Submitter : **Dr. Malcolm Moore** **Date: 01/24/2005**

Organization : **Eye Center of Central Georgia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am protesting the reimbursement of Rocephin, J0696. Our cost is $12.20 per 250mg. The reimbursement after Jan. 1, 2005 is $6.57 per 250mg, 54% of what we pay for the medication. We will not be able to provide this medication to our patients with this reimbursement.
Also, butorphanol, J0595, we pay $3.68 per 1G, the reimbursement now is $1.82 per gram.
Please let me know where we can purchase these drugs at this price, or adjust your reimbursement to a fair level.

Submitter : Dr. Jorge Ferrer **Date: 03/29/2005**

Organization : Veterans Health Administration

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-2-Attach-1.DOC

Submitter : **Dr. Stuart Levine** **Date: 03/29/2005**

Organization : **Institute for Safe Medication Practices**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-0011-P-3-Attach-1.DOC

CMS-0011-P
Medicare Program; E-prescribing and the Prescription Drug Program

Comments from the Institute for Safe Medication Practices
Prepared by Stuart Levine, Pharm.D, Informatics Specialist

We are disappointed that the regulation will not increase the utilization of computerized prescriber order entry (CPOE). We believe that this is a primary method of reducing medication errors in the prescribing phase of the medication use process. Studies indicate a 55% to 90% decrease in the number of medication errors with the use of CPOE.

We are pleased by the number of elements that will be required for those that wish to continue using CPOE. We do have some concerns regarding the quality of those elements as follows:

1. For other drugs listed in the medication history the only information required of the history is the drug name. No additional information is provided on the sig. We believe that information regarding the dose and frequency should be included with medications in the medication history for completeness.
2. Information that relates to the medical history does not appear to include patient's weight. Therefore the only criteria for dose adjustment would be based on laboratory values. This impacts particularly the pediatric patient and does not allow for independent calculation of the dose by the pharmacy. Serious potential errors are 3 times higher in pediatric patients than adult patient. Weight must be a specified element of the patient history.

Thank you for reviewing our concerns.

CMS-0011-P-4 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Ms. Lynne Gilbertson **Date & Time:** 03/30/2005

Organization : NCPDP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-4-Attach-1.DOC

NCPDP

March 30, 2005

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

Dear Centers for Medicare and Medicaid Services:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,300 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

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.

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. We are concerned that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

NCPDP 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.

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.

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. While multiple coverages may present other problems at the point of care as well, such as which formulary and benefit information to show, 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 t o p articipate i n el ectronic p rescribing w hile el iminating t he 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.

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 t he e- prescribing m odel m ust 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)
NCPDP Response:
NCPDP requested clarification of CMS that at this point, long-term care is not addressed in this regulation. 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…

NCPDP Response:

Please see NCPDP 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.

NCPDP Response:

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing. NCPDP appreciates that HHS is looking to name a minimum standard of NCPDP SCRIPT Version 5.0, but not stifle industry movement to versions above this, as business needs arise. 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 Standard Version 5.0 gives the industry the "floor".

It is important to allow the evolution of the industry. The support of a new version takes time as products are developed and rolled out to the industry.

NCPDP has had several discussions about version management methods whereby newer versions of a standard could be adopted and older versions retired in order to balance the needs of stakeholders who are working to expand the capabilities of a given standard versus those who are merely wishing to comply with the minimum necessary standards. W e o ffer the following recommendations for your consideration. NCPDP would welcome the opportunity to meet with HHS and other SDOs to further discuss the issues related to the management of standard versioning under MMA, especially if there are areas that the current Federal rulemaking requirements may be in conflict with the scenarios we describe. (Note, in the context of the recommendations, "HHS" is used. You may determine that CMS is the more appropriate authority for this role.

In addressing version management, NCPDP is attempting to accommodate a diverse set of requirements in order to achieve optimal effectiveness of the technical standards we and other SDOs develop. One overarching philosophy behind our recommendations is that the industry stakeholders collectively offer the best source for knowing the optimal range of capabilities within the industry. Thus, we need a mechanism for advancing the industry as a whole that doesn't force everyone to stay in lock step with each other in order to maintain interoperability. Naming one version of a standard as the only acceptable v ersion f or u se i mpedes p rogress and i nnovation; requiring simultaneous adoption of newer versions can create disruptive and inefficient transitions that are prone to error rather than a more natural evolutionary process; allowing for newer versions of a standard while still supporting older versions helps to alleviate some of these problems, but has a secondary effect of creating inefficiencies over time as backward compatibility must be maintained to the oldest version in order to retain some level of interoperability.

We note that in other industries where market forces play a greater role than regulatory requirements, there is a relatively organic process by which new versions are introduced and adopted by stakeholders when the perceived advantages of the new version offer a competitive advantage over maintaining an older version. For example, a large organization using Microsoft Windows® as an operating system may not choose to

upgrade to a new version every time it comes out, but would "leapfrog" to save the transition costs and inefficiencies inherent in change. They would also stagger the transition so that some colleagues would be on Windows 2000 and others on XP. But they would also make sure that no one stayed on Windows 98 to avoid problems with backward compatibility and employee inefficiencies.

The strategy we propose attempts to address all these issues while maintaining an open process that allows all stakeholders to voice their opinions during the decision-making process.

