only intended to apply to Part D without regard for Medicaid or other prescriptions. Second, the potential exists for an increase in the total volume of prescriptions filled by pharmacies, since a proportion of hand-written prescriptions never reach the pharmacy and thus are not dispensed. Also, e-prescribing inherently promotes an increased utilization due to the menu driven approach to prescribing at the point of care.

Third, we agree with the expected efficiencies discussed at the beginning of this section, it is possible that an increase in e-prescriptions may result in an increase in the number of prescriptions that are not picked up by patients and therefore create additional administrative workloads for pharmacy staff.

A potential volume increase coupled with a condensed timeline for adoption, could potentially pose burdensome to pharmacies and other dispensers.

G. Impact on Small Businesses (pg 6271-2)

In the section on Impact on Pharmacies, it was stated that 75% of the 57,208 pharmacies already have e-prescribing capabilities and the majority of pharmacies are currently highly networked. Based on this information, it was assumed that the marginal cost of e-prescribing is likely to be small. However, the pharmacies referred to above are likely to be large business and/or chain pharmacies and may not represent the state-of-the-art for small and/or independent pharmacies. The proposed foundation standards will likely have disproportionably higher implementation costs for small pharmacies compared to large pharmacies. Also, small businesses will be less likely to absorb the implementation cost compared to larger pharmacies, especially given the delayed or minimal return on investment. Thus, if pharmacies are required to implement these foundation standards, certain pharmacies may decide not to contract with PDP Sponsors, particularly including: small/independent pharmacies, pharmacies in rural areas, and Indian Health Services/Tribes and Tribal Organizations/Urban Indian Health Program (ITU) pharmacies. This would most likely result in pharmacy access issues for geographical areas in which few pharmacy providers may be present. Most ITU and territory pharmacies do not operate with technology today, yet CMS mandates the inclusion of these pharmacies to meet pharmacy access standards.

Comments to Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program

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Submitter : **Ms. Anne Canfield** **Date: 04/05/2005**

Organization : **Rx Benefits Coalition**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-49-Attach-1.DOC

Rx BENEFITS COALITION

Safety + Affordability + Innovation

April 7, 2005

Deleted: April 5, 2005

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

Dear Madams/Sirs:

The Rx Benefits Coalition (RxBC), a coalition representing a diverse group of employers and other payers and providers of prescription drug benefits committed to ensuring that consumers have access to safe and affordable prescription drug services, The RxBC appreciates the opportunity to submit its comments in response to the Notice of Proposed Rulemaking (NPRM) implementing section 1860D-4(3) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), which the Center for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (HHS) issued on February 4, 2005. 70 *Fed. Reg.* 6256-6274.

This comment letter discusses both the rule that HHS will promulgate based on comments to the NPRM (referred to in this letter as the Interim Rule), and the rules adopting additional standards that, according to the NPRM, HHS intends to promulgate in the future based on pilot testing of additional standards and functions necessary to the full implementation of the Part D electronic prescribing program (referred to in this letter as the Final Rules). The RxBC is primarily concerned with two subjects mentioned in the background section of the NPRM – the extent to which the standards promulgated under the Interim and Final Rules will preempt state law, and the structure of the standards approval process created by the Interim Rule.

SCOPE OF PREEMPTION

BACKGROUND, A. Statutory Basis, 2. State Preemption

PROVISIONS, B. Proposed Definitions

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Statutory Basis

NPRM, page 6257. "We believe the best reading of [Section 1860D-4(e)(1)]- as well of the intent of Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans, . . . We believe that 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.' . . . 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."

State Preemption

NPRM, page 6258-59. "The MMA addresses preemption of State laws at section 1860D-4(e)(5) of the Act as follows:

> *(5) Relation to State Laws. The standards promulgated under this subsection shall supercede any State law or regulation that –*
>
> *(A) Is contrary to the standards or restricts the ability to carry out this part; and*
>
> *(B) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.*

. . .

"We view [section 1860D-4(e)(5)] 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)"

. . .

"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 wish to make the following key points with respect to preemption of state laws and regulations that conflict or interfere with e-prescribing and the MMA:

1. The narrow interpretation of the preemption language proposed in the NPRM conflicts with the express intent of Congress and would greatly impede e-prescribing when the Interim Rule is adopted. In its current form, the NPRM merely adds one more narrow set of rules for e-prescribing standards on top of the confusing web of state legal restrictions. If enacted as proposed, this interpretation will impede the timely development, implementation and adoption of an effective uniform, interoperable, nationwide e-prescribing system.

2. Rather than issuing a narrow interpretation, HHS should clearly state that the standards adopted in the Interim and Final Rules issued by HHS preempt state laws or regulations to the extent that they affect e-prescribing . Only then can the HHS regulations facilitate an interoperable e-prescribing system within the timeframe envisioned in the MMA.

3. If HHS is not ready to issue regulations that clearly and effectively preempt the conflicting state laws and regulations, then it should postpone addressing preemption until it issues standards in all areas of the electronic prescription drug program and obtains information from the conclusion of the pilot testing that the MMA requires.

4. HHS should reserve for itself in the Interim Rule the authority to establish a flexible guidance process so that the Department can issue handbooks or other written guidance without needing to reopen the formal regulatory process.

5. For e-prescribing to become a reality, HHS should incorporate in the Final Rule all of the functions that are necessary to create a uniform, interoperable, nationwide set of standards.

In addition to presenting the policy arguments in support of these positions, this comment letter includes Attachment A, a legal analysis of the application of existing case law to the preemption language of Section 1860D-4(e).

I. The Scope of Preemption Proposed in the NPRM Should be Broadened so that the Standards Issued Under the Interim and Final Rules Facilitate Rather than Impede Nationwide e-Prescribing and Thereby Help to Lower Healthcare Costs and Improve Patient Health

For e-prescribing to succeed, comprehensive uniform, interoperable, nationwide standards are essential. Without federal preemption that is not possible.

The NPRM itself recognizes that e-prescribing will bring many benefits to the American healthcare system. The U.S. healthcare delivery system currently is complex, inefficient, and highly fragmented. The Institute of Medicine has concluded that the

application of health information technology can improve both the efficiency and the quality of healthcare.[1]

The application of such technology to prescriptions is an especially important source of potential improvements. Patient health will benefit from a reduction in medication errors and adverse drug events which, according to the Institute of Medicine, account for over 770,000 injuries or deaths each year in hospitals. E-prescribing can reduce the incidence of medication errors by, among other things, helping to prevent illegible scripts and by providing prescriber access at the point of prescription to information about potentially dangerous drug interactions. One study cited by the Institute for Safe Medication Practices (ISMP) found a 55 percent reduction in medication errors after e-prescribing was instituted.[2]

E-prescribing also can reduce the burdens and costs on physicians and pharmacists The NPRM cites estimates that almost 30 percent of prescriptions require pharmacy callbacks that result in 900 million prescription-related telephone calls placed annually. (NRPM, p. 6260). Electronic interactions through e-prescribing can greatly reduce the number and extent of such interruptions for prescribers, dispensers and patients. As the NRPM concludes (p. 6260), "...even small improvements in quality that are attributed to e-prescribing may translate into significant health benefits."

A. E-Prescribing Requires Nationwide Standards That Allow for Development and Implementation of Interoperable Electronic Systems

The MMA's Comprehensive Approach to E-Prescribing

Due to these acknowledged benefits, the MMA created a comprehensive electronic prescription program for payors, providers and pharmacies that manage benefits and prescribe and dispense covered Part D drugs. Congress did not expressly mandate the adoption of e-prescribing by Prescription Drug Plans (PDPs), Medicare Advantage Organizations offering Medicare Advantage-Prescription (MA-PDs) plans or providers, but provided that HHS would promulgate uniform standards for those that do adopt e-prescribing. In the NRPM, however, HHS would mandate that PDPs and MA-PDs implement electronic prescribing and that the programs utilizing the foundation standards would be available on January 1, 2006. While participation by providers and pharmacies is voluntary, some will utilize e-prescribing because of contractual requirements of a health benefit plan in which they participate.

The MMA requires that e-prescribing include real-time electronic delivery of certain specific information on eligibility, benefits, drug interactions, warnings, dosage

[1] Institute of Medicine, To Err Is Human: Building a Safer Health System (Washington, DC: November 1999) and Crossing the Quality Chasm: A New Health System for the 21st Century (Washington, D.C.: March 2001).

[2] Institute for Safe Medication Practices (ISMP), white paper, "A Call to Action: Eliminate Handwritten Prescriptions Within 3 Years!" 2000.

adjustments, medication history, and the availability of generic substitutes to providers and pharmacists. This information must be provided in a secure format that complies with health privacy requirements. The system also must permit the electronic exchange of FDA drug labeling and listing information. E-prescribing systems are intended to provide a near-term foundation for the continuing implementation of systems for electronic medical records.

The MMA contains a statutory requirement for HHS to issue regulations that provide standards for e-prescribing that pertain to electronic prescribing programs. It sets an aggressive schedule for issuance of the e-prescribing standards and their implementation.

The Need for E-Prescribing Incentives

Three factors are critical to the development of a nationwide e-prescribing capability. First, the parties who benefit from e-prescribing must have flexibility to compensate one another and create incentives for prescribers and pharmacies to adopt new e-prescribing systems. This is needed because participation in e-prescribing – especially by physicians – is voluntary. Physician reluctance to adopt new e-prescribing technologies has been well documented.[3]

Moreover, the adoption of e-prescribing systems involves externalities; the benefits also accrue to other parties besides the physician or pharmacy that adopts the system. The MMA recognizes this and authorizes the Secretary of HHS to provide incentive payments to physicians to help defray their costs. The MMA also provides for a safe harbor from federal anti-kickback laws and an exemption from federal limitations on physician referrals (the "Stark law") so that stakeholders in the e-prescribing network can compensate one another for joining.

The Need for Scale

The second critical factor in e-prescribing is scale. In other words, similar to the expansion of the telephone or Internet, the e-prescribing system will offer increasing benefits that multiply according to the number of participants in the system. To achieve scale requires that as many appropriate parties as possible – physicians, pharmacies, hospitals, pharmacy plans, pharmacy benefit managers, etc. – be included in the expanding network. Scale also requires a nationwide system that is accessible by parties who are located in all parts of the country. Again, the MMA recognizes this and requires HHS to issue regulations to create national uniform standards that preempt any state law or regulation that conflicts or interferes with the e-prescribing program. This preemption

[3] "In health care, the average investment in information technology computer hardware, software, and services is only about $ 3,000 annually for each worker, compared with $ 7,000 a worker on average for private industry and nearly $ 15,000 a worker in banking....But health care remains a fragmented industry, with much of the care still provided by physicians in small practices." Steve Lohr, "Health Industry Under Pressure to Computerize," *New York Times*, February 19, 2005.

would include standards that pertain to the electronic transmission of a medication history as well as information on eligibility, benefits, and prescriptions for covered Part D drugs.

The Need for Interoperability

The third necessary element in e-prescribing is interoperability. As used in this comment letter, the term includes interoperability not only in the more narrow technical sense, but also operationally. The history of electronic technology development is littered with multiple systems that could not talk to one another. Today, even companies that produce potentially proprietary information technology systems recognize the benefits of interoperability.[4] This relates to scale. With interoperability, the participants in an information network reap substantially greater benefits than if that network is divided into smaller fiefdoms.

Again, the MMA addresses this issue in multiple ways.[5] In order to institute a nationwide e-prescribing system, MMA requires the Secretary of HHS, with recommendations by the National Committee on Vital Health Statistics (NCVHS), based on consultations with a range of industry and government stakeholders, to adopt, recognize, or modify uniform standards for the e-prescribing program. The Secretary must develop initial standards by September 1, 2005 and must pilot test them beginning in 2006 unless the Secretary determines that the initial standards reflect "adequate industry experience." Final standards must be in place by April 1, 2009.

To assure interoperability, and preclude the division of the country into separate areas that might lack access to the common e-prescribing network, the MMA provides that the standards will preempt state laws and regulations that conflict or interfere with e-prescribing programs. That preemption is needed to assure both the scale and interoperability that are required for a successful nationwide system.

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[4] See, e.g., Steve Lohr, "High-Tech Alliance on Base for a Digital Health Network," *New York Times*, January 26, 2005. ("Eight of the nation's largest technology companies, including IBM, Microsoft and Oracle, have agreed to embrace open, nonproprietary technology standards as the software building blocks for a national health information network.")

[5] In addition to creating the Electronic Prescription Drug Program, the MMA provides for a number of initiatives that relate to electronic or technology-enabled programs to reduce costs and improve quality of care. These initiatives include: a) grants to physicians to implement electronic prescription drug programs (Section 101); b) an IOM Study on Safety and Quality to provide a blueprint for system-wide change (Section 107); c) an IOM Study on Performance Measures to identify information technology requirements in aligning performance to payment for service (Section 238); d) an extension of telemedicine demonstrations and doubling the available authorized funding for patient safety improvements using information technology (Section 417), e); a 3 year CMS pay-for-performance demonstration program using health care information technology at 4 separate sites (Section 649); f) establishment of a new Council for Technology and Innovation within CMS for oversight of technology enhancements (Section 942), g) establishment of a new Commission on Systemic Interoperability to focus on standards development acceleration and adoption (Section 1012); and h) creation of a health care infrastructure loan program including $200 million in grant funding over 54 months for loans to providers to implement technology (Section 1016).

B. E-Prescribing Can Become a Practical Reality Within the Timeframe Mandated by the MMA Only if HHS Adopts A Broad Scope of Preemption That Effectively Preempts Those State Laws and Regulations That Conflict With the Standards

The e-prescribing regulations that HHS will issue to implement the MMA have the potential to help overcome the significant barriers to e-prescribing. The NPRM, however, takes a cautious approach that should be modified in the Interim Rule if it is to help, rather than hinder the expansion of an e-prescribing network.

The primary impediment to achieving the scale and interoperability needed for e-prescribing is the patchwork of laws and regulations in the 50 states, the District of Columbia, Puerto Rico, etc. Section 1860D-4(e)(5) of the MMA addresses this impediment in clear language. In our view, the MMA directs HHS to issue standards that preempt any state law or regulation that conflicts or interferes with the standards pertaining to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs and that is contrary to the standards or restricts the ability to carry out the MMA.

Unfortunately, the NPRM proposes to limit (p. 6257) any preemption to prescriptions with respect to covered Part D drugs *prescribed for Part D eligible individuals*. As is discussed further in Appendices A and B to this comment letter, this approach unreasonably narrows the scope of the MMA with respect to e-prescribing. E-prescribing depends on the ability of prescribers and other members of e-prescribing networks to conform their e-prescribing systems to a single set of standards that apply across the nation. The public is not well served by policies that permit conflicting state laws and regulations to preclude a nationwide e-prescribing system.