In the following example, the adoption of a new version or release of a standard would be independent of the retiring of an older version; they could happen simultaneously, but introducing a new version or release would not automatically force the retiring of an older version or release. Other assumptions of the model we present include the following:

- The timing of version or release development can vary. When there are many advances in the industry around electronic interchange, there may be a need to have a more rapid cycling of the standard; as a standard arena stabilizes, the need to advance to a new version or release will slow. Therefore, we haven't included specific lifecycle timelines in the model, but rather have established dependencies as to what order changes must occur.
- The number of versions or releases that are accepted as "active" standards can change over time. The decision of whether a change to a standard constitutes a "version", "release" or merely a "document revision" is SDO dependent and should not be constrained by the Federal standard version naming process. It would be problematic to require, for example, that every new version go through the Federal approval process in the case where the changes to a version were made for reasons that are not tied to a specific law or regulation (like the introduction of pediatric dosing that would not apply to Medicare Part D). While it is reasonable to assume that there wouldn't be a need for more than four versions to be active at any one time, it would be better to allow the SDO vetting process to determine the best timing for each new version approval or retirement.
- Similarly, a new federally approved version of a standard could be a true "version" (i.e., v7.0 to v8.0) or a "release" (i.e., v7.4 to v7.5). From this point forward, "version" will be assumed to mean either version or release unless stated otherwise.
- The Federally approved versions do not have to be directly sequential. For example, versions 5.0, 5.1, 6.0, 7.0, and 7.1 are approved. The three versions chosen by the industry to have active might be 5.0, 6.0, and 7.1, based on the business requirements.
- HHS would work in cooperation with the SDOs to determine the best timing for advancing and retiring versions of the standard.
- For named transactions/standards, at least two versions would be Federally approved at any given time. The actual number of versions that would be approved at any given time would be determined by through the SDO voting process.
- When a new standard was being adopted for the first time, the most current version would possibly be the only version approved.
- Implementers of the standard would be able to use any version/release in the current valid range of version/releases for their exchanges through networks or trading partners. But implementers of later versions would have to be capable of sending or receiving transactions in the older approved. This would allow implementers to take advantage of technical advances within a standard when exchanging information with other advanced implementers, but would not force

those implementers using older, but still valid, version/releases to upgrade before they are ready.

- Implementers will likely "skip" through the versions (i.e., use Windows 98 for a few years, but skip over Windows 2000 when Windows XP comes out.).
- HHS would establish an alert mechanism (an email listserv, for example) that interested stakeholders could subscribe to with respect to a specific standard so that they would be aware of upcoming open forums, introductions of new versions and plans to retire old versions. HHS could choose to request that individual SDOs maintain this process.

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.

Version Management Process for Advancing a New Version:

1. The SDO works through its normal consensus process to advance a new version of a standard.
2. The SDO achieves internal consensus (workgroup level) for a new version and votes whether this version should be presented to HHS as an MMA standard.
3. The SDO prepares the version for ballot and in the case of an affirmative vote, the SDO presents the incremental changes in the standard to NCVHS to allow for public comment and invites interested stakeholders to participate in the ballot. This process takes place before or in parallel with the SDO balloting process so that no time is lost. (Alternatively, this open hearing could be an SDO- or HHS-managed process via publicly announced teleconference.)
4. NCVHS sends a letter of notification to HHS within 15 days of the hearing with its recommendation to accept the standard when balloted successfully and notes any substantive comments received during the hearing.
5. The SDO ballots the standard.
6. The SDO reconciles negative votes. (As the SDOs are ANSI-accredited, they must ensure that all stakeholders have adequate opportunity to voice opposition and that due process was followed.)
7. Upon successful resolution of ballot, the SDO submits to HHS (and copies NCVHS on) a request for this new version to be adopted, with an implementation timeframe.
8. HHS announces the new version in Federal Register. The implementation date would be the date of publication as the adoption of this latest version would be voluntary. The version(s) that have been announced previously are still valid for use until retired.

Version Management Process for Retiring an Old Version:

1. The SDO works through its normal consensus process to discuss the retirement of an older version of the standard. At least two newer versions must have been approved through the process outlined above. Conditions for retirement may include:
    a. Industry consensus that maintaining active use of an older version would no longer be cost effective or would not support what are considered to be current best practices
    b. Industry consensus that the older version is no longer in wide-spread use
2. The SDO achieves internal consensus (at the workgroup level) that a version should be retired and prepares to put this recommendation to an SDO-wide vote.

3. While preparing for the full-SDO vote, the SDO presents their proposal to retire the version to NCVHS to allow for public comment and invites interested stakeholders to participate in the voting.
4. NCVHS sends a letter of notification to HHS within 15 days of the hearing with its recommendation to retire the version/release of the standard should the SDO ballot be successful and notes any substantive comments received from the hearing.
5. The SDO conducts an SDO-wide vote on retiring the version.
6. Upon passage, the SDO submits to HHS (and copies NCVHS on) a request to retire the version, with an implementation timeframe that does not cause undue burden on implementers.
7. Upon review, HHS announces retirement of the version in the Federal Register.

NCPDP 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. NCPDP 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)
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 P lans (PDP), L TC p harmacies, p hysicians and nu rsing 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.
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 to 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.

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® be 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 HCId®, the NPI, the DEA and o ther possible identifiers such as State license number and UPIN number may 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:

NCPDP 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:

NCPDP Response:

See above.

(F.R. page 6263)

We propose the following critical characteristics for medication history standards:

NCPDP Response:

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.

NCPDP 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).