Virtually all payors' and providers' patient population bases are served by many different benefit programs. Applying the standards only to Part D beneficiaries for covered Part D drugs creates multiple problems. In states that prohibit e-prescribing, for example, a prescriber would create an e-prescribing system exclusively for prescriptions for Part D individuals, while continuing to prescribe by hand for all other prescriptions for those states.[6]

In states that permit e-prescribing but have laws or regulations that conflict with the standards that will be issued by HHS, a prescriber who wants to electronically prescribe for all patients will be required to maintain two e-prescribing systems, one for patients enrolled in Medicare Part D and one for all other patients. In multi-state areas, such as the Washington, D.C. metropolitan area, where physicians practice across state lines, this problem is multiplied. In reality, most prescribers cannot determine who the payors will be. They will not go through the expense of maintaining two or more

[6] The testimony of the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004, identifies South Carolina and South Dakota as states that do not allow electronic transmission of prescriptions. See p. 10.

systems and will elect not to e-prescribe at all; physicians will simply continue to use paper prescriptions.

Also, in cases where Part D coverage might be denied for a patient at a time after the physician has written a prescription for an eligible Part D drug,[7] the physician then would face the prospect of being found in violation of a state law or regulation that otherwise would have been preempted. The pharmacy that dispensed the prescription would also find itself at legal risk. Limiting preemption to Part D enrollees rather than covered Part D drugs is simply not practical.

Besides the fact that certain states prohibit e-prescribing outright, the most important problem that exists involves the myriad of often small differences between state laws or regulations. Cumulatively, these differences can prevent e-prescribing from achieving needed scale and degree of coverage to be attractive to many prescribers. For example, specific electronic authentication requirements differ among the states, as do requirements about whether the physician may transmit the prescription to the pharmacy through an intermediary, such as a router. Another potential impediment for prescribers is the variation in state laws with respect to the format of prescriptions. A national standard for the format of prescriptions is needed to achieve a uniform, interoperable nationwide system for electronic prescribing. Only with such a standard format can the needs of elderly patients who may travel from their homes and their prescribing physicians to warmer climates in the winter and for those physicians practicing in multi-state jurisdictional areas be accommodated.

While any one standard may be beneficial, a multiplicity of requirements makes uniform, interoperable, nationwide system for e-prescribing difficult, if not unworkable. Consider the following state requirements presented in testimony of the National Association of Boards of Pharmacy (NABP) to the NCVHS Subcommittee on Standards and Security[8]:

- The states of Nevada and Ohio require that the state Board of Pharmacy approve the e-prescribing system (NABP, pp. 10 and 13).
- The state of Washington requires such Board approval every three years (NABP, p. 17).

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[7] This could occur, for example, in some cases where a patient may have dual coverage and receives a Part D drug that is not eligible to be paid for under Part D. *See* the Notice of Proposed Rulemaking dated August 3, 2004, 69 *Fed. Reg.* 46632-46863 implementing the Medicare Part D benefit at page 46647 where HHS discussed the complexity of determining whether a drug prescribed for a Medicare beneficiary was a covered under Part D or under Part A or B. By way of example, the NPRM pointed out that "Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (*e.g.*, a beneficiary who had his or her transplant paid for by a private insurer when he or she was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for these beneficiaries since Part B is prohibited by statute from paying for them."

[8] *Ibid.* at the pages indicated.

- In Maryland, any "commercial intermediary must guarantee the confidentiality and security of transmission process in a manner approved by the Board" (NABP, p. 6).
- The states have varying requirements for prescription forms. For example, the state of Alabama allows electronic transmission but requires that the prescriber must write "Brand Medically Necessary" whenever a specific brand must be dispensed (NAPB, p. 1).
- The states have a variety of requirements concerning whether a prescriber may provide the electronic prescription to a pharmacy through an intermediary and the nature of permitted intermediaries.
- The states have a variety of electronic signature requirements.

A copy of the NABP table of state requirements is appended to this comment letter as Attachment B.

Such requirements are serious obstacles to the expansion of e-prescribing. For example, the requirement for board approval of the system creates the risk that the board of pharmacy of a single state might preclude operation of an e-prescribing system in which the e-prescriber has made a significant investment and which is acceptable under the rules of other states. It also risks freezing the level of technology in cases where a board publishes an approved list of e-prescribing systems that is only infrequently updated.

Depending on the state, some of the conflicting requirements are set by law while others appear in board of pharmacy rules and interpretations. Indeed, such rules and interpretations can be more troublesome than state statutes because (1) they can often be proposed and adopted with little public notice (as compared to state statutes) and (2) they can be difficult for a party to obtain, compared to statutes that the states codify.

Prescribers face significant sanctions if their e-prescribing fails to comply with each of the variable and changing state requirements. This creates enough uncertainty that prescribers are unlikely to actively implement an e-prescribing system even if they were able to achieve technical compliance with each state's requirement at a particular time. At a minimum, technology vendors are likely to avoid service to states where the requirements are onerous, unclear, or at variance with requirements of a number of other states. The Government Accountability Office observes:

> "[H]ealth care providers are uncertain about what would constitute violations of those laws or create a risk of litigation. To the extent that there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT."[9]

[9] *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, p. 44.

In summary, preemption of conflicting state laws is needed to make sure that the MMA, as implemented by HHS in its regulations, in fact leads to creation of nationwide, uniform, interoperable standards. Otherwise, e-prescribing cannot succeed except at the margins.

C. If HHS is Not Ready to Take the Needed Broad View of Preemption, Then it Should Defer its Analysis of Preemption Until HHS (A) Issues the Complete Set of Standards Needed for E-Prescribing Under the MMA, and (B) Evaluates the E-Prescribing Pilot Tests

The MMA does not require HHS to issue regulations defining the scope of that preemption. Rather, the preemption language at Section 1860D-4(e)(5) is self-executing: the standards themselves automatically preempt conflicting or burdensome state laws and regulations. The purpose of any HHS action to define the scope of preemption in regulations should be to make the process of implementing the standards as smooth as possible to facilitate and encourage their adoption so that HHS can meet the tight deadlines for e-prescribing that the MMA sets.[10]

If HHS is not ready to take the view of preemption that is needed to assure that e-prescribing is implemented within the timeframes set by the MMA in the context of the Interim Rule, then we respectfully urge that HHS should remain silent in the current rulemaking. Instead, HHS should defer presenting any analysis of preemption until it issues all of the standards for e-prescribing that are envisioned under the MMA. Additionally, HHS should wait until information is available from the pilot testing that the Department is undertaking. We urge that HHS utilize its pilot tests to explore the need for preemption and the necessary scope. Then the pilots can reveal clearly to HHS the burdens on e-prescribing that conflicting state laws and regulations impose.

It is premature to narrow the scope of preemption in the present rulemaking, before the entire group of standards has been issued and information from the pilot tests is available. Otherwise, e-prescribing will remain a dream rather than a practical reality for many years to come.

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[10] The HHS responsibility to preempt state laws and regulations that are contrary to or restrict federal e-prescribing standards derives from the language of the MMA itself. President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335 provides additional reason for HHS to give the preemption provisions of the MMA a practical rather than restrictive interpretation. That executive order calls upon HHS, among other requirements, to, "[a]dvance the development, adoption, and implementation of health care information technology standards nationally through collaboration among public and private interests, and consistent with current efforts to set health information technology standards for use by the Federal Government"

The NPRM mentions President Clinton's Executive Order 13132 on federalism, as the basis for its cautious approach so that the proposed new regulations would narrow the degree of preemption permitted under the MMA. However, the NPRM omits to acknowledge this more recent executive order that provides a basis for assuring that preemption is appropriate for the department's mandate to meet the MMA's aggressive timetable for adoption of e-prescribing standards.

II. Legal Analysis Demonstrates that Congress Intended the MMA's Preemption Provisions to have Broad Application

The NPRM (p. 6259) invites comments on its proposed position that Section 1860D-4(e)(5) of the MMA that preempts state laws should be interpreted in a manner that provides for "conflict" preemption as opposed to "field" preemption. The NPRM also requests comments on whether: (1) there are state laws that should be preempted (presumably in order to achieve the goals of the MMA) that would not be preempted under HHS' more narrow interpretation, and (2) the preemption provisions apply only to transactions and entities that are a part of an Electronic Prescription Drug Program under Part D or to a broader set of transactions and entities.[11]

These comments will first demonstrate that Congress expressly provided for broad, i.e., "field" preemption at least with regard to all aspects of an e-prescribing program. In support of this position, we will point out state laws that could interfere with e-prescribing programs that may not be interpreted as being in direct conflict with standards promulgated by HHS and the potential threats to adoption of e-prescribing programs raised by HHS asserting a narrow interpretation of the preemption provisions at this time. Since Congress intended to preempt the "field" of at least e-prescribing programs, the preemption provisions apply to any state laws or regulations that are not only contrary to but that restrict the ability to carry out such programs.

Congress Expressly Preempted the Field of E- Prescribing

A. The MMA Covers the Field of E-Prescribing Programs

[11] We are responding to the manner in which HHS has posited this issue. We note, however, as set forth in Attachment A, that Congress has expressly and broadly preempted state law based upon the plain reading of the language of section 1860D-4(e)(5)and other principles of statutory construction. The issue of field versus conflict preemption arises in cases in which preemption is not express but implied, which is not the case here. We would point out here that "Established principles of implied preemption" support a broad view of the scope of preemption Congress adopted in the MMA. Even without an express preemption provision, the Supreme Court has found that "state law must yield to a congressional Act in at least two circumstances." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). First, "when Congress intends federal law to 'occupy the field,' state law in that area is preempted." *Id.* (When Congress chooses to occupy the field, state law can be preempted even if Congress chooses not to regulate a specific aspect of the "occupied" field. *See Chamber of Commerce of the U.S. v. Lockyer*, 364 F.3d 1154, 1169 (9th Cir. 2004).) Second, even if Congress has not occupied the field, state law is preempted to the extent of any conflict with a federal statute. *Crosby*, 530 U.S. at 372; *see English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Such a conflict exists either where (1) compliance with both the state and federal law is "a physical impossibility," or (2) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Moreover, Congress' inclusion of an express preemption clause "'does *not* bar the ordinary working of conflict preemption principles.'" *Sprietsma v. Mercury Marine*, 537 U.S. at 65 (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in *Geier*)). *Boggs v. Boggs*, 520 U.S. 833, 844 (1997) (quoting *Gade v. Nat'l Solid Wastes Management Assn.*, 505 U.S. 88, 98 (1992)).

A legal analysis of the federal common law on preemption and statutory construction as applied to the preemption provisions is attached as Appendix A. Without repeating the points of Appendix A, this analysis will focus specifically on the NPRM's position and request for comment.

The main support in the NPRM's proposed interpretation for its "plain language" interpretation of the preemption provisions is Congress' use of the term "and" between parts (A) and (B). The NPRM's attempt to narrow the scope of the preemption intended by Congress fails under the NPRM's own analysis.

In order to properly assess the intent of Congress, the language of the statute needs to be considered along with the full scope of the MMA and the Part D benefit. Congress recognized that e-prescribing was an important step in establishing an electronic infrastructure for the U.S. health care system. Thus, Congress mandated these broader initiatives because it recognized that multiple barriers exist and those barriers will prevent the development of an e-health infrastructure . See footnote 5 *supra.*

In addition, the meaning of the term "standards' is important. Congress intended that a comprehensive drug benefit and attendant health care components would be greatly enhanced by an electronic prescribing program. As such, the statutory scope of the term "standards" is very broad.[12] These standards address not only the transmission of information but also, as the MMA specifies, the actions necessary to insure that the objectives of patient safety, quality of care and efficiencies and cost savings are met. §1860D-4(e)(3)(B). Because the MMA includes requirements for patient compliance and care management program as an integral part of the Part D benefit, it is clear that the term "standards" as used in the express language that "[t]he *standards* promulgated under this section shall supersede any state law or regulation ..." was intended to refer to all of the components of an electronic prescribing program as it supports the Part D benefit. § 1860D-4(e)(5) (emphasis added).

This plain reading of this language is further bolstered by the additional language Congress included in part (A) that the state laws that are superseded include not only

[12] Congress defined the Part D benefit to include far more than the cost of the drugs. As a component of the Part D benefit, beneficiaries are entitled to the following: (1) access to drug specific information on covered Part D drugs, including through pharmacy networks, how a PDP or MA-PD formulary functions and how a beneficiary can obtain access to information about access to covered Part D drugs and pharmacy networks, formularies and beneficiary cost-sharing requirements, (2) mechanisms for responding to beneficiary questions and providing information via the Internet about changes to formularies and explanations of benefits, (3) access to pharmacies, (4) meeting requirements for development of formularies that must include products in every therapeutic category and periodic evaluations of treatment protocols and procedures, and (5) cost and utilization management, quality assurance and medication therapy management programs. The medication therapy management programs are targeted to beneficiaries with multiple conditions, taking multiple drugs and likely to exceed drug spending targets set by HHS. The elements of the program include patient compliance regimens, (refill reminders, special packaging and other programs and means), and coordination with chronic care improvement programs. By definition, the full scope of the Part D benefit goes far beyond the act of paying for covered Part D drugs and includes a broad set of entities and transactions.

laws that are "contrary to" the standards but also (through the term "or") any state law or regulation that "*restricts the ability to carry out this part.*" § 1860D-4(e)(5) (emphasis added). The term "part" is clearly defined in the statute to include all of the Part D benefits including access, utilization, quality assurance and care management programs. Part (A) clearly includes the disjunctive term "or" between "contrary to the standards" and "restricts the ability to carry out." The NPRM's interpretation hinges only on the "contrary to the standards" language and improperly reads the "restricts the ability to carry out this part" language of part (A) totally out of the statute.

Moreover, the use of the term "and" between (A) and (B), even if read as "conjunctive," does not eliminate the application of "restricts the ability to carry out this part" language in (A). Even under the NPRM's proposed reading, the statute expressly requires any standard promulgated by HHS to preempt any state law or regulation pertaining to the transmission of medication history and of information on eligibility, benefits and prescriptions with respect to covered Part D drugs under this part that "**restricts the ability to carry out this *part*....**"

That it is essential to give meaning to this phrase in part (A) is made clear by an examination of the language in part (B). The term "pertains" is very broad and applies to the "transmission of electronic information" in all of the elements of the electronic prescription drug program as defined in Part D: 1) medication history, 2) information on eligibility, 3) benefits (which include access to information, formulary, pharmacy networks, beneficiary cost-sharing, explanation of benefits, quality assurance and medication therapy management programs), and 4) prescriptions. Given the full scope of benefits provided under Part D, the phrase "with respect to covered part D drugs under this part," must of necessity include all aspects of an electronic prescribing program, compelling the conclusion that 1860D-4(e) applies to medication history and the other components with respect to covered Part D drugs prescribed for any individual, not just for Part D eligible individuals.