NCPDP Response:

NCPDP supports these foundation standards. NCPDP recommends 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 NCPDP's 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.

NCPDP Response:

NCPDP can see 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 br oad and m ay be i mplemented i n di fferent t imeframes and m ay 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.

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.*

NCPDP Response:

NCPDP 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.

NCPDP supports the definition of electronic media.

NCPDP 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.

NCPDP Response:

NCPDP agrees with the recommendations from NCVHS that when transmitting information outside the enterprise, the named standards should be used (NCPDP SCRIPT, etc). NCPDP does not believe that the standards should be required for e-prescribing transactions within the enterprise. We do not see an advantage to require this within the same time period as outside of the enterprise.

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.

NCPDP Response:

NCPDP supports this approach. NCPDP supports trading partners using these transactions, especially in the 2006 pilots. We have completed the creation of additional documentation clarifying the proper use these transactions. These additions will be included in the next NCPDP SCRIPT Standard Implementation Guide.

(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

NCPDP Response:
NCPDP supports this list.

(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.
NCPDP Response:
There is a difference between "adopt" and "require". NCPDP recommends 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.
NCPDP 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.*

NCPDP Response:

Please see NCPDP's 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.

NCPDP Response:

Please see NCPDP's 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.

NCPDP 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.

NCPDP 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)

NCPDP 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.

NCPDP 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)

NCPDP Response:

Please see NCPDP's 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.

NCPDP Response:

NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard. Please see NCPDP's comments in Section *"G. Electronic Prescription Drug Program (F.R. page 6261)."* NCPDP 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.

(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.

NCPDP Response:

NCPDP 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

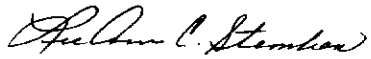
NCPDP supports phasing in electronic prescribing in a way that leverages industry momentum and builds on the considerable experience and success the industry has had to date.

To encourage the voluntary adoption of electronic prescribing by prescribers and dispensers and facilitate consistent implementation by payers, technology providers, and intermediaries, NCPDP supports a single, national, comprehensive set of regulations applicable to all electronic prescriptions, not just electronic prescriptions for Part D enrollees. Otherwise, the Part D program becomes yet another set of regulations that must be reconciled by each participating entity with the current 50-state scheme for regulating electronic prescribing. NCPDP believes adding

complexity to an already-challenging regulatory environment will hinder voluntary adoption rather than facilitate it—particularly since compliance would require definitive coverage information at the point of prescribing.

NCPDP stands ready to assist CMS in the continued success of electronic prescribing. NCPDP members and staff are committed to the actions cited in the MMA, have brought forth standards forward where available or needed, and facilitated industry task groups dedicated to the implementation of e-prescribing.

Sincerely,



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cc: NCPDP Board of Trustees

CMS-0011-P-5 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Ms. Patricia Wilson **Date & Time:** 03/31/2005

Organization : Associates & Wilson

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0011-P-5-Attach-1.DOC

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March 31, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P.
Submitted to http://www.cms.hhs.gov/regulations/ecomments
Re: CMS-0011-P. Comments on E-Prescribing Proposed Rule 70 Fed. Reg. 6256 (Feb. 4, 2005)

Dear Sir or Madam:

This letter constitutes our comments on the E-Prescribing proposed rule cited above. Comments are submitted on "Provisions" specifically recommending that proposed 423.159 be expanded to incorporate a new paragraph (b) requiring that all new prescriptions contain the diagnosis (or diagnoses), and that the definition of "prescription-related information" in proposed 423.159(b) include the diagnosis. This letter is being submitted electronically to www.cms.hhs.gov/regulations/ecomments as a Microsoft Word document. The submission was made before the deadline of 5PM on April 5, 2005.

We propose adding the requirement of a ***diagnosis (Dx) on the prescription (Rx)*** to the e-prescribing rules. We call it *Dx on Rx*. Requiring a diagnosis on the prescription:

1. Supports many of the Medicare electronic prescription drug program requirements and in some cases is necessary to achieve the program requirement.
2. Complies with HIPPA.
3. Is supported by adequate industry experience and therefore would not require pilot testing.
4. Supports and is consistent with MMA cost control and quality improvement requirements.

1. *Dx on Rx* supports other electronic prescription drug program requirements

The Act requires an electronic prescription drug program to provide for the electronic transmittal of certain information to the prescribing health care professional and to the dispensing pharmacy and pharmacist. The following statute-required information would be greatly facilitated if the diagnosis was on the prescription:

- **Information on eligibility and benefits** (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) is required by the statute. *Dx on Rx* has the benefit of helping to determine eligibility for prescription plan coverage. Some prescription drugs have multiple uses. Some of those uses are eligible for coverage under Medicare and some are not. Without knowing the diagnosis, plans and pharmacy benefit programs have a limited ability to efficiently check whether the plan's coverage criteria have been met. Examples of how inclusion of the diagnosis on the script facilitates coverage decisions include:
    - **Zofran** or any anti-nausea or anti-vomiting drug is covered by Medicare under Parts A and B by most plans when used for "medical care and treatment", such as following

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chemotherapy or for the prevention of post-operative nausea and vomiting. A use usually not eligible for plan coverage is nausea associated with seasickness for an upcoming summer cruise or fishing trip.

- **Botox Cosmetic** and its identical cousin Botox are aggressively marketed. Botox has approved uses for several conditions with doses substantially higher for cervical dystonia than for other medical uses. Botox Cosmetic for wrinkles is seldom (knowingly) an eligible plan expense. Since Botox is identical to Botox Cosmetic, it could be used as a cosmetic treatment. Having the diagnosis on the prescription as the representation of the physician's intended use is an efficient mechanism to determine whether the expense is eligible or ineligible for coverage under the plan.

- **Information on drug-drug interactions, warnings or cautions and when indicated, dosage adjustments)** is required by the statute. The Institute of Medicine has identified medication errors as a major cause of preventable death. To reduce and prevent widespread errors, The Institute of Medicine advocates "designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing". *Dx on Rx* is a system design that meets the Institute's criteria and facilitates the Medicare e-prescribing requirement to provide information on interactions, warnings or cautions and dosage adjustments. The following current practices increase the likelihood of medication error. A "systems design" of *Dx on Rx* can improve patient safety by helping to prevent medication errors.

  - **Same Drug; Multiple Uses:** It is common for one drug to have multiple uses. For each condition, where use is FDA approved or recommended by an authoritative group, the recommended initial dose and the duration of therapy can vary significantly depending on the needs of each patient and on their specific conditions. Without knowing the diagnosis, it is impossible to provide reliable information on dosage adjustments and other important warnings and cautions. Examples include:
    - **Prilosec**: Prilosec has eight approved indications. The recommended dose of Prilosec for an active duodenal ulcer is 20 mg once a day for a period of 4 weeks. Some patients may need an additional 4 weeks. However, if the patient has Zolinger-Ellison Syndrome, the recommended dose is 60 mg once a day, with continuous treatment.
    - **Coreg**: The appropriate dose when used for congestive heart failure would be 3.125 mg twice a day. But if Coreg is used for hypertension, the recommended dose is twice as high.

  - **Different Drugs, Different Uses, Confusing Names:** *Sometimes medication is selected in error because the names are similar with slightly different spelling or pronunciation.* Dx on Rx *allows prescribers, dispensing pharmacists, Pharmacy Benefit Managers (PBMs) – and more importantly – systems with artificial intelligence to check the diagnosis code against the dosing specific to the patient's condition. Examples of drugs that have been mixed up include the following:*
    - Imferon (an iron replacement) and Interferon (for cancer therapy)
    - Xanax (for anxiety) and Zantac (for ulcers)
    - Celebrex (for arthritis) and Celexa (for depression)
    - Quinine (for nocturnal leg cramps and treatment of malaria) and quinidine (for abnormal heart rhythms).

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Dx on Rx can help prevent medical errors and improve care. It's simple, easy, systems-driven, and effective. By avoiding mistakes, *Dx on Rx* improves patient care. It can be done routinely before a medication is dispensed or a claim is processed. Without knowing the diagnosis, it would be difficult to provide the information required in the statute, for example, dosage adjustments.

- ***Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed*** is required by the statute. Without knowing the diagnosis, accurate information about lower cost or therapeutically appropriate alternatives cannot be provided in many cases. In fact, too often prescriptions are written when there is no evidence that the drug is either appropriate or effective. Marketing efforts coupled with new products and more approved indications for an existing product have contributed to prescribing patterns that fall outside reasonable guidelines. There are many possible examples, including:
  - The patient "asked for it" or "expected it". Antibiotics are often cited as examples.
  - The medication was selected in error.
  - The medication was selected as an experimental approach without evidence. Neurontin is an example where aggressive marketing efforts resulted in 78% non-FDA approved use of the drug. There are reports that off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines.
  - The prescribing physician is involved in research that has not yet been published, but benefits to the patient are quantifiable and substantial. Best practice begins somewhere – and when substantiated as effective and appropriate, sharing with others sooner is to the benefit of all.

The diagnosis on the prescription indicates the physician's intended use. If the medication and intended use do not match, the dispensing pharmacist calls the prescriber. *Dx on Rx* can help clarify appropriateness of use and target availability of lower cost, therapeutically appropriate alternatives for the drug prescribed. It's simple, easy, systems-driven, and effective. *Dx on Rx* can improve patient care and be done routinely before a medication is dispensed or a benefit claim is processed.

- ***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*** is required by the statute. The statue recognizes the importance of the medical history (medical history relates to information about the patient's health status, for example, allergies, laboratory test results and chronic conditions) and intends to propose standards for communicating medical history at a future date. Clearly, if medical history is important, current medical status (diagnosis) should be an even higher priority.

2. *Dx on Rx* Complies with HIPPA

The statute requires that information shall only be disclosed if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) under the Health Insurance Portability and Accountability Act of 1996. The

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department of Health and Human Services has confirmed that requiring a diagnosis or diagnosis code on a prescription requires no separate special authorization because it falls within the treatment, payment and healthcare operations category of the privacy rule.

However, it is recognized that there may be specific circumstances under which *Dx on Rx* is deemed inappropriate by the prescriber or patient, e.g., when doing so might compromise patient adherence to therapy or confidentiality. Therefore we suggest when it may be inappropriate to include the diagnosis or indication on the prescription, this information can be communicated to the pharmacy concurrent with the prescription being placed (verbally or written separately), or after the drug is dispensed. A concurrent transmission is preferred, as it prevents delay in dispensing and counseling, or the need to address dispensing or counseling errors after the fact. Any privacy concerned can be addressed and is not a barrier to implementing *Dx on Rx*.