B. Common Sense Further Supports Express Preemption of the "Field" of E-Prescribing Programs

Existing state laws and regulations apply to all participants in an electronic prescribing program, including the NPRM-identified stakeholders (p. 6260) of prescribers, pharmacists and associated staff, vendors, hospitals and health systems, patients, health plans, and pharmacy benefit managers, among others. The only parties that potentially would not be participants in Part D benefits are those providers that treat only children, i.e., pediatricians and children's hospitals or physicians or other providers who do not accept assignment of Medicare (even these may have patients who pay them out of their pocket, but who would receive Part D benefits). State laws and regulations, however, do not tend to make any distinction among the type of patient treated, e.g., child as opposed to adult. In the same vein (apart from Medicaid and similar programs), state laws and regulations do not tend to make any distinctions based upon the party that is paying for the benefit, whether it is paid for by Medicare, commercial insurance or out of a patient's pocket. Accordingly, the distinction that HHS seeks to impose between

covered Part D drugs received by Part D enrollees and the same drugs received by others merely adds another complication to the pattern of state laws and regulations that already conflicts with e-prescribing.

As set forth previously, there are many examples of state laws and regulations that are not clearly preempted by the NPRM's "contrary to" approach. For example, consider the difficult scenario where the states impose additional prescriber or pharmacy identifiers or requirements different from the federal identifier that the NRPM proposes be promulgated. This may not constitute a "conflict" for purposes of the preemption language of the proposed rule. Given the patchwork of laws on this and related topics under electronic prescribing, this would certainly create havoc in the industry, including for PDPs and MA-PDs that have multiple state jurisdictions to serve.

Common sense and the clear evidence of Congress' awareness of problems that exist compels conclusion that Congress intended expressly to preempt the field of electronic prescribing programs for covered Part D drugs prescribed for any individual.

III. The Final Rule Should Include In The E-prescribing Standards All Of The Functions Necessary To Facilitate E-Prescriptions

As noted at the beginning of this comment letter, a uniform standard that includes all of the components necessary to e-prescribing is critical if an effective nationwide interoperable e-prescribing system is to become a reality. The NPRM at page 6262 identifies a number of functions that NCVHS in its September 2, 2004 letter to the Secretary that should be included in "standards needed for the interoperable electronic exchange for most of the categories of information enumerated in Section 1860D-4(e)(2)" of the MMA. In addition to the functions identified in the NPRM, NCVHS in its March 4, 2005 letter to the Secretary beginning at page 10 identifies "a number of message format, terminology, and identifier standards and important related issues associated with e-prescribing" that should be considered in the context of developing Part D e-prescribing standards. We believe it is essential to incorporate most, if not all, of those functions in the standards promulgated under the Final Rule and, as indicated earlier in this comment letter, that the standards preempt all state laws and regulations that impede or conflict with the implementation of a nationwide interoperable e-prescribing system.

In addition to the functions identified in the September 2, 2004 NCVHS letter and expanded upon in the March 4, 2005 letter, the Final Rule should also include any other remaining functions that were not identified in those letters but are important to the creation of a nationwide interoperable e-prescribing system. Examples of those functions include, but are not limited to a standard drug prescription format that can be used in all jurisdictions; a standard rule that implements the Stark (anti-referral) exception and the anti-kickback safe harbor promulgated by the Secretary pursuant to Section 1860D-4(e)(6) of the MMA that would be the sole rule applied in all jurisdictions; a standard that addresses authentication of electronic prescriptions across jurisdictions; and others.

Proposed Definitions

NPRM, page 6265. "We propose to amend Section 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 wit the term "Electronic Prescription Drug Program" which we are proposing to define below. The proposed definitions are as follows:

. . .

- *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.*

. . .

- *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."*

Based on our view that Congress intended to have the e-prescribing standards adopted by the Secretary under Section 1860D-4(e) apply to covered Part D drugs prescribed for any individual – rather than be limited to covered Part D drugs prescribed for Part D eligible individuals – the definitions of "Electronic Prescription Drug Program" and "Prescription-related information" in Section 423.159(a) of the proposed regulation (NPRM, p. 6273) should be revised to read as follows:

> "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~~."
>
> "Prescription-related information means information regarding eligibility for drug benefits, mediation history, or related health or drug information for ~~Part D eligible~~ individuals ~~enrolled in a~~ *for whom covered* Part D ~~plan~~ *drugs are electronically prescribed*."

STANDARD SETTING PROCESS

BACKGROUND, A. Statutory Basis

BACKGROUND, F. Evolution and Implementation of an Electronic Prescription Drug Program

Also relates to BACKGROUND, H. Summary of Status of Standards for an Electronic Prescription Drug Program

Statutory Basis

NPRM, p. 6257. "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 this pilot testing requirement 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."

Evolution and Implementation of an Electronic Prescription Drug Program

NPRM, p. 6261. "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...We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the 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."*

Summary of Status of Standards for an Electronic Prescription Drug Program

NPRM, p. 6264. "...At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience... 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 and could serve as foundation standards."

Evolution and Implementation of an Electronic Prescription Drug Program

NPRM, p. 6261. "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."

Standards Approval Should Not be Dependent upon ANSI Accreditation

For the development and implementation of standards under the e-prescribing system, the NPRM offers for comment three criteria to give meaning to the statutory requirement that a candidate foundation standard have "adequate industry experience." These criteria are:

1) the standard is American National Standards Institute (ANSI) accredited
2) 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
3) the standard is recognized by key industry stakeholders as the industry standard

For a complete description of the three criteria, see p. 6261 of the NPRM quoted above.

There is no indication in the NPRM that these criteria are to be considered in the alternative or cumulatively. Moreover, there is a confusing subsequent paragraph in the section implying that ANSI accreditation criterion is the sole criterion in determining whether a candidate standard met the requirement of "adequate industry experience." The NPRM asserts on page 6261 that "[t]he standards [for electronic prescribing] should

be vendor neutral and technology independent, and developed by Standards Development Organizations (SDOs) that are accredited by the ANSI."[13]

To the extent the NPRM intends to require that any standard, whether it is a "foundation,"[14] initial or future standard, be ANSI accredited (and/or developed by an SDO that is ANSI accredited) before it can be approved, we oppose such a requirement. We support the position that a candidate standard may be approved in HHS' discretion if it 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" and the standard "is recognized by key industry stakeholders as the industry standard," even if it has not been accredited by ANSI or an ANSI accredited organization. Our position is consistent with Congress' express intent in MMA.

Congress Provided that Standard Setting Responsibility be Retained by HHS

Congress provided that the process to follow in approving standards for the e-prescribing program include broad criteria and consultation with multiple stakeholders. In doing so, Congress clearly required an expansive process and did not limit it to one in which ANSI accreditation constitutes the sole or final determinant. The basis for Congress' intent to have a broader set of criteria and stakeholders utilized is that there is not an SDO today that has representative participation from all the requisite industry stakeholders. To further clarify this important point, as well as the need for a broader process, MMA specifically requires that all industry stakeholders as enumerated in the statute need to be offered an opportunity to participate in the standard-setting process. MMA appoints NCVHS to play a primary role under the oversight of HHS, which is to retain discretion for the e-prescribing program both for "initial" standards and as the standards evolve under the e-prescribing program. It also identifies the requisite stakeholders with whom NCVHS should consult in developing initial standards as follows: 1) standard setting organizations; 2) practicing physicians; 3) hospitals; 4) pharmacies; 5) practicing pharmacists; 6) pharmacy benefit managers; 7) state boards of pharmacy; 8) state boards of medicine; 9) experts on electronic prescribing; and 10) other appropriate Federal agencies. Section 1860D-4(e)(4)(B). MMA provides for consulting with standard setting organizations, of which NCPDP is one, as well as the other requisite stakeholders, but does not defer overall approval for standards to such an organization.

NCPDP traditionally has enjoyed significant participation from the pharmacy stakeholders. The physician community, which is critical to the success of the e-

[13] We also note that the NPRM (p. 6261) identifies as the first criterion for determining "adequate industry experience" that the "the standard is American National Standards Institute (ANSI) accredited." Note that the September 2, 2004 NCVHS recommendation letter to the Secretary of HHS stated as "guiding principles for selecting standards" (p. 4) that standards "should be vendor neutral and technology independent, preferably be developed by standards development organizations accredited by the American National Standards Institute (ANSI), and have suitable indications of market acceptance." (emphasis added) We assume the NPRM's reference to ANSI includes organizations that are recognized by ANSI, as set forth in the NCVHS recommendation.

[14] The NPRM defines on page 6261 "foundation" standards as standards that do not need to be pilot tested because adequate industry experience with those standards already exists.

prescribing program, is a prime example of a group historically without significant participation in NCPDP. As the e-prescribing program and other emerging e-health initiatives continue, there may be other bodies including standards setting organizations that will organize in the near term with relevant expertise and experience with whom HHS would be well-served to consult for standards approval. In addition, standards may meet the requirements of implementation and stakeholder recognition through means other than an ANSI accreditation process.

The legislative history evidences Congress' intent on the issue of managing the approval of standards. The House passed bill contained language providing that the standards under the e-prescribing program be issued by a standards organization accredited by ANSI.[15] This specific provision, however, was removed during conference, and the final version of the enacted statute did not retain this requirement. This is strong evidence of Congress' preference that HHS receive the input of not only ANSI accredited organizations but all stakeholders, including those not currently represented by such bodies. As a result, the role of NCVHS working in conjunction with HHS to ensure that the process includes all industry stakeholders (identified in MMA) and is conducted in a neutral manner and in a time frame required by MMA, is clearly intended by Congress. For the NPRM to establish requirements that include an ANSI certification as a stand-alone or overarching requirement is contrary to what Congress specified in MMA and risks that standards will not be available within the set time frames or that useful and otherwise valuable standards will be by-passed.

In addition, the ANSI accreditation process is, as acknowledged by the NPRM, a time consuming process. If there is a requirement that such accreditation occur before a standard is adopted, there is the risk of substantial delay, which contradicts the express will of Congress as reflected in the deadlines set forth in MMA and the NPRM's own even more aggressive timeline.

Moreover, if a standard meets the second and third criteria, it can still become ANSI accredited, but HHS does not need to wait for such a final decision. If, for any reason, there is a different or updated standard that comes out of the ANSI accreditation process after adoption of a standard, HHS is free to incorporate such a result in light of its standard setting process. See discussion, *infra*, with regard to updating standards.

Congress intended that the standard setting process be neutral and include consultation with multiple stakeholders in the e-prescribing industry. Defining the process that ANSI accreditation is the sole and final determinant for standards approval (foundation, initial or future) does not reflect this intent, nor the requirements of MMA. We recommend that HHS be the final arbiter of the standard-setting process to ensure that all industry stakeholders are adequately represented, that the process remains neutral and expeditious, that the statutory deadlines are met, and appropriate future standards are promulgated in a timely fashion.

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[15] H.R. 1.EH, The "Medicare Prescription Drug and Modernization Act" passed by the House on June 27, 2003. See Section 1860D-3(d)(3)(B)(iii)(III).

Support for Adoption of RxHub Standards as Foundation Standards Demonstrating Adequate Industry Experience

As an example, of standards that do not need to go through the ANSI accreditation process, we point to the RxHub standards[16] for formulary/benefits information and for medication history (RxHub standards or standards) to be adopted as foundation standards. The RxHub standards meet criteria two and three set forth in the NPRM, and each of these criteria provide sufficient evidence to satisfy the requirement that there be adequate industry experience. The standards are in wide use today, after being developed in the spirit of other standard-setting organizations giving credence to an open, consensus-building process to multiple stakeholders and working to improve existing standards.

The RxHub standards were developed after the company was formed in 2001 through an open, public workgroup process that it facilitated in several U.S. cities. RxHub sought the consensus of stakeholders including technology vendors, PBMs, health plans, pharmacies, pharmaceutical manufacturers, hospitals and other routing companies. RxHub began with existing standards already being utilized in the industry. RxHub published the proposed standards on the Internet with an open public comment period to obtain feedback from the industry. Production pilots were performed starting in 2002 to test the standards, including applicability to physician office and technology vendor application workflow. RxHub's standards have been modified as experience has been gained. The RxHub standards are in broad use today, including: thirty three partners use the transactions in production applications; five additional partners are certified, ready for production; five additional partners are currently certifying on RxHub transactions; and others are developing to RxHub specifications. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing process further validates the conclusion that the standards meet the two criteria demonstrating adequate industry experience, and hence the RxHub standards should be approved as foundation standards.

RxHub has submitted the standards to NCPDP for accreditation. NCPDP accreditation includes an extensive and time consuming process. The time to achieve NCPDP accreditation for a proposed new standard can take a year or more. The NPRM clearly recognizes that this is a complex, time consuming process. As the standards clearly satisfy criteria two and three evidencing "adequate industry experience," it serves as a prime example of why ANSI certification should not be required for approval as foundation standards. Obviously, the e-prescribing program can nevertheless incorporate standards developed through the ANSI accredited standard setting process.

The RxHub standards meet two of the three criteria outlined in the NPRM for approval as foundation standards, and the NCPDP accreditation process is underway. This functionality meets the requirements of MMA and is critical to the success of the e-prescribing program. If HHS is not prepared to approve these protocols as foundation

[16] As stated *infra*, we endorse these standards, not only because of the process that was followed in their adoption, but based upon their merits.

standards, it should include the protocols in pilot testing to ensure that the tight time frames are met.

Comments on HHS Provision of Guidance

The difficulties that HHS has faced in simultaneously setting up a framework for the substantive standards on e-prescribing and establishing the first of those standards argue in favor of HHS providing more guidance in regulating e-prescriptions than can be set forth in any rulemaking. Moreover, they suggest that HHS will have to be prepared to provide that guidance over time, allowing itself flexibility in the development of standards for compliance. Rather than confining itself to the Interim Rule and the Final Rules, HHS should also make provisions for issuing additional guidance to compliance with the e-prescription regulations over time. We recommend that this guidance take the form of a compliance handbook, which HHS can update as necessary. This will give HHS the flexibility crucial to being able to respond effectively to technological changes, regulatory controversies and other developments.

HHS Should Provide Guidance on Future Standards As Needed

In raising the issue of the e-prescribing program's future standards, the NPRM suggests that it is best to establish now a predetermined procedure for all standards that may be proposed in the future, and the NPRM appears to conclude that future standards should be approved if they meet the single criterion of ANSI accreditation. As noted above, given the need for broader consensus building, neutrality and participation by all industry stakeholders, we are concerned about the blanket imposition of an ANSI accredited standard setting process as the sole requirement for approval. We also believe, however, that it is premature to set the technical standards in stone. So much remains uncertain, including how readily different stakeholders will accept individual standards (which may depend in part on how involved they are in the standards-setting process) and how effective federal preemption will be (or will be allowed to be) in making any accepted standards uniform nationwide. It seems unnecessarily ambitious to suggest that a permanent framework for standards setting can be established at this point, before the marketplace has had a chance to operate and issues have had a chance to surface.

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We would recommend, instead, that HHS take the opportunity in the Interim Rule to set up a flexible guidance process, designed specifically to prevent the e-prescription standards-setting rules from becoming prematurely rigid. HHS already is empowered to issue guidance from time to time as necessary as it gains experience with the issues and oversees the e-prescribing program's implementation. As needs for future or evolving standards become clear, HHS can use this guidance to address matters related to the standards that remain within the scope of MMA and impact the maintenance of "backwards compatibility" among e-prescribing program participants. There will be ample time for HHS to issue a final formula for approving future standards when and if the need for such a formula is clearly identified, which we expect will be some time after the foundation and remaining initial standards are successfully implemented.

HHS can Enhance Its Rule-Based Regulatory Authority Through Creation of an Effective Guidance Structure

While it may seem that HHS would be incapable of establishing the same certainty as to the procedures to be adopted with respect to e-prescriptions by guidance as it could by rulemaking, in fact that is not necessarily the case. Other informal guidance structures established by federal agencies are fully the equivalent of formal rules in the effectiveness with which they shape the compliance activities of persons subject to them. For example, the Department of Housing and Urban Development's Federal Housing Administration ("FHA") not only has issued regulations that set forth the framework of standards under which private parties such as approved lenders may make mortgage loans and obtain FHA insurance for those loans, but has also provided in those regulations that it would issue a variety of handbooks that contain much more specific guidance for industry participants. These officially issued handbooks effectively define what constitute permissible practices with respect to FHA-insured mortgages.[17] This is particularly of interest in the case of the Interim Rule under the MMA because like the MMA, the National Housing Act under which the FHA regulation has been promulgated by HUD does not specify that the FHA should provide regulatory guidance in this manner. HHS has the authority to implement the MMA in this way if it should determine that this would be the most effective method of providing practical guidance in the implementation of electronic prescription provisions of the MMA. We believe that the FHA has found that this mechanism has given it flexibility to adjust rapidly to changing market conditions and advances in technology. The existence of this mechanism allows FHA to issue guidance to the market without going through a slow notice and comment rulemaking process so long as the guidance remains within the broader regulatory framework. Finally, we note that the markets and the courts have accepted this guidance as legally binding, and even preemptive of state law to the same extent as the statute and the regulations.

The essential step for HHS to take now, in order to enable such a structure, is to authorize it in the Interim Rule itself. This should be done explicitly, perhaps by inserting into the Interim Rule a sentence along the lines of "The Secretary shall publish guidelines for electronic prescription procedures, which shall be provided to all participants in this program." That having been done, HHS can in due course determine the appropriate structure for such guidance – whether as a continuously updated question and answer document, discrete letters in response to questions submitted by industry and consumers, or a connected handbook on the order of HUD's guides. Having the ability to produce such guidance, in whatever form, means that HHS will not have to resolve all questions of process before promulgating the Interim Rule, and will not have to resolve all substantive questions before promulgating the Final Rules.

[17] See, e.g., 24 C.F.R. 203.5(c) (Direct Endorsement Program) ("The Secretary shall publish guidelines for Direct Endorsement underwriting procedures in a handbook, which shall be provided to mortgagees . . ..")

PROPOSED FOUNDATION STANDARDS

BACKGROUND, G. Electronic Prescription Drug Program and

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

Also relates to: PROVISIONS OF THE PROPOSED REGULATION, E. Proposed Standards]

Electronic Prescription Drug Program

NPRM, p. 6263. "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...

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 protocols as a basis, and indicated its belief that this appeared possible in time to adopt the standards as a foundation standards.

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 set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging..., 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..."

Summary of Status of Standards for an Electronic Prescription Drug Program

NPRM, p. 6264. "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 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.*
- *The...ASC X12N 270/2711 Transaction.*

• *The...NCPDP Telecommunication Standard."*

Eligibility Inquiry and Response

We support the designation of the ASC X12N 270/271 transaction set as a "foundation standard" for purposes of the eligibility inquiry and response functionality required under the e-prescribing program. The candidate standard meets the requisite criteria for approval as a foundation standard. Sufficient evidence exists to establish "adequate industry experience" with ASC X12N 270/271. This transaction is broadly used among and interoperable with multiple parties to verify patients' eligibility for coverage in the context of e-prescribing. Importantly, this standard transaction has already been implemented to be in compliance with the HIPAA privacy requirements for communications between the prescriber and PBMs/payors. An additional integral capability that this standard transaction supports is coordination of benefits by notifying the prescriber that a patient is enrolled in more than one health benefit for which there is coverage.

After review of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims (E1 Message) in the context of the statute's requirements for "adequate industry experience," we do not support designation of the E1 Message as a foundation standard at this time. In our research, we cannot conclude that there is widespread or time-tested experience among the required participants in the e-prescribing program. The E1 Message is limited to verification of a patient's cardholder status under a particular benefit plan and does not include the functionality to manage industry-critical coordination of benefits requests.

It is our recommendation that the E1 Message be tested further in a pilot environment and modified as warranted prior to consideration as a standard for eligibility transactions.

We also make reference to the fact that eligibility and response transactions can be used with information source organizations other than health plans (i.e., for transactions that are not standard transactions as defined by HIPAA). *See, e.g.,* ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, Page 11, Section 1.3.1. We therefore request that CMS define the two eligibility transactions for which it proposes standards as "eligibility inquiries and responses submitted and received by pharmacies" and "eligibility inquiries and responses submitted and received by prescribers." This would not change the fact that a provider that is not otherwise a covered entity under HIPAA would become a covered entity if it conducts an e-prescribing transaction that is also a HIPAA standard transaction, such as exchanging 270/271 eligibility and response transactions with a health plan.

Drug Order for New Prescriptions, Renewals, Cancellations, and Change Orders

We support designation as a foundation standard the most current version of the NCPDP SCRIPT standard to conduct transactions between prescribers and dispensers as to new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers. We understand that this transaction standard also contains several additional messaging capabilities within it. We recommend that there be further experience with the additional messaging capabilities (other than the functionality above) before the additional messaging capabilities are determined to be standards under the e-prescribing program.

Formulary/Benefit Coverage Information and Medication History

We support the designation as foundation standards of the formulary and benefits coverage information standard and the medication history standards developed by RxHub (RxHub standards). We are strongly of the view that there is sufficient evidence for HHS to determine that there exists "adequate industry experience" with the RxHub standards for them to be approved without delay as foundation standards.[18]

The RxHub standards are the most utilized transaction formats in the marketplace today for the MMA-required functions of formulary and benefit coverage information as well as medication history. The e-prescribing industry has ample experience with the standards for them to be named as foundation standards. In great part this is attributable to the industry stakeholders themselves offering comment through a public workgroup process as to what would best serve them from their individual perspectives and advance the interests of industry "interoperability" as a whole. These collaborative industry efforts resulted in the development of the RxHub standards in use today. After they were developed and tested, the standards were further scrutinized in production environments with multiple participants to move beyond the testing platform into a full operational environment upon which prescribers and payors can and do rely.[19] More specifically, the standards are used by most of the e-prescribing solution providers and each of the three largest PBMs (managing the pharmacy benefits of over 150 million people), which has been the case for several years.

NCVHS recognized the current usage of the RxHub standards among prescribers and payors in the marketplace, including the stakeholders who will participate under the e-prescribing program. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing industry demonstrates the breadth and duration of industry experience with the RxHub standards. It is important to note that there are no alternative standards for this functionality today. As a result of this comprehensive review of candidate standards in the context of MMA requirements,

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[18] We also refer to the discussion, *supra*, regarding the standard-setting process, particularly the criteria on page 6261 of the NPRM for determining "adequate industry experience."

[19] For additional information about the development of the RxHub standards, see the discussion, *supra*, regarding the standard-setting process.

NCVHS recommended to the Secretary that HHS actively support using the standards as the basis for swift deployment of a standard to address the functionality of formulary/benefits coverage information and medication history.

It is our understanding that RxHub has submitted the standards to NCPDP. Although NCPDP has and continues to make contributions to participating members of the industry, it does not include all of the requisite stakeholders under MMA. The RxHub standards were made open for comment from all interested parties and have been adopted by a broad group of interested stakeholders, including PBMs/payors, prescribers and the technology vendors that interface with them. In light of the process that was followed by RxHub, the current use within the industry, and that there are no alternative standards at present, there is no reason to subject the standards to further review or testing. Moreover, as previously discussed, we do not believe that ANSI accreditation should be a prerequisite before the Secretary can approve a standard. See the discussion, *supra*, regarding ANSI accreditation.

Since there is "adequate industry experience" with the RxHub standards, they should be adopted as foundation standards. If, however, HHS is not prepared to act accordingly, it should include the standards in pilot testing to ensure timely adoption. Approval of the RxHub standards as foundation standards is vital to the successful implementation of a nationwide e-prescribing program.

DEFINITIONS OF "ELECTRONIC MEDIA" AND "E-PRESCRIBING"

BACKGROUND, A. Statutory Basis

PROVISIONS, B. Proposed Definitions

NPRM, page 6257. "Electronic media is defined under HIPAA to include both electronic storage media and transmission media... 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."

The HIPAA definition of "electronic prescribing" at 45 CFR 160.103 reads as follows:

"Electronic media means:

(1) Electronic storage media, including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private

networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission."

The definition of "e-prescribing" on page 6265 and 6273 of the NPRM includes the term "electronic media" and reads as follows:

"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."

Subject to the caveat regarding electronic faxes discussed below, we support the use of the definition of "electronic media" to determine when prescribers and dispensers are electronically transmitting prescription information, and as a result of such activity, should be required to comply with the e-prescribing standards.

We would note, however, that we interpret the definition of "electronic media" to include electronic faxes, which we are advised are currently utilized by some e-prescribing systems to transmit prescribing information. Electronic faxes are computer generated files transmitted by fax that never exist in non-electronic form and thus do not fall within the exception set forth in the last sentence of HIPAA's definition of "electronic media." Because electronic faxes do not comply with the NCPDP SCRIPT foundation standard, they could not be used to e-prescribe under the NPRM as currently drafted.

Unless HHS is comfortable that e-prescribing systems currently utilizing electronic faxes should undergo the additional expense and training required to move from fax to electronic data interchange prior to January 1, 2006, the Department may want to include a transition period in the Interim Rule during which those systems could continue to utilize electronic faxes for the electronic transmission of prescribing information.

PROVIDER AND DISPENSER IDENTIFIERS

BACKGROUND, G. Electronic Prescription Drug Program

NPRM, page 6262. "HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. . . . Accelerated NPI usage for e-prescribing may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. . . . We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions. . . . and alternatives to the NPI, particularly in the short term. . . . NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers

and the NCPDP HCIdea 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), . . . in the event the NPI is not available for use, and we invite public comment on this as well."

We concur with the concerns raised in the NPRM that may make it difficult for HHS to accelerate the use of National Provider Numbers (NPIs) for the e-prescribing program by January 1, 2006 (*i.e.*, insufficient capacity to issue NPIs to all covered provides by that date and well as "unforeseen system or budget concerns"). There are several moving parts that need to be in place and operational on January 1, 2006 to assure the success of the e-prescribing program for covered Part D drugs and there is little logic to accelerating the use of NPIs when existing identifiers are in place to facilitate e-prescribing.

For dispensers, the NCPDP Provider Identifier Number suggested in the NPRM as an interim identifier is in wide use. For prescribers, the suggested NCPDP HCIdea identifier as a possible identifier is not widely adopted.

Testimony before the NCVHS by a variety of groups involved in e-prescribing did not indicate any concerns related to the current use of identifiers by dispensers or prescribers. Since, as noted in the NPRM, "the MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers or dispensers in e-prescribing transactions," it is not necessary that HHS approve specific identifiers for use by the January 1, 2006 effective date.

We recommend that the Interim Rule affirm that HHS intends to require the use of approved identifiers for use by entities participating in the e-prescribing program in the Final Rule upon completion of the pilot tests and that it authorizes the use of current identifiers until the Final Rule is issued.

The NPRM notes that the NPI may be the "preferred option" as an identifier "because it is standard that many entities will be required to use under HIPAA." That may well be the case and pilot testing will indicate whether the NPI, which is designed for the processing of claims can be successfully modified to meet the additional requirements regarding the identification of prescribers (*i.e.*, identification of the individual prescriber for security validation and medication history and other purposes as well as identification of the specific location where the prescriber provides for the patient, etc.).

STARK EXCEPTION AND ANTI-KICKBACK SAFE HARBOR

BACKGROUND, A. Statutory Basis, 3. Anti-kickback Safe Harbor and Stark Exception

IMPACT ANALYSIS, B. Impact on Health Plans/PBMs and C. Impact On Prescribers

Anti-kickback Statute Safe Harbor and Stark Exception

NPRM, p. 6259. "Section 1860D-4(e)(6) of [MMA] requires the Secretary to promulgate regulations that provide a "safe harbor under the anti-kickback statute . . . and an 'exception' under the physician self-referral statute for certain nonmonetary remuneration related to e-prescribing information technology items and services.

. . .

"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."

Impact on Health Plans/PBMs

NPRM, p. 6269. "We expect many plans to offer [financial incentives and technical assistance] to prescribers to offset initial costs of installing the hardware and software, thereby encouraging the adoption of e-prescribing."

. . .

"Health plans have a substantial incentive to subsidize the cost of physician's 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 effects on plans would be positive rather than negative."

Impact on Prescribers

NPRM, p. 6270. "We expect e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, but the magnitude and timing of savings will have to be demonstrated to many prescribers to induce them to make the 'up front' investment in new systems."

. . .

"One of the barriers to early adopting of e-prescribing by prescribers is the cost of buying and installing a system. . . . Since these costs may be defrayed by the incentives that are being offered, or may be offered, we expect a steady increase in the number of electronic prescribers."

Participation in the e-prescribing program by prescribers is voluntary. Congress recognized at Section 1860D-4(e)(6) of the MMA that prescribers would need incentives to participate in a voluntary program and that the current safe harbors available under the anti-kickback statute and the existing Stark exceptions were too restrictive to provide the necessary incentives.

While the availability of incentives is important to encourage prescribers who do not currently e-prescribe to install an e-prescribing system, it is crucial to those prescribers, of which there are many, who installed e-prescribing systems in the past only to walk away when the systems did not produce anticipated results. The need for incentives would become more pronounced if the e-prescribing system prescribers are being asked to install were to be confined to electronic prescriptions of covered Part D drugs for Part D eligible individuals enrolled in Part D plans.[20]

The NPRM at pages 6270 and 6271 requests information that will assist in assessing the "costs [to prescribers] of implementing" e-prescribing systems. We agree with the NPRM that key factors in calculating "the overall costs of buying and installing [e-prescribing] systems" include the "hardware and software" as well as the need to (i) change business practices of prescribers offices, (ii) changing record systems from paper to electronic and (iii) training staff. Even with these factors, costs can increase if the factors are broadly interpreted. By way of example, does the NPRM contemplate the cost of "changing record systems from paper to electronic" to be limited to the cost of moving to electronic records from the point the system becomes effective, or does it also include the cost of converting a patient's existing medication history from paper to electronic?