3. *Dx on Rx* is supported by adequate industry experience and doesn't require pilot testing.

At this time, CMS can only propose to adopt as final standards, those standards with which there is adequate industry experience. Otherwise, pilot testing is required. While generally pharmacy benefits are unique in healthcare for paying claims submitted without requiring diagnosis or indication for service, there are at least three notable exceptions to this rule. We believe these exceptions provide adequate industry experience so that pilot testing would not be necessary. The three exceptions are as follows:

- **Medicare beneficiaries.** For the limited number of drugs covered by Medicare/CMS prior to the introduction of the Medicare Modernization Act (diabetic supplies, transplant drugs, etc.), there is no reimbursement for these drugs unless the diagnosis is submitted with the claim. Here the requirement is about fraud and coverage mechanics and not quality of care since there is no coverage review before the drug is dispensed.
- **Medicare/Medicaid nursing home residents.** The Institute of Medicine (IOM) issued a report in 1986 titled *Improving the Quality of Care in Nursing Homes*. One concern then was the widespread use, as chemical restraints, of psychopharmacologic drugs including anti-anxiety drugs, sleeping pills, barbiturates and antipsychotic drugs. That report led to Federal regulations which require that nursing home residents be free of all "unnecessary" drugs. To ensure compliance with these regulations, a patient's physician must document the indication for the use (Dx) of each drug (Rx) in a resident's medical record so that a pharmacist, as part of the federally-mandated Drug Regimen Review requirement, can review the complete medical record each month and report apparent irregularities to the individual who has the ability to correct them. While quality of care improvements and cost savings were anticipated results, the most common recommendation made by the pharmacist, and accepted by the physician, may have been unexpected by some. It is to discontinue Rx therapy because it is inconsistent with the diagnosis (Dx).
- **Veterans Administration (VA).** The VA hospital system began requiring *Dx on Rx* in 1993. In 1999 the electronic infrastructure had no space for the diagnosis but a new project is underway to reinstitute it. However, during the 6 year period when *Dx on Rx* was in place, the VA found something unexpected. By simply putting their health condition (i.e. high blood pressure) on the pill bottle, patient compliance to take the medication increased. This was in addition to improvements in quality of care and a decrease in prescribing errors.

4. *Dx on Rx* Supports MMA Objectives

Dx on Rx supports and facilitates the Medicare Modernization Act's cost control and quality improvement requirements. Specifically the MMA regulations state:

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- *Each plan sponsor must have established a drug utilization management program, a quality assurance program, a Medication Therapy Management Program and a program to control fraud, abuse and waste.*
- *A reasonable and appropriate drug utilization management program must include incentives to reduce costs when medically appropriate; maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.*
- *A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use...*

Knowing the diagnosis is key to any utilization management program. Without the diagnosis, presumptions and guess work replace fact-based decision making. In many cases, utilization management programs spend time and money to confirm a diagnosis so that utilization review can be performed. *Dx on Rx* not only supports and facilitates the MMA objectives, but it can reduce the need for prior authorization and other utilization management programs. The diagnosis would illustrate the prescribing physician's intended use and thereby eliminate or reduce the need to contact the physician. An efficient, fact-based process should translate to easier approvals (or denials) of prescription plan coverage with savings in the tens of millions to Medicare and Rx drug benefit plan sponsors.

Dx on Rx will facilitate the efficient approval of covered plan expenses and reduce the frequency or intensity of Prior Authorization procedures required by some PDPs and MA-PDPs.

Conclusion

E-prescribing is in its infancy. But it will grow up fast. Many will look to the Medicare e-prescribing standards as a model. *Dx on Rx* is both practical and doable. Patients deserve the advantages that *Dx on Rx* offers for:

- Preventing medical errors and improving care
- Highlighting the appropriateness of use, and
- Eliminating surprises by determining up-front eligible plan expenses.

Dx on Rx represents progress in terms of maintaining a viable Medicare prescription program by improving the quality of care while managing costs.

Sincerely,

Patricia L. Wilson

Patricia L. Wilson
Consultant

CMS-0011-P-6 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Mr. Shawn Bloom **Date & Time:** 03/31/2005

Organization : National PACE Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-6-Attach-1.DOC

CMS-0011-P-6-Attach-2.DOC

March 31, 2005

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

RE: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Sir/Madam:

The National PACE Association (NPA), on behalf of its members, would like to submit the following comments regarding the proposed rule on E-Prescribing and the Prescription Drug Program.

For the most part we would like to use the comment as an opportunity to describe the manner in which PACE organizations currently provide prescription drug coverage and identify certain issues that we hope CMS will take into consideration with regard to applying additional Part D requirements to PACE organizations.

PACE organizations are comparatively small in size relative to other Medicare managed care providers. Moreover, our focus is on the direct provision of health care services, as opposed to operating a large health insuring entity. The largest of our 32 programs enrolls less than 2,000 enrollees; the average census at PACE programs nationwide is approximately 350. Primary medical care is generally provided directly by staff physicians who participate on an active interdisciplinary team (IDT) involving numerous additional professional and paraprofessional staff. PACE primary care physicians and other IDT members closely monitor the prescription drug use of all PACE enrollees and are well informed of the consequences of medication mismanagement on both patient outcomes and costs. If medical specialists, e.g. cardiologists, neurologists, etc., are involved in the delivery of care to PACE enrollees, they act primarily as consultants. In most cases, they make recommendations regarding prescription medications to the PACE primary care physician. The primary care physician then writes the prescription as requested by the medical specialist or, to the extent the prescription might interact with other medications the enrollee is on, etc., the primary care physician would contact the specialist to coordinate care.