We concur with NPRM's expectation at page 6269 that health plans, including PDPs and MA-PDs, will want to offer to prescribers "financial incentives and technical assistance" beyond that currently permitted under the Stark exceptions and anti-kickback safe harbors to "encourage the adoption of e-prescribing."

We recommend that, in developing the Stark exception and the anti-kickback safe harbor required under Section 1860D-4(e)(6), HHS should provide a broad interpretation of incentives that would be made available for use by health plans to encourage e-prescribing including the contribution of the equipment (hardware, software, etc) necessary to an e-prescribing system as well as reimbursement for costs incurred in training staff to operate the system and hiring staff to convert paper records to electronic together with incentives for rewarding prescribers for quality of performance achieved through the use of e-prescribing.

* * *

[20] *See* the analysis, *infra,* that the narrow scope of preemption proposed in the NPRM would leave a number of conflicting state e-prescribing laws and regulations in place with the result that prescribers would be unable to use the Part D e-prescribing program for their non-Part D eligible patients without violating state laws.

The RxBC appreciates the opportunity to comment on the NPRM. We look to working with the Department as the process moves forward and to reaching our mutual goals of moving to a health care system that not only improves the quality of care, but reduces the cost of health care by harnessing the benefits technology can bring to the health care sector.

With best regards, I am

Sincerely,

Anne C. Canfield
Executive Director

ATTACHMENT A

MEMORANDUM

November 23, 2004

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Preempts State Laws and Regulations that Restrict or Impede a National Electronic Prescribing System

EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") creates a new outpatient prescription drug benefit for Medicare beneficiaries. As part of this benefit, Congress mandated the creation of a national electronic prescription and health care data access system (referred to collectively in this memorandum as "e-prescribing"). This system includes not only the electronic transmission of a prescription from the prescriber's office to the pharmacy, but also provides for electronic transmission of the patient's medication history, drug to drug interactions, and the availability of lower cost alternatives. Congress recognized that e-prescribing can reduce medical errors and improve efficiency in the health care system and directed the Department of Health and Human Services ("HHS") to develop uniform national standards for e-prescribing in order to promote its adoption.

Because of the importance Congress placed on the need to foster e-prescribing, it expressly determined in section 1860D-4(e)(5) of the MMA that

> 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.

This memorandum examines, among other points, whether the "and" between subparagraphs (A) and (B) means that a state law or regulation must offend both provisions before it is preempted. Such a reading would negate both the goals Congress sought to achieve and render superfluous one of the two provisions. Thus, subparagraphs (A) and (B) must be read to have independent meaning.

The MMA both expressly and impliedly preempts state law. The express statutory preemption language is broad; words such as "pertains," "relates," and "refers" are words of

broad construction, and the Supreme Court has repeatedly emphasized that the use of a "related to" preemption clause signals a "clearly expansive" preemptive intent. *See Rush*, 536 U.S. at 365-66 (ERISA preemption clause which uses "relate to" language "seems . . . to preempt everything"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992) (preemption provision using term "relating to" must be given broad reading). *See also Egelhoff v. Egelhoff*, 32 U.S. 141, 146 (2001); *Barnett Bank of Marion County, NA v. Nelson*, 517 U.S. 25, 38 (1996).

In addition, the language of the e-prescribing section as a whole demonstrates that Congress preempted state law with regard to all covered part D drugs. Section 1860D-4(e)(1) of the MMA explicitly references "covered part D drugs *prescribed for part D eligible individuals* . . ." (emphasis added). In contrast, section 1860D-4(e)(5)(B), the preemption provision at issue here, makes reference merely to "covered part D drugs under this part," which is simply a broad list of commonly used prescription products. It does not limit its reach to those drugs *prescribed for part D eligible individuals*, though Congress clearly knew how to do that if it wished to. Moreover, section 1860D-4(e)(3)(C)(i) states that the HHS standards shall "not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists." The burden of having separate and conflicting systems for prescribing to patients covered by Medicare would contradict this requirement. This is so regardless of how one reads subparagraphs (A) and (B).

Even in the absence of an express preemption provision, the MMA would impliedly preempt state law because to the extent state laws and regulations either vary dramatically with each other and the to-be-adopted federal standards, or simply do not address issues addressed by the federal standards, state law is an obstacle to achieving what Congress set out to achieve. The existence of varying and conflicting state laws makes a uniform e-prescribing system – the goal of the MMA – unattainable. Accordingly, state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Boggs v. Boggs*, 520 U.S. 833, 844 (1997) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)).

I. Introduction

While the federal government has been involved in purchasing drugs through the military and veterans' health care systems, this is the first program that will ultimately reach all Americans when they qualify for Medicare.[1]

Evidencing Congress's considerable interest in the scope and parameters of such a program, the MMA contains a variety of provisions concerning healthcare information technology. Among these is a comprehensive electronic prescribing program for Medicare beneficiaries, a program which Congress envisions as encompassing significantly more than simply how to transmit a prescription electronically:

[1] The Medicare Catastrophic Coverage Act of 1988 created a prescription drug benefit for Medicare beneficiaries. The act was repealed in 1989, however.

> 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.

§ 1860D-4(e)(2)(A).

> In addition, HHS is directed to:
>
> provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) [quoted above] 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.

§ 1860D-4(e)(2)(B).

The breadth of the national e-prescribing standards is a logical corollary to Congress' goal that a uniform national standards will "serve as a vehicle to reduce medical errors and improve efficiencies in the health care system . . . ." House Conf. Rept. 108-391 at 28. (Appendix A, attached, contains a detailed summary of the provisions relating to electronic prescribing contained in the MMA.) The Centers for Medicare and Medicaid Services has also recognized this dual potential of an effective e-prescribing system. *See* Centers for Medicare and Medicaid Services, Proposed Rule, Medicare Program; Medicare Prescription Drug Benefit, 69 Fed. Reg. 46,631, 46,672 (Aug. 3, 2004). While participation in the program is not mandatory, the standards are mandatory if any electronic prescription is used.

The need to improve patient safety is real. A National Academy of Sciences\Institute of Medicine report estimates that medical errors cost the nation approximately $37.6 billion each year, about $17 billion of which is associated with preventable errors. TO ERR IS HUMAN: BUILDING A BETTER HEALTH CARE SYSTEM 23 (1999), *available at* http://books.nap.edu/html/to_err_is_human/Ch2.PDF). Medication errors are caused by a wide variety of factors: poor communication; ambiguities in product names, directions for use, medical abbreviations or writing; poor procedures or techniques; or patient misuse because of poor understanding of the directions for use of the product. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, "Medication Errors," *at* http://www.fda.gov/cder/handbook/mederror.htm (last visited Oct. 1, 2004).

In order to ensure that the standards promulgated by HHS are successful, the MMA tasks the National Committee on Vital and Health Statistics (NCVHS), a public advisory body to the

Secretary of HHS, with the job of recommending e-prescribing standards to HHS after consultations with a variety of industry and government stakeholders. NCVHS's initial recommendations to HHS identify technical standards on which e-prescribing software and systems either have been built or can be built. NCVHS noted there that, "Standards for e-prescribing must not only meet the requirements of MMA but must also be compatible with all other standards that are becoming part of the National Health Information Infrastructure (NHII). This includes standards developed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Consolidated Health Informatics Initiative (CHI)." NCVHS letter to Tommy G. Thompson at 1 (Sept. 2, 2004) *available at* http://www.ncvhs.hhs.gov/040902lt2.htm. It is important to recognize, as NCVHS has, that it is not writing on a clean slate, nor did Congress direct it to do so. To the extent possible, it has proposed using existing, open architecture standards which do not provide a commercial advantage to any particular company.

To establish a uniform national system that improves patient safety and increases efficiency while not imposing an undue burden on the health care system, Congress determined that federal law shall rule in this area: "The [e-prescribing] standards . . . shall supercede any state law or regulation that (A) is contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part." § 1860D-4(e)(5).

This provision must be read broadly, as a call for federal occupation of the entire e-prescribing field with respect to covered part D drugs, or it will be ineffective in addressing the goals that Congress made explicit in the statute. A restrictive reading of the provision will add conflict and confusion to the current landscape of e-prescribing, which is already littered with varied and inadequate state laws.

II. Only National E-Prescribing Standards Can Solve the Problems Congress Sought to Address in the MMA

Significant state law barriers stand in way of building an effective e-prescribing system. Specific state laws and regulations that have hindered the adoption of electronic prescribing include:

- Requirements of special patient consent to the use of electronic prescribing. *See, e.g.*, Nev. Admin. Code ch. 639, § 7105.2(b) (2001); Fla. Admin. Code Ann. r. 64B16-28.130 (2001).

- Prohibitions on intermediaries facilitating transmission of prescription information (e.g., anti-depot rules). *See, e.g.*, Del. Admin. Code tit. 24, § 2500.5.10.1.1 (2001); Ohio Admin. Code § 47-29-5-10(A) (2001).

- Restrictions on prescription content and format, especially those drafted with only paper prescriptions in mind. *See, e.g.*, N.C. Admin. Code tit. 21, r. 46.1813(b)(2), (3); N.C. Gen. Stat. § 90-85.28(b) (2001); N.J. Rev. Stat. § 45:14-14.2 (2001); N.J. Rev. Stat. § 24:6E-7 (2001);

- Absence of an objective achievable standard on which pharmacists can rely for authenticating the source of electronic prescriptions. *See, e.g.*, Mich. Admin. Code. r. 338.3162a(3)(b) (2001); Tex. Health & Safety Code Ann. § 483.021(a); N.M. Admin. Code tit. 16 § 19.6.23(F) (2004); N.Y. Comp. Codes R. & Regs. tit. 8, § 63.6(a)(7) (2004).

- Varying state privacy laws and restrictions (*e.g.*, requirements that certain drugs be filtered out of medication histories unless the source of the medication history obtains the patient's consent). *See, e.g.*, Mass. Regs. tit. 247, § 9.01(19) (2001); Tex. Occ. Code Ann. § 562.015 (2001).

Accordingly, in some states e-prescribing is, if not prohibited, difficult and cumbersome, as noted above. Even where e-prescribing is possible, different formats and requirements (e.g., with respect to authentication and prescription format) make a uniform e-prescribing system unattainable. In addition to the legal impediments to e-prescribing, the lack of uniform national standards also means that software vendors must design multiple systems, adding both to the expense of the systems and the risk that different systems will not interface readily. The risk of standards that do not interface is that physicians and pharmacies will be hesitant to purchase multiple systems and thus avoid e-prescribing altogether. It is against this patchwork of state regulation – and omission – that Congress sought to provide uniform national standards for e-prescribing.

III. A Broad Interpretation of the MMA's E-Prescribing Provisions Is Mandated by the Plain Language of the Statute and Judicial Precedent

A. The Plain Language of the MMA Expressly Preempts State Law

In directing the Secretary of HHS to adopt national standards under the MMA's electronic prescribing program, Congress expressly determined that these standards would broadly preempt state law. The e-prescription preemption provision, to be codified at 42 U.S.C. § 1395w-104(e)(5), provides that:

> 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.

§ 1860D-4(e)(5).

The concept of federal preemption of state laws is rooted in the U.S. Constitution. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000). Federal preemption of state laws or regulations can be either explicit or implicit: preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

"It is well-established that within Constitutional limits Congress may preempt state authority by so stating in express terms." *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203 (1983); *see Jones*, 430 U.S. at 525. Where a statute contains an express preemption provision, the "'task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

The MMA expressly preempts state law. The express statutory language of subparagraph (A) is unambiguous: the federal standards "*shall supercede*" state law or regulation that is contrary to the standards or restricts the ability to carry out "this part." As used in this sentence, "part" means all of the provisions of the MMA which create the prescription drug benefit for Medicare beneficiaries. *See* Sec. 101(a)(2) of the MMA. This language not only preempts state laws that are contrary to the standards adopted by the Secretary pertaining to e-prescribing, but any state law that restricts the ability to carry out any provision of the MMA regarding the part D prescription drug benefit.

Similarly, the statutory language of subparagraph (B) is equally broad. It preempts any state law or regulation that "pertains" to the electronic transmission of medication history and of specified information with respect to covered part D drugs under this part. Words such as "pertains," "relates," and "refers" are words of broad construction, and the Supreme Court has repeatedly emphasized that the use of a "related to" preemption clause signals a "clearly expansive" preemptive intent. *See Rush*, 536 U.S. at 365-66 (ERISA preemption clause which uses "relate to" language "seems . . . to preempt everything"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992) (preemption provision using term "relating to" must be given broad reading). *See also Egelhoff v. Egelhoff*, 532 U.S. 141, 146 (2001); *Barnett Bank of Marion County, NA v. Nelson*, 517 U.S. 25, 38 (1996).

The breadth of the preemption provision must be read against the breadth of the components of the national electronic prescribing program which Congress has mandated. *See* page 3, *supra*. Based upon the strong "plain wording" of each clause, the preemption provision should be read so that state laws and regulations that fall under (A) are preempted and state laws and regulations that fall under (B) are preempted.

1. The Scope of Subparagraph (A)

Subparagraph (A) preempts any state law or regulation which "is contrary to the standards or restricts the ability to carry out this part...." Were this the only preemption language in the statute, there would be little disagreement that Congress expressly preempted a

wide range of state laws and regulations. However, Congress used "and" to join subparagraphs (A) and (B), thus raising the question of whether (A) and (B) are independent preemption provisions.

The fact that Congress used the word "and" to connect subparagraphs (A) and (B) cannot be interpreted in a manner in which subparagraph (B) limits subparagraph (A) without conflicting directly with the broad preemptive language employed by Congress. Courts have held that a "statute's use of disjunctive or conjunctive language is not always determinative." *United States v. Bonilla-Montenegro*, 331 F.3d 1047, 1051 (9th Cir. 2003). Rather, courts "give effect to the plain, common-sense meaning of the enactment without resorting to an interpretation that def[ies] common sense." *Id.* (internal quotation marks omitted). *Cf. Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) ("Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, *unless the context dictates otherwise.*") (emphasis added). Here, the "context dictates otherwise" because only that interpretation gives meaning to both (A) and (B).

A requirement that a state law or regulation offend both (A) and (B) before it is preempted would render one of the two provisions redundant. It would also mean that a state law which directly conflicted with the national standards, but did not pertain to the transmission of the information identified in (B) would not be preempted (unless by implication, *see infra*). Likewise, it would mean that a state law which did not directly "pertain to" the transmission of information, yet which nonetheless "restricted" the government's ability to carry out the standards would not be expressly preempted. Such an interpretation would nullify (A), a result the courts have rejected. "The rule against superfluities complements the principle that courts are to interpret the words of a statute in context. See 2A N. Singer, Statutes and Statutory Construction §46.06, pp. 181.186 (rev. 6th ed. 2000) ('A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .' (footnotes omitted))." *Hibbs v. Winn*, 540 U.S. ___ (June 14, 2004). Congress' clear intent to preempt state laws that are contrary to the standards, or that restrict the ability to carry out the Medicare outpatient drug benefit, should be fully effectuated in its own right.

2. The Scope of Subparagraph (B)

The preemptive effect of (B) is aimed squarely at any state law or regulation which "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." Thus, any state law or regulation which broadly pertains to the listed subjects is preempted.

The first issue with regard to (B) is whether the phrase "with respect to covered part D drugs under this part" modifies all of (B) or only modifies the immediately preceding phrase, "information on eligibility, benefits, and prescriptions." The plain language makes clear that the latter interpretation is what Congress intended. Use of the word "of" in front of "medication history" and again in front of "information on eligibility" indicates that there are two categories of information and the reference to covered part D drugs modifies only the second category.

The next issue is whether the phrase "covered outpatient drugs under this part" refers to all outpatient drugs that are eligible for compensation under part D or to only those drugs that are actually compensated under part D. The context of the MMA provisions on e-prescribing make clear that the former is the correct interpretation.

For example, section 1860D-4(e)(1) of the MMA explicitly references "covered part D drugs *prescribed for part D eligible individuals* . . ." (emphasis added). In contrast, section 1860D-4(e)(5)(B), the preemption provision discussed here, makes reference merely to "covered part D drugs under this part," which is simply a broad list of commonly used prescription products. It does not limit its reach to those drugs *prescribed for part D eligible individuals*, though Congress clearly knew how to do that if it wished to.

The Congressional goal of improving patient safety would be undermined if the other elements of the e-prescribing package – medication history, eligibility and benefits – were limited to part D drugs *paid for* under this part. A drug which a beneficiary bought and paid for without reimbursement by Medicare or that was reimbursed by another payor would be as relevant a part of the patient's medical history as drugs paid for under this part. In addition, even as to eligibility, benefits and prescriptions, Congress clearly wanted to include information regarding dual coverage (where another payor might be obligated to pay for the drug) or those instances in which the Medicare benefit requires the patient to pay out of pocket. This information is of great importance to the provider, patient, and the proper administration of the part D benefit. In addition, the plain language of the e-prescription section as a whole demonstrates that Congress preempted state law with regard to all part D drugs. Section 1860D-4(e)(3)(C)(i) states that the HHS standards shall "not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists." But the burden of having separate and conflicting systems for prescribing for patients covered by Medicare would frustrate this requirement, just as having conflicting state laws would.

This interpretation is consistent with the plain language of subparagraph (B) as well as court decisions cited, *supra*.[2]

3. The Legislative History Confirms that Congress Intended to Give Effect to (A) and (B)

The legislative history further confirms that Congress intended a broad interpretation of the express preemptive effect of the MMA e-prescribing standards. *See Oklahoma v. New Mexico*, 501 U.S. 221, 234 n.5 (1991)(courts consult legislative history when a statute's meaning is ambiguous). The House Conference Report states simply and without qualification: "The electronic prescribing standards shall supercede any contrary state laws." House Conf. Rept. 108-391, p. 456.

The broad sweep of the preemption provision is necessary if the Congressional goals of reducing medication errors and more efficiently delivering services is to be achieved. Subparagraph (B) reaches those state laws and regulations which "pertain" to the specific subject matter of the specified standards to be adopted; that is, any state law or regulation on the same

[2] This is the case regardless of whether one reads subparagraphs (A) and (B) as disjunctive or conjunctive.

subject. Subparagraph (A) sweeps even more broadly: it recognizes that there may be state laws and regulations which are "contrary to" or which "restrict the ability" to carry out the goals of the national standards. They, too, are preempted. Thus, a general state law or regulation (such as one dealing with electronic payment of health insurance claims for prescription drugs) which "restricts the ability to carry out this part" is preempted even if it does not pertain to the transmission of information specified in (B). This reading of the preemption provision accords with the canon that courts "give effect to the plain, common-sense meaning of the enactment without resorting to an interpretation that def[ies] common sense." *Bonilla-Montenegro*, 331 F.3d at 1051 (internal quotation marks omitted).

Finally, under the rules of statutory construction cited *infra*, an interpretation that the language of (B) limited (A) would not change the broad scope of preemption with regard to the e-prescribing provisions of the MMA. As noted above, an electronic prescription as defined in the MMA includes more than the transmission of the prescription from the prescriber to the pharmacy, but also includes information regarding eligibility, benefits, medication history and drug to drug interactions. The standards and the ability to carry out the part D program with regard to an electronic prescription system all pertain to the content and scope of information as well as to standards pertaining to the actual electronic transmission of information. Congress' use of the term "pertaining" preempts "everything," *see Rush*, 536 U.S. at 365-66, which in this case would include the information content and the actual electronic transmission of the information. Accordingly, state laws and regulations which conflict with the standards relating to the e-prescribing system with regard to the part D prescription drug benefit would also be preempted to the extent of the conflict. The result, at least in the area of e-prescribing, of reading (B) as conjunctive with (A) is the same as a disjunctive reading.

B. The Law of Implied Preemption Would Preempt State Law Relating to the E-prescribing System Had Congress Not Chosen To Do So Expressly

Established principles of implied preemption support a broad view of the scope of preemption Congress adopted. Even without an express preemption provision, the Supreme Court has found that "state law must yield to a congressional Act in at least two circumstances." *Crosby*, 530 U.S. at 372. First, "when Congress intends federal law to 'occupy the field,' state law in that area is preempted." *Id.* (When Congress chooses to occupy the field, state law can be preempted even if Congress chooses not to regulate a specific aspect of the "occupied" field. *See Chamber of Commerce of the U.S. v. Lockyer*, 364 F.3d 1154, 1169 (9th Cir. 2004).) Second, even if Congress has not occupied the field, state law is preempted to the extent of any conflict with a federal statute. *Crosby*, 530 U.S. at 372; *see English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Such a conflict exists either where (1) compliance with both the state and federal law is "a physical impossibility," or (2) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Moreover, Congress' inclusion of an express preemption clause "'does *not* bar the ordinary working of conflict preemption principles'" *Sprietsma*, 537 U.S. at 65 (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in *Geier*)). *Boggs*, 520 U.S. at 844 (quoting *Gade*, 505 U.S. at 98).

Here, state law and regulation "which restricts the ability to carry out" the e-prescribing system would be impliedly preempted had Congress not included an express preemption

provision in the MMA. To the extent that state laws and regulations either vary dramatically with each other and the to-be-adopted federal standards, or simply do not address issues addressed by the federal standards, they "restrict the ability" to achieve what Congress sought the achieve. The existence of varying and conflicting state laws makes a uniform e-prescribing system – a key goal of the MMA – unattainable. Accordingly, state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Boggs*, 520 U.S. at 844 (quoting *Gade*, 505 U.S. at 98), and is impliedly preempted. *See also Colorado Public Util. Comm'n v. Harmon*, 951 F.2d 1571, 1582-83 (10th Cir. 1991) (where "Congress directed that safety be achieved through uniformity," state regulations that "inhibit and obstruct uniformity" are preempted).

Congress could not have intended, for example, that a multi-state vendor such as a mail order pharmacy research and analyze the laws, regulations, and practices of all the states in which it wishes to do business in order to design an acceptable e-prescribing program. The difficulties of designing a national program that complies with the various standards Congress mandated would be prohibitive if state standards are included as well. The barriers such an approach could create include complicated and various systems, enormous added expense, and contradictory regulatory requirements.

Such problems would clearly discourage physicians and pharmacists from participating in an e-prescribing program. Just as it would be difficult for a mail order pharmacy to design a program that is compliant with all state laws, physicians and pharmacists have neither the time nor training to determine whether a particular e-prescription for a patient who may fill it in another state, or which has additional state requirements because of the type of payor or for other reasons, would be legal. Requiring physicians and pharmacists to expose themselves to such professional liability risk could only serve to discourage their participation in e-prescribing programs.

Given the statutory language, the case law, and the goals Congress seeks to achieve, it is clear that, explicitly and implicitly, the federal government has fully occupied the field.

IV. Conclusion

The MMA's e-prescription preemption provision both expressly and impliedly preempts state laws that restrict the ability to carry out the e-prescribing provisions and also state laws that pertain to the electronic transmission of medication history and certain information with respect to certain covered drugs. This broad provision supports Congress' goal of achieving national uniformity with regard to healthcare information technology. Though Congress elsewhere demonstrated the ability to limit MMA's provisions to covered part D drugs prescribed for part D eligible individuals, it chose not to do so in the preemption provision, instead preempting state laws regarding any covered part D drugs. Accordingly, MMA's e-prescription preemption provision reaches beyond just those prescriptions written for Medicare part D beneficiaries.

APPENDIX A
to Memorandum

Summary of provisions related to electronic prescribing in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The following is a summary of the statutory provisions relevant to electronic prescribing contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

I. Plans may require prescriptions to be written and transmitted electronically.

Sec 101, Part D, Subpart 1, Sec. 1860D-3(c)(1)(A) & (B), provides the means by which PDP sponsors (qualified prescription drug plans that do not offer other health or medical coverage or benefits) may mandate the use of electronic prescribing by participating providers and in-network pharmacies. The section **requires** PDPs to have in place:

- Cost-effective drug utilization management programs, including incentives to reduce costs;
- Quality assurance measures and systems to reduce measures and systems to reduce medication errors and adverse drug interactions and improve medication use; and
- Medication therapy management programs for "targeted beneficiaries" (with certain chronic diseases) that the covered part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce risk of adverse events including adverse drug interactions

While physicians are not required to participate in e-prescribing programs, PDPs may require, as a condition of participation in the plan, the use of e-prescribing technologies by participating providers and pharmacies as part of its programs and measures to meet the requirements of this provision for reducing medication errors and costs. The legislation also permits certain plans to financially reward participating physicians for doing so (see Sec 102(b)).

II. Prescribing health providers would receive relevant information on medical history, lower cost drugs, eligibility and benefits, drugs included on the formulary, and information on potential adverse drug interactions.

Section 101, Part D, Subpart 1, Sec.1860D-3(e) establishes the "Electronic Prescribing Program" so that any party submitting electronic transactions under this

program for covered Part D drugs prescribed for eligible individuals must do so in accordance with the uniform standards promulgated by the Secretary as follows:

- **Application of Standards**
  - Prescriptions and "front-end" information written and transmitted electronically for Medicare beneficiaries receiving covered Medicare drugs **must conform** to the uniform standards established pursuant to this legislation no later than **April 1, 2009.**
  - The Secretary may require conformity sooner.
- **Delivery and Information requirements**
  - Under the Medicare electronic prescribing program, information on the following must be provided to providers and pharmacists:
    - eligibility
    - benefits (including applicable formulary and tiered formulary structure and any requirements for prior authorization)
    - information on drug interactions, warnings, and when indicated, dosage adjustments
    - other drugs listed on the medication history
    - information on the availability of generics
  - Patient *medical* history related to the drug shall be provided upon request by "professionals or pharmacists involved." However, this provision is not effective until standards have been established for such purpose and the Secretary specifies an effective date.
  - Electronic transmissions must be HIPAA compliant.
  - Information shall be exchanged in an interactive real-time basis to the extent feasible.

III. The Secretary of HHS, in consultation with appropriate stake holders, must develop and adopt initial standards by September 1, 2005. A pilot program to test the initial standards must begin by January 1, 2006. The Secretary must evaluate the pilot program, submit a report to Congress by April 1, 2007 and issue final standards by April 2, 2008.

Section 101, Part D, Subpart 1, Sec.1860D-3(e)(3)-(5) further provides the following:

- **Requirements:** The Secretary shall provide for the promulgation of uniform standards:

- Must be consistent with improving patient safety, quality of care, and cost efficiencies in delivery of care.

- Must be designed to avoid undue administrative burden to the extent practicable.

- Must be compatible with HIPAA administrative simplification standards (Part C), Subsection (b)(2)(b)(1) (use of standardized technology) of the Medicare bill, and general health information technology standards.

- Must permit electronic exchange of FDA drug labeling and listing information.

- Must relate messaging to the appropriate prescribing of drugs, including quality assurance measures.

- Must permit beneficiaries to designate a particular pharmacy without impact on benefits.

- **Development of Standards and Deadlines**

  - *Initial* uniform standards must be developed, adopted, recognized or modified by **September 1, 2005**.

  - The Secretary must consider recommendations (if any) from the National Committee on Vital and Health Statistics (NCVHS).

  - NCVHS must consult with:

    - practicing physicians
    - hospitals
    - pharmacies
    - PBMs
    - state boards of pharmacy and medicine
    - experts on electronic prescribing
    - other appropriate Federal agencies

- **Pilot Project to Test Initial Standards**

  - The Secretary must conduct a pilot project to test standards between **January 1, 2006 and December 31, 2006,** before uniform final standards may be promulgated.

  - Standards are exempt for this pilot project if the Secretary, in consultation with effected standard setting organizations and industry users, determines adequate industry experience exists.

- Participation of physicians and pharmacies in the pilot is voluntary; the Secretary must enter into agreements with participants who transmit prescriptions electronically under such standards.

- The Secretary must report to Congress by **April 1, 2007.**

- **Final Standards – The** Secretary must promulgate final uniform standards not later than **April 1, 2008.**

- **Federal Preemption** - Standards shall preempt any state law or regulation that:

  - conflicts with a federal standard

  - restricts the ability to carry out the Medicare electronic prescribing program

  - pertains to the electronic transmission of medication history, information on eligibility, benefits, and prescriptions for covered Medicare drugs

IV. Plans, hospitals and group practices are allowed to purchase hardware and software for doctors in establishing the programs.

Section 101, Part D, Subpart 1, Sec.1860D-3(e)(6) mandates the Secretary of HHS, in consultation with the Attorney General, to establish a "Safe Harbor" exception to Stark and Fraud and Abuse statutes.

- Permits the following entities to provide hardware, software, information technology and training services to receive and transmit electronic prescription information in accordance with standards promulgated under this subsection:

  - hospitals (to medical staff)

  - group practices (to its members)

  - PDP sponsors or MA organizations (to prescribers and to in-network pharmacies)

V. MA-PD plans (Medicare Advantage plans that provide qualified prescription drug coverage in addition to other health and medical benefits

- Such payments may be increased for participating physicians who significantly increase:

  - formulary compliance;

  - generic use;

- reductions in adverse drug interactions; and
- efficiencies in filing prescriptions through reduced administrative costs

VI. Discretionary grants are authorized to assist providers in implementing electronic prescription programs.

Section 108 authorizes the Secretary of HHS to make grants to physicians to implement the electronic prescription drug program.