In the vast majority of cases, prescriptions are written by the PACE primary care physicians. In this regard, we anticipate that many PACE organizations would not consider it advantageous or necessary to create e-prescribing capacity as a means of improving patient care. Consequently, the NPA would like to confirm that e-prescribing will not be mandated in the future. Further, to the limited extent that prescriptions may be written by contract physicians, we ask that CMS consider the impact of additional information systems requirements on PACE organizations, taking into account their size and overall approach to care coordination and service delivery. The implementation of Part D is already generating substantial additional administrative costs for PACE organizations – we are extremely concerned that additional requirements may make implementation of PACE prohibitively costly for prospective providers.

I would be pleased to discuss NPA's comment with you in more detail or respond to any questions you may have. I can be reached at (703) 535-1567 or shawnb@npaonline.org. Thank you.

Sincerely,

Shawn M. Bloom
President and CEO

CMS-0011-P-7 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Judith Cahill **Date & Time:** 04/01/2005

Organization : Academy of Managed Care Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issues

Background

See attachment

Collection of Information Requirements

no comment

Provisions of the Proposed Regulation

See attachment

Regulatory Impact Analysis

no comment

CMS-0011-P-7-Attach-1.DOC

CMS-0011-P-7-Attach-1.DOC

CMS-0011-P-7-Attach-1.DOC

CMS-0011-P-7-Attach-1.DOC

CMS-0011-P-7-Attach-1.DOC

AMCP Academy of Managed Care Pharmacy

April 1, 2005

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

Delivered electronically to: [http://www.cms.hhs.gov/regulations/ecomments]

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

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Centers for Medicare & Medicaid Services (CMS) on its proposed rule for E-Prescribing and the Medicare Prescription Drug Program.

AMCP is a national professional association of pharmacists who have responsibility for managing prescription benefits in the private sector for health plans and pharmacy benefit management companies. Our 4,800 members provide comprehensive services to the over 200 million Americans served by managed care organizations. They are responsible for a broad and diversified range of clinical, quality-oriented services, programs and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

Electronic prescribing is a tool that should be of great benefit to prescribers, dispensers and patients. The process improvements that e-prescribing will foster include:

- Patient Safety - drug utilization review and drug interaction checking at the time of prescription ordering rather than at prescription dispensing
- Quality of Care - reduction in medication errors, clinical decision support information for prescribers
- Efficiency - reduction in number of phone calls for prescribers, pharmacists and payors

The Medicare Modernization Act (MMA) establishes an e-prescribing program to be used for Medicare beneficiaries. The private sector should be encouraged to follow its lead when establishing its own e-prescribing programs.

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Suite 400
Alexandria, VA 22314
P: 703.683.8416

Proper implementation of an e-prescribing program will require a set of standards to ensure ease of use among all stakeholders. To fully implement the e-prescribing program, the set of standards must support the entire electronic prescribing industry, not just Medicare. The endorsing of one set of standards for all e-prescribing programs has many benefits, including:

- Ensuring consistency - all prescription information will be transmitted in the same manner regardless of the e-prescribing program
- Providing efficiency - programs will only need to adhere to one set of standards, and will not be required to use a different set for each program.

This consistency and efficiency will allow easier and more rapid implementation of e-prescribing programs.

The Academy is pleased to provide comments on the following specific areas of the proposed rule:

Background

The comments that follow address specific issues found in the "Background" section of the preamble to the proposed rule.

Definition of Electronic Media

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines electronic media to include both electronic storage media and transmission media, including the internet, extranet, dial-up lines, private networks and the physical movement of removable/transportable electronic storage media. CMS has asked for comments on:

- When to apply this definition to determine when prescribers and dispensers are electronically transmitting prescription information
- When should prescribers and dispensers be required to comply with the e-prescribing standards
- Whether the HIPAA definition is broad enough to embrace new technologies as they are developed

The Academy believes that the HIPAA definition adequately describes all current electronic media, and CMS should use it as the basis for the e-prescribing standards. It follows that programs that electronically transmit prescription information that meet the above criteria should be subject to and comply with the e-prescribing standards set by CMS.

Finally, the definition delineated in HIPAA appears to be broad enough in its scope to encompass possible advances in technology for the foreseeable future. The Academy believes that the definition does not require modifications at this time.

Adequate Industry Experience with Proposed Standards

Under the Medicare Modernization Act (MMA), pilot testing of proposed standards for electronic prescribing is required if adequate industry experience with the standard is lacking.

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The National Committee for Vital and Health Statistics (NCVHS) held hearings with various groups of constituencies on e-prescribing standards while identifying and examining standards for possible adoption. CMS staff attended those hearings and concluded that there is adequate industry experience for the standards proposed in the rule, but is seeking additional input on this issue.

The Academy agrees with the CMS determination that the standards proposed in this rule are based on adequate industry experience. Further, the Academy wishes to emphasize the importance of the adoption of one standard for each type of transaction. As stated above, the adoption of one set of standards ensures consistency, improves efficiency and may lead to a more widespread adoption of e-prescribing programs in both the public and private sector.