- Authorizes $50 million for fiscal year 2007, and such amounts "as necessary" for fiscal years 2008 and 2009.
- Grants may be used to purchase, lease and install software and hardware (including handheld technologies), to make upgrades to existing technologies to implement the Medicare electronic prescription program, and to provide education and training to physicians' staff.
- Requires applicant to obtain a minimum of 50% matching funds directly or from public or private entities.
- Special consideration is given to physicians serving a disproportionate number of Medicare patients and physicians serving rural or underserved areas.

VII. Commission on Systemic Interoperability

Section 1012 establishes a new Commission (separate from the exiting national health information infrastructure (NHII)) to develop a comprehensive strategy for adoption and implementation of health care information technology standards.

- Prohibits the Commission from interfering with any standards development underway it the private or public sector or to replicate such activities or the HHS - NHII.
- Requires the Commission to issue a report to Congress by October 31, 2005.
- Provides membership criteria:
  - 11 members
  - Appointed by the President and House and Senate leadership
  - Nationally recognized for expertise in health finance and economics, health plans and integrated delivery systems, reimbursement, practicing physicians and pharmacists, health technology and information systems, and other related fields.

ATTACHMENT B

ELECTRONIC TRANSMISSION OF PRESCRIPTIONS: COMPUTER TO COMPUTER STATE COMPARISION

STATE	ALLOW FOR ELECTRONIC TRANSMISSION OF PRESCRIPTIONS	EXAMPLES OF MISCELLANEOUS REQUIREMENTS	PRESCRIPTION AUTHENTICATION FOR NON-CONTROLLED SUBSTANCE PRESCRIPTIONS	ELECTRONIC OR DIGITAL SIGNATURES FOR NON-CONTROLLED SUBSTANCE REQUIREMENTS	LANGUAGE SIMILAR TO NABP MODEL RULES
Alabama	Yes	Electronic transmission allowed except when a specific brand must be dispensed, prescriber must write "Brand Medically Necessary"			
Alaska	Yes				
Arizona	Yes	Verify and manually initial – must be recorded in writing by the pharmacist			
Arkansas	Yes				Yes
California	Yes	Must be immediately reduced to writing unless and electronic copy may be printed out upon request for three years	The "furnisher" shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent		Yes
Colorado	Yes				
Connecticut	Yes	Exclusive access or direct lines from prescriber to pharmacy not allowed; Requires same			

This comparison chart is by no means all-inclusive or comprehensive. The purpose of this chart is to highlight examples of variances that exist in the electronic transmission of regulations between the states. Controlled substances are not addressed.

(This chart has been retyped in order to submit it electronically, in Word format, as an attachment to the Rx Benefit Coalition's comment letter. The original chart was submitted in testimony by the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004.)

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		verification as any oral or telephone prescription Pharmacist must record on a form or computerized printed rx record including name and address of prescriber; name, dosage form, strength, and amount of drug prescribed; patient name and address, etc.			
Delaware	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order		Yes
District of Columbia	Not addressed	Not addressed	Not addressed	Not addressed	Not addressed
Florida	Yes	Prescriptions not received in written form must be reduced to writing and retained for at least two years form date of last filling Electronically transmitted	Phamacist shall take such measures necessary to ensure the validity of all prescriptions received		

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		prescriptions may only be sent upon approval of patient			
Georgia	Yes	Orders must be reduced to writing and filed with the original Rx received before dispensing Orders are consistently highly confidential and shall not be compromised by interventions, control, change, altering, or manipulation by any other person or party in any manner whatsoever	Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order		Yes
Hawaii	Yes *Under jurisdiction of the Department of Health, Food, and Drug Branch*	Prescription must be reduced to writing by pharmacist immediately upon receipt and maintained in pharmacy in 5 years If a system is used that is capable of printing a copy of the	Practitioners and pharmacist to exercise prudent and professional judgment	Prescriptions must be irrefutably traceable to prescriber by image of signature and or oral designation, electronic signature or digital signature.	

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		prescription, the printer copy may be used to satisfy the requirement that prescriptions transmitted electronically be reduced to writing			
Idaho	Yes. The code section addressing this issue is not part of pharmacy code or rules.				
Illinois	Yes, no specific regulation. Act allows for electronic prescriptions				
Indiana	Not prohibited.	A prescription transmitted by practitioner by means other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist.			

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Iowa	Yes	Any system or computer utilized shall have adequate safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders.		Computer transmission must include prescriber's electronic signature (a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory) and is deemed the original if all other requirements are met	Yes
Kansas	Yes	Electronically transmitted prescription order must be immediately reduced to hard copy and be maintained for the time required by state and federal law	Order must identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and identity of the pharmacy intended to receive the transmission, responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity,		Yes

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			and authenticity of rx order		
Kentucky	Yes				
Louisiana	Yes	Reduce to hard copy if necessary and indicate on hard copy the mode of transmission and phone number of prescriber making transmission	Verification of accuracy and authenticity is responsibility of pharmacist		
Maine	Yes		Order must be verified and authenticated by the pharmacist; must identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the identity of the drug outlet intended to receive the transmission	If the order is transmitted by email or file transfer, it must contain the signature or electronic equivalent of a signature of the prescriber and shall be electronically encrypted ()to prevent access, alteration, or use by unauthorized person)	Yes
Maryland	Yes	Commercial intermediary must guarantee the confidentiality and security of transmission process	Pharmacist responsible for ensuring validity of rx order, must be conveyed in a form		

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		in manner approved by the board	containing an alternative method of communication for indicating that an authorized prescriber has personally originated or approved the prescription or be processed by a commercial intermediary that guarantees the confidentiality and security of the transmission process in a manner approved by the board		
Massachusetts	Yes	Electronically transmitted prescriptions must have reasonable and appropriate security measures to invalidate an rx if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised;	Electronically transmitted orders must be validated and authenticated (meaning the identities of the parties sending & receiving electronic rx data are duly verified); must utilize a system that includes a combination of technical security measures	Must have an electronic signature (defined as "an electronic sound, symbol or process attached to or logically associated with an rx record and executed or adopted by a practitioner with the intent to sign and prescription record") which is unique to an identified	

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		Drug order shall be marked "Electronically Transmitted Prescription"		practitioner, originated solely by and under the ultimate control of the practitioner, and capable of verification;	
Michigan	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order; technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement	Prescription order to include name and address of the prescriber, an electronic signature or other board-approved mefans of ensuring prescription validity, prescriber's telephone number for verbal confirmation of the order, the date and time of transmission, and the name of the pharmacy intended to receive the transmission;	
Minnesota	Yes				Yes
Mississippi	Yes	Must be filed and maintained on paper of permanent quality	Responsibility of pharmacist to exercise professional judgment		

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			regarding the accuracy or authenticity of order;		
Missouri	Yes		Pharmacist shall ensure the validity of the prescription as to its source of origin	Electronic signatures is (a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory) may be sent as part of an electronic transmissions prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient	
Montana	Yes		Pharmacist is responsible for assuring the validity of the electronically transmitted prescription	Both prescriber and pharmacist must have secure (encrypted or encoded) system for electronic transmission from computer to	Yes

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				computer; prescriber's electronic signature or other secure method of validation shall be provided with electronically transmitted order	
Nebraska	Yes			Prescription must be a written, signed medical order and stature defines signature as a handwritten or digital signature. Cannot dispense based on electronic signature.	
Nevada	Yes	A practitioner may not transmit an order to the pharmacy unless he is only person who will have access to the order until it is received by pharmacy and the patient consents to the electronic transmission as well as approves		Electronically transmitted prescriptions are not required to contain the signature of the prescriber if it contains a facsimile signature, security code or other mark that uniquely	

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		the pharmacy to where the order will be transmitted; info must be transmitted in a way to ensure confidential info may not be altered by a person other than the pharmacist; practitioner may however use routing company in transmission; routing company may store rx info for audit purposes, but may not add to, delete or modify an rx or any confidential info it receives		identifies the practitioner or a voice recognition system, biometric identification technique or other security system approved by the board is used to identify the practioner Electronic prescription computer systems must be approved by BoP, and system must require user provide unique identification (fingerprint / retinal scan, PIN, or other) before each use	
New Hampshire	Yes		Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order		Yes
New Jersey	Yes	Must reduce to writing or enter	Prescriber must provide DEA	A practitioners electronic	

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		into computer within 24 hours of receipt, and shall place copy in the file Pharmacist shall not enter into any agreement with a prescribing practitioner that requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies the patient the right to have the order sent to the pharmacy of the patient's choice	number or prescriber's license number at time of transmittal: verifying authenticity of questionable orders is ultimate responsibility of pharmacist, who may request verbal verification from prescriber or agent if rx is in question	signature or other secure method of validation shall be provided with the electronic prescription unless the rx is transmitted by an authorized agent	
New Mexico	Yes	Order must be reduced to hard copy and be marked "Electronically Transmitted Prescription" or "ETP"	Pharmacist must exercise "professional judgment" regarding the accuracy and authenticity of the prescription	Prescriber's electronic signature, or other secure method of validation shall be provided with the electronically transmitted prescription or drug order	Yes
New York	Yes	Electronically transmitted prescriptions shall be		Prescription must contain prescriber's signature (or	

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		electronically encrypted to prevent access, alteration or use by any unauthorized person		electronic equivalent) and be electronically encrypted	
North Carolina	Yes		Pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of order	Electronically transmitted prescriptions must contain an a "written signature" or an digital signature unique to the practitioner; order must include transmitter's phone number for verbal confirmation, time and date of transmission, and identity of the pharmacy intended to receive the transmission	Yes
North Dakota	Yes				
Ohio	Yes		Prescription not valid unless Board-approved system assures that only authorized prescribers have issued the electronically transmitted prescription	Each electronic transmission system must have "true positive identification" of the prescriber sending the	

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				prescription; pharmacist must be able to verity that the rx is legitimate; compute generated signatures re not recognized as a means of positive ID	
Oklahoma	Yes	Prescriptions received other than in writing shall be promptly recorded in writing by the pharmacist and the written record shall constitute the original prescription			
Oregon	Yes	There shall be no additional charge to the patient because the prescription order was electronically transmitted			Yes
Pennsylvania	Yes				
Rhode Island	Yes			Prescription must contain the prescriber's electronic or digital signature (defined	

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				as an electronic sound, symbol or process attached to or associated with the rx)	
South Carolina	No				
South Dakota	No				
Tennessee	Yes	No person or entity may supply electronic equipment to a prescriber in exchange for transmitting orders (Safe harbor)		Order must include phone number or authorized prescriber (to allow verbal confirmation of the validity and accuracy of order), date & time of transmission, name of pharmacy to which order is being transmitted, prescribing practitioner's electronic signature or other secure method of validation (electronic signature is process that secures the user authentication, or proof of identity at the time signature is generated – ex.	Yes

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				biometrics, fingerprints, retinal scans, hand written signature verification, etc.) and identify of prescriber's agent if applicable.	
Texas	Yes		Pharmacist to exercise sound professional judgment with respect to the accuracy and authenticity of rx order		
Utah	Yes	No agreement may be met between a prescriber and pharmacy requiring that the order be transmitted by electronic means from the prescriber only to that pharmacy.	Order to contain the date and time transmission and name of the pharmacy intended to receive the transmission; pharmacist's responsibility to exercise professional judgment regarding the accuracy and authenticity or order		
Vermont	Yes	Order to be transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having	R.Ph. exercise professional judgment re accuracy, validity, and authenticity of order		

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		access to the prescription drug order (but does not apply to the computer transition systems and persons necessary for the electronic transmission of Prescriptions); persons other than those bound by a confidentiality agreement shall not have access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients			
Virginia	Yes				Yes
Washington	Yes	E-prescribing system must be approved by the board; new approval required every three years			Yes
West Virginia	Yes	The prescription must be transmitted directly to a pharmacist in a licensed	Order must show date and time of transmission and name of person transmitting the order		

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		pharmacy of the patient's choice with no intervening person having access to the prescription and must be communicated in a way to ensure against unauthorized access			
Wisconsin	Yes			Order must include electronic signature, or other secure method of validation, sender's name and phone number for oral confirmation, time and date of transmission, pharmacy intended to receive the transmission, and is designated as "electronically transmitted prescription" or something to that effect;	Yes
Wyoming	Yes		Responsibility of pharmacy to	Electronically transmitted	Yes

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			exercise professional judgment regarding the accuracy, validity, and authenticity of the order	prescriptions must be authenticated by a digital signature/electronic signature (depending on method of transmission)	

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Date: 04/05/2005

Submitter : Mr. Mark Ugoretz

Organization : The ERISA Industry Committee

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-50-Attach-1.DOC

CMS-0011-P-50-Attach-2.DOC

THE ERISA INDUSTRY COMMITTEE

1400 L Street NW, Suite 350, Washington DC 20005 (202) 789-1400 fax: (202) 789-1120 www.eric.org

Advocating the Benefit and Compensation Interests of America's Major Employers

April 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule Regarding Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Administrator McClellan:

The ERISA Industry Committee (ERIC) respectfully submits these comments in response to proposed regulation "Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule" (42 CFR Part 423) published in the *Federal Register* on February 4, 2005. ERIC, representing the interests of America's major employers, is pleased to offer our comments on the recent CMS proposed standards for electronic prescribing in the electronic prescription drug program under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003. This regulation details electronic prescribing standards for Medicare's new Part D, the Voluntary Prescription Drug Program.

Our primary goal in these comments is to present feedback to CMS from the standpoint of America's large employers, who will be party to the electronic prescription program through retiree health plans. A majority of ERIC's members offer a retiree health plan. We support the use of electronic prescribing for its capacity to increase accuracy, effectiveness and patient safety, as well as its potential to lower the administrative burden on healthcare providers and physicians. However, we are aware that the use of electronic prescribing warrants a cautious approach and precise uniformity of computer programs, and that all actors involved must play a role in maintaining the confidentiality of patients' medical data.

We look forward to working with you and your staff to further discuss our suggestions and recommendations. If you would like to schedule a meeting or conference call to discuss these comments, please contact Edwina Rogers, ERIC's Vice President for Health Policy at 202-789-1400.

I. Purpose of Proposed Electronic Prescribing Regulations

On February 4, 2005, CMS released a set of proposed rules and standards for the e-prescribing and prescription drug program of the Medicare Prescription Drug, Improvement and Modernization Act (MMA). This proposal would be the first set of uniform standards for the electronic prescribing program, and would ensure interoperability between all prescribing healthcare entities, prescription dispensers, and insurers encompassed under Medicare. CMS has requested public comments on this proposal in order to tailor a comprehensive and complete final set of standards.

II. Introduction

A. The ERISA Industry Committee

The ERISA Industry Committee is a nonprofit association committed to the advancement of employee retirement, health and other benefit plans of America's largest employers. ERIC's members provide comprehensive retirement, healthcare coverage, and other economic security benefits directly to some 25 million active and retired workers and their families. ERIC has strong interests in proposals affecting its members' ability to deliver those benefits, their cost and effectiveness, and the role of those benefits in the American economy.

B. Statement of Interest

The proposed rule would require Prescription Drug Plan (PDP) sponsors – as well as Medicare Advantage Organizations offering prescription drug plans and other Part D sponsors – to support and comply with final standards as soon as they come into effect. Although not all prescriptions will immediately be made electronically, Part D sponsors must be able to accommodate any that are electronic. This mandate will extend to providers that prescribe or dispense Part D drugs only when certain other standards for health information technology are in place.

Many ERIC members are PDP sponsors who would be immediately affected by final standards. ERIC maintains it necessary to incorporate the perspective of our members, America's major employers, in refining the process for any standards that will amount to new mandates.

III. Privacy and Liability

A. Issue for Discussion

While the benefits of moving to an electronic system are numerous, the potential for lapses in privacy is equally great. Much focus and attention must be placed on securing the transactions between doctors, pharmacies, and insurers. We are concerned that any

privacy rules CMS implements will be tangled in a complicated web of state laws that could make the policy meaningless. ERIC, along with other members of the Confidentiality Coalition, sent a letter on January 18, 2005, to Dr. David J. Brailer, the National Coordinator for Health Information Technology, addressing this issue.

B. ERIC Recommendation: Nationwide Standards

ERIC urges that the final regulations regarding electronic prescribing include rigorous safeguards to protect patient privacy and data security. We also urge that CMS preempt state laws when it comes to privacy standards, as currently there are problems with HIPAA and other state health privacy protections, involving some states that have significantly different and conflicting requirements. It would be to the benefit of all involved if CMS adopted uniform standards for privacy and data security, and could assure these standards were utilized nationwide, to accommodate multi-state employers. If PDP sponsors and insurers were required to meet multiple privacy standards, lack of standardization would cause unnecessary confusion and reduce the efficiency of moving to an electronic system. When uniform standards are adopted and adhered to, PDP sponsors should not be held liable for any data or security loss that takes place while complying with these uniform standards.

IV. Preemption

A. Issue for Discussion

CMS has adopted a narrow view of when federal laws preempt state laws. Preemption occurs when a state law meets the following two-part test: "[i]s contrary to the standards or restricts the ability to carry out this [regulation]" and also "[p]ertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under this [regulation]." This interpretation limits preemption to only prescriptions written for beneficiaries enrolled in Part D when the prescription is made, rather than all Medicare recipients. It also limits preemption to only drugs covered by Part D, while Medicare recipients can have drug coverage from other sources, even other parts of the Medicare program. Further, under this view of the preemption rule, a state law would have to be in full disagreement with the federal standards to warrant preemption, instead of a wider range of state laws that interfere with the policy goals of uniform federal electronic prescribing standards.

B. ERIC Recommendation: Broader Preemption Provision

ERIC urges CMS to adopt a broader interpretation of the preemption provision, so that the federal law will preempt any state laws that contradict the federal standards explicitly or implicitly. This view of federal preemption has precedent and would be more effective in ensuring that the uniform federal standards for electronic prescribing are adhered to and not compromised by a patchwork of contradictory state laws. This wider interpretation of the preemption provision would make the e-prescribing standards far easier to administer for care providers, dispensers, and insurance entities, especially those

who operate in multiple states. There are several types of state laws that clearly would be prohibitive to the electronic prescribing standards, including statutes requiring that prescriptions be given by doctors directly to dispensers, laws that require patient permission to release information about certain conditions, and state prescription format laws.

V. Stark (Anti-Kickback) Laws and Regulations

A. Issue for Discussion (BACKGROUND (A) 3)

The Stark laws severely restrict transfers of any type of assets to healthcare providers. These laws were designed to maintain the integrity of doctors and hospitals from the reach of bribery, conflicts of interest or deal-making. The Stark laws have been interpreted to prohibit reimbursement of hospitals, healthcare providers, and dispensers of drugs for expenses involving technologies such as the purchase of hardware, software, and related training. Unfortunately, even if purchases are made for the specific purpose of advancing or simply complying with emerging health information technology standards, electronic prescribing would be covered under the law.

B. ERIC Recommendation: Creation of Stark Law Exception

ERIC applauds the efforts of CMS to amend the anti-kickback statute in order to facilitate the training of healthcare professionals and to allow hospitals to distribute hardware and software to their doctors. While the issue is not resolved in these proposed rules, we urge CMS to support the necessary legislative change needed to create a Stark law exception for electronic prescribing as quickly as possible. Encouraging wide use of electronic prescribing must continue to be a top priority in the implementation of the MMA, and would do much to promote cost-effectiveness, save time and advance patient safety.

VI. Messaging Standards

A. Issue for Discussion (BACKGROUND (G))

The MMA stipulates that messages may be sent through the e-prescribing system to providers for the purpose of improving patient safety, but not for advertising purposes. The limitations for messaging, however, are nebulous and without any specifications. The final standards must include detailed stipulations on messaging.

B. ERIC Recommendation: Limit Messaging

We urge CMS to adopt standards that allow messaging only to help protect patients. Rigorous safeguards should be in place to prevent any interference with physicians' decisions, excepting only scientific advice concerning drug conflicts, etc. Messaging input should be properly prioritized as well as limited by its timing in the prescription process; drug suggestions should not be sent to physicians by any outside sources before they make an initial recommendation. ERIC supports firm limitations on messaging

between parties via electronic prescribing systems, and supports it in order to advance patient safety only.

VII. Pilot Testing

A. Issue for Discussion (BACKGROUND (F))

CMS has proposed to forego any pilot testing due to what it describes as "adequate industry experience" with electronic prescribing. This has the effect of speeding up adoption of final uniform standards, but also may decrease the program's initial efficiency due to lack of a limited trouble-shooting phase. While pilot testing would delay the implementation of new systems and standards, it also may help CMS to see and avoid potential problems that may arise when e-prescribing becomes more widely practiced.

B. ERIC Recommendation: Adoption of Pilot Testing

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IX. Conclusion

In conclusion, ERIC appreciates the opportunity to provide suggestions to the proposed standards, and realizes that CMS must take into account the interests and commentary of multiple stakeholders. We urge you to revise the standards as suggested here, and to mold the electronic prescription process into one that is mutually beneficial to large employers, their employees, physicians and healthcare providers, and other crucial parties to the program. ERIC firmly believes that CMS can, in cooperation with those that will be sponsoring PDPs, create comprehensive uniform standards that will implement the necessary changes in privacy rules and anti-kickback legislation, and will include all the required functions and necessary safeguards to ensure a properly working system.

As requested by CMS, ERIC is submitting these comments (without any duplicates by mail or by hand) electronically to www.cms.hhs.gov/regulations/ with the text attached in the preferred Microsoft Word format.

Sincerely,

[signed]

Mark J. Ugoretz
President
The ERISA Industry Committee

THE ERISA INDUSTRY COMMITTEE

1400 L Street NW, Suite 350, Washington DC 20005 (202) 789-1400 fax: (202) 789-1120 www.eric.org

Advocating the Benefit and Compensation Interests of America's Major Employers

April 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule Regarding Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Administrator McClellan:

The ERISA Industry Committee (ERIC) respectfully submits these comments in response to proposed regulation "Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule" (42 CFR Part 423) published in the *Federal Register* on February 4, 2005. ERIC, representing the interests of America's major employers, is pleased to offer our comments on the recent CMS proposed standards for electronic prescribing in the electronic prescription drug program under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003. This regulation details electronic prescribing standards for Medicare's new Part D, the Voluntary Prescription Drug Program.

Our primary goal in these comments is to present feedback to CMS from the standpoint of America's large employers, who will be party to the electronic prescription program through retiree health plans. A majority of ERIC's members offer a retiree health plan. We support the use of electronic prescribing for its capacity to increase accuracy, effectiveness and patient safety, as well as its potential to lower the administrative burden on healthcare providers and physicians. However, we are aware that the use of electronic prescribing warrants a cautious approach and precise uniformity of computer programs, and that all actors involved must play a role in maintaining the confidentiality of patients' medical data.

We look forward to working with you and your staff to further discuss our suggestions and recommendations. If you would like to schedule a meeting or conference call to discuss these comments, please contact Edwina Rogers, ERIC's Vice President for Health Policy at 202-789-1400.

I. Purpose of Proposed Electronic Prescribing Regulations

On February 4, 2005, CMS released a set of proposed rules and standards for the e-prescribing and prescription drug program of the Medicare Prescription Drug, Improvement and Modernization Act (MMA). This proposal would be the first set of uniform standards for the electronic prescribing program, and would ensure interoperability between all prescribing healthcare entities, prescription dispensers, and insurers encompassed under Medicare. CMS has requested public comments on this proposal in order to tailor a comprehensive and complete final set of standards.

II. Introduction

A. The ERISA Industry Committee

The ERISA Industry Committee is a nonprofit association committed to the advancement of employee retirement, health and other benefit plans of America's largest employers. ERIC's members provide comprehensive retirement, healthcare coverage, and other economic security benefits directly to some 25 million active and retired workers and their families. ERIC has strong interests in proposals affecting its members' ability to deliver those benefits, their cost and effectiveness, and the role of those benefits in the American economy.

B. Statement of Interest

The proposed rule would require Prescription Drug Plan (PDP) sponsors – as well as Medicare Advantage Organizations offering prescription drug plans and other Part D sponsors – to support and comply with final standards as soon as they come into effect. Although not all prescriptions will immediately be made electronically, Part D sponsors must be able to accommodate any that are electronic. This mandate will extend to providers that prescribe or dispense Part D drugs only when certain other standards for health information technology are in place.

Many ERIC members are PDP sponsors who would be immediately affected by final standards. ERIC maintains it necessary to incorporate the perspective of our members, America's major employers, in refining the process for any standards that will amount to new mandates.

III. Privacy and Liability

A. Issue for Discussion

While the benefits of moving to an electronic system are numerous, the potential for lapses in privacy is equally great. Much focus and attention must be placed on securing the transactions between doctors, pharmacies, and insurers. We are concerned that any

privacy rules CMS implements will be tangled in a complicated web of state laws that could make the policy meaningless. ERIC, along with other members of the Confidentiality Coalition, sent a letter on January 18, 2005, to Dr. David J. Brailer, the National Coordinator for Health Information Technology, addressing this issue.

B. ERIC Recommendation: Nationwide Standards

ERIC urges that the final regulations regarding electronic prescribing include rigorous safeguards to protect patient privacy and data security. We also urge that CMS preempt state laws when it comes to privacy standards, as currently there are problems with HIPAA and other state health privacy protections, involving some states that have significantly different and conflicting requirements. It would be to the benefit of all involved if CMS adopted uniform standards for privacy and data security, and could assure these standards were utilized nationwide, to accommodate multi-state employers. If PDP sponsors and insurers were required to meet multiple privacy standards, lack of standardization would cause unnecessary confusion and reduce the efficiency of moving to an electronic system. When uniform standards are adopted and adhered to, PDP sponsors should not be held liable for any data or security loss that takes place while complying with these uniform standards.

IV. Preemption

A. Issue for Discussion

CMS has adopted a narrow view of when federal laws preempt state laws. Preemption occurs when a state law meets the following two-part test: "[i]s contrary to the standards or restricts the ability to carry out this [regulation]" and also "[p]ertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under this [regulation]." This interpretation limits preemption to only prescriptions written for beneficiaries enrolled in Part D when the prescription is made, rather than all Medicare recipients. It also limits preemption to only drugs covered by Part D, while Medicare recipients can have drug coverage from other sources, even other parts of the Medicare program. Further, under this view of the preemption rule, a state law would have to be in full disagreement with the federal standards to warrant preemption, instead of a wider range of state laws that interfere with the policy goals of uniform federal electronic prescribing standards.

B. ERIC Recommendation: Broader Preemption Provision

ERIC urges CMS to adopt a broader interpretation of the preemption provision, so that the federal law will preempt any state laws that contradict the federal standards explicitly or implicitly. This view of federal preemption has precedent and would be more effective in ensuring that the uniform federal standards for electronic prescribing are adhered to and not compromised by a patchwork of contradictory state laws. This wider interpretation of the preemption provision would make the e-prescribing standards far easier to administer for care providers, dispensers, and insurance entities, especially those

who operate in multiple states. There are several types of state laws that clearly would be prohibitive to the electronic prescribing standards, including statutes requiring that prescriptions be given by doctors directly to dispensers, laws that require patient permission to release information about certain conditions, and state prescription format laws.

V. Stark (Anti-Kickback) Laws and Regulations

A. Issue for Discussion (BACKGROUND (A) 3)

The Stark laws severely restrict transfers of any type of assets to healthcare providers. These laws were designed to maintain the integrity of doctors and hospitals from the reach of bribery, conflicts of interest or deal-making. The Stark laws have been interpreted to prohibit reimbursement of hospitals, healthcare providers, and dispensers of drugs for expenses involving technologies such as the purchase of hardware, software, and related training. Unfortunately, even if purchases are made for the specific purpose of advancing or simply complying with emerging health information technology standards, electronic prescribing would be covered under the law.

B. ERIC Recommendation: Creation of Stark Law Exception

ERIC applauds the efforts of CMS to amend the anti-kickback statute in order to facilitate the training of healthcare professionals and to allow hospitals to distribute hardware and software to their doctors. While the issue is not resolved in these proposed rules, we urge CMS to support the necessary legislative change needed to create a Stark law exception for electronic prescribing as quickly as possible. Encouraging wide use of electronic prescribing must continue to be a top priority in the implementation of the MMA, and would do much to promote cost-effectiveness, save time and advance patient safety.

VI. Messaging Standards

A. Issue for Discussion (BACKGROUND (G))

The MMA stipulates that messages may be sent through the e-prescribing system to providers for the purpose of improving patient safety, but not for advertising purposes. The limitations for messaging, however, are nebulous and without any specifications. The final standards must include detailed stipulations on messaging.

B. ERIC Recommendation: Limit Messaging

We urge CMS to adopt standards that allow messaging only to help protect patients. Rigorous safeguards should be in place to prevent any interference with physicians' decisions, excepting only scientific advice concerning drug conflicts, etc. Messaging input should be properly prioritized as well as limited by its timing in the prescription process; drug suggestions should not be sent to physicians by any outside sources before they make an initial recommendation. ERIC supports firm limitations on messaging

between parties via electronic prescribing systems, and supports it in order to advance patient safety only.

VII. Pilot Testing

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