State Law Preemption

According to the 2003-2004 Survey of Pharmacy Law[1] thirty-eight states allow for the electronic transmission of prescriptions. However, the scope and substance of state legislation varies widely. The MMA addresses preemption of state laws such that federal law would supercede any state law or regulation that is contrary to the standards or restricts the ability of the electronic transmission of medication history and information on eligibility, benefits and prescriptions with respect to Medicare Part D. CMS has proposed to interpret that section of the Act as preempting state law provisions that conflict with federal electronic prescription program drug requirements that are adopted under Part D. CMS views the statute as mandating federal preemption of state laws that are either contrary to the federal standards or that restrict the ability to carry out the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or pertain to Part D enrolled individuals. CMS has asked for comments on the interpretation of the scope of preemption, and whether it 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.

Using strict adherence to the rules of grammar, the more narrow interpretation of the statute language endorsed by CMS appears to be appropriate. This means that the preemption of state regulations applies only to transactions and entities that are part of an electronic prescription drug program under Medicare Part D. However, the Academy believes that preemption of all state laws that would otherwise prohibit or fail to permit electronic prescribing and electronic transfer of prescription information must occur to promote successful implementation and uptake of e-prescribing in both the Medicare and commercial prescription drug programs.

Approach to Adoption of Standards, "Adequate Industry Experience"

CMS has proposed to adopt foundation standards for electronic prescribing. Their definition of foundation standards is "standards that do not need to be pilot tested because adequate industry experience with those standards already exists." CMS is soliciting comments on the criteria that will be used to assess "adequate industry experience." The criteria are based on testimony presented to the NCVHS and include:

- The standard is American National Standards Institute (ANSI) accredited

[1] National Association of Boards of Pharmacy Survey of Pharmacy Law, ©2003 NABP, Park Ridge, IL

- 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, and
- The standard is recognized by key industry stakeholders as the industry standard

The NCVHS Subcommittee on Standards & Security has done extensive work in researching electronic prescribing, and that committee followed similar guidelines in making its recommendations for foundation standards. The Academy believes that the criteria proposed by CMS, which are based on those NCVHS guidelines, can appropriately be used to determine whether "adequate industry experience" exists for proposed electronic prescribing standards.

The National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1; NCPDP Telecommunications Standard Implementation Guide, Version 5, Release 1; and the Accredited Standards Committee (ASC) X12N 270/271 Eligibility Benefit Inquiry and Response, Version 4010 are the foundation standards that CMS has proposed for adoption. Although the standards proposed in this regulation are important foundation standards, they do not represent the full set of standards that will be necessary to implement an electronic prescription drug program effectively. CMS must ensure that NCVHS continues to research additional standards and identify those that will be required to fully implement the e-prescribing program.

Provider Identifiers

Although the MMA does not require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions, CMS is considering requiring the use of the National Provider Identifier (NPI) as the provider identifier for an electronic prescription program under Medicare Part D. The NPI is the preferred option because it is the standard that will be required under HIPAA. The effective date for the NPI is May 23, 2005, which marks the beginning of the implementation period. The NPI must be used in all standard transactions no later than May 23, 2007. NCVHS has recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and that the NCPDP HCIdea® for identifying prescribers in the event that insufficient numbers of providers have been enumerated when the Medicare Part D electronic prescription drug program becomes effective. It is unknown how many providers will have had an NPI enumerated by January 1, 2006, approximately 7 months into its implementation period. CMS is inviting comments on the possible use of the NPI for e-prescribing transactions; the earliest time when the NPI should be required for use, and alternatives to the NPI, particularly in the short term.

The Academy recommends that the NPI become the mandatory provider identifier for the Part D e-prescribing program upon its effective date of May 23, 2007. Until the mandatory implementation of the NPI, it should remain an optional identifier, and the use of supplemental identifiers will be necessary. Other provider identifiers that may be used until such time as the NPI is mandatory include:

- The NCPDP Provider Identifier Number
  This identifier is nearly universally accepted for retail prescription drug claim

transactions in the United States and may used to determine the dispensing pharmacy. Note: This identifier can only indicate the dispensing pharmacy and not the pharmacist who dispensed the medication. Pharmacists may apply for an NPI, and the NPI could be used to pinpoint the dispensing pharmacist.

- The Medicare provider number
  This identifier has broad acceptance, and could be used to determine prescribers. However, providers who do not participate in the Medicare program are not assigned a number, and could not be identified.
- HCIdea®
  This proprietary database of health care providers is an initiative of the National Council for Prescription Drug Programs (NCPDP). It is gaining acceptance as a prescriber identifier for use in retail pharmacy claims transactions, and includes both the NPI and Medicare provider number as elements within the prescriber record. According to testimony presented on August 17, 2004, by NCPDP to the NCVHS Subcommittee on Standards and Security, NCPDP estimates that the HCIdea® database currently contains 1.2 million records, or in excess of 86% of prescribers.[2]

Formulary and Medication History Standards

Adoption of standards for formulary representation and medication history would clearly enhance e-prescribing capabilities. Such standards would make it possible for the prescriber to obtain information on the patient's benefits as well as information on medications the patient is already taking. CMS is considering adopting an NCPDP standard for formulary and medication history based on the RxHub protocol.

A formulary is a continually updated list of medications which represent the current clinical judgment of physicians and other experts in the diagnosis and treatment of disease and preservation of health.[3] Prescription drug programs employ a Pharmacy and Therapeutics (P&T) Committees when making decisions about what drugs are to be included in their formularies. The P&T Committee regularly reviews a plan's formulary and ensures that the medications listed are appropriate to cover the medical needs of the plan's membership. Each plan tailors its formulary to meet the needs of its own population. The Academy believes that in considering standards for formulary and medication history that CMS adopt a standardized format for transmission of formulary information and not standardization of formulary content. Plans would then be able to provide the necessary information about their formulary in a uniform manner, but would retain the ability to make their own decisions about which drugs should be included for coverage.

Provisions

The comments that follow address specific issues found in the "Provisions" section of the preamble to the proposed rule.

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[2]Lee Ann Stember and Phillip D. Scott, NCPDP testimony to NCVHS Subcommittee on Standards and Security, August 17, 2004.

[3] AMCP's Concepts in Managed Care Pharmacy: A Series; Formulary Management. ©1998, AMCP, Alexandria, VA

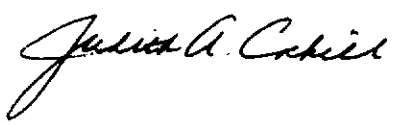
Should Plans be Required to use the Standards for E-prescribing Transactions within the Enterprise

The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with the electronic drug program standards once final standards are effective. Many closed networks currently conduct e-prescribing within the confines of their enterprise. They typically use Health Level 7 (HL7) messaging within a hospital or for a prescription transmitted to the organization's own pharmacy. NCVHS has recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards. The NCVHS recommendation differs from the HIPAA transaction requirements. The HIPAA Transactions Rule states that a covered entity that conducts a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard transaction.

This issue has been raised because of the numerous systems using several different transmission protocols in existence today. HL7 messaging is generally accepted within the hospital setting and some integrated health systems. Although the use of HL7 within the same enterprise is not HIPAA compliant, it does not appear that requiring these organizations to adopt new standards internally would be beneficial to promote electronic prescribing. The expense, both in dollars and time required, of acquiring and installing new compliant systems and training staff to operate them would be counterproductive and could delay implementation of the e-prescribing program indefinitely. As technology improves, and these legacy systems are replaced, CMS should require that any new or replacement system is compliant with the HIPAA transaction requirements.

AMCP appreciates this opportunity to submit these comments to CMS regarding the Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. If you have any questions about our comments, or require additional information, please do not hesitate to contact me at (703) 683-8416 or jcahill@amcp.org.

Sincerely,



Judith A. Cahill, C.E.B.S.
Executive Director

Submitter : Mrs. Kristen Cusick **Date:** 04/01/2005

Organization : Quest Diagnostics Incorporated

Category : Laboratory Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-8-Attach-1.DOC

Quest Diagnostics Incorporated
815 Connecticut Avenue, NW
Suite 330
Washington, DC 20006
202.263.6260
202.728.0338 FAX

April 1, 2005

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

Re: 70 Federal Register Page 6256ff. [Feb. 4, 2005]
"Medicare Program; Prescribing and the Prescription Drug Program; Proposed Rule"

File Code CMS-0011-P

Ladies and Gentlemen:

Quest Diagnostics, the nation's leading provider of diagnostic testing, information and services, and MedPlus, Inc. a subsidiary, appreciate the opportunity to respond to the Agency's NPRM Adopting Standards for an Electronic Prescription Drug Program. Attached are our comments and an executive summary is below.

Executive Summary:

- We support CMS' proposal to adopt foundation standards as final standards, but we have concerns about the ability of providers to conform to future standards without major regulatory changes.
- We recommend CMS adopt both the NPI and a unique patient identifier to avoid errors and mismatches of patient data.
- We support the preemption of all State laws affecting e prescribing to ensure unfettered interoperability.
- We believe that CMS, as authorized by changes in law if necessary, should broaden the proposed anti-kickback safe harbor and Stark exception to allow for free and fair competition and to facilitate the adoption of the e-prescribing standards.
- Finally, we believe that the NCPDP should be the arbiter of which versions of the e-prescribing standards are considered "current," which versions are considered "compatible" with the current version, and which versions should continue to be supported by "certified" vendors.

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed standards and future standards for e prescribing. Please do not hesitate to contact us should you have any questions about this information or need any further information. I can be reached at 202-263-6263 or Kristen.m.Cusick@questdiagnostics.com.

Sincerely,

Kristen Cusick
Director, Government Affairs

Attachment

Comments of Quest Diagnostics Incorporated
on the Proposed Rule Adopting Standards for an Electronic Prescription Drug Program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

File Code: CMS-0011-P

Quest Diagnostics Incorporated ("Quest Diagnostics") is pleased to submit these comments on the proposed rule published in the Federal Register on February 4, 2005 regarding standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Quest Diagnostics is the nation's leading provider of diagnostic testing, information and services. Quest Diagnostics offers the broadest access to diagnostic testing services through its network of more than thirty full-service laboratories in major metropolitan markets across the United States and in Mexico and the United Kingdom. Quest Diagnostics utilizes health information technology to provide insights that enable physicians, hospitals, managed care organizations and other healthcare professionals to make decisions to improve health. MedPlus, Inc., a subsidiary of Quest Diagnostics, offers an electronic prescription service to healthcare professional across the United States and would be affected by this proposed rule.

I. Background

A. Statutory Basis

1. *The scope of the proposed rule, as a practical matter, will be much broader than prescription drugs covered under the Medicare Part D program.* In the Statutory Basis section of the preamble to the proposed rule, CMS clarifies that the statute is applicable to covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically. The Medicare Prescription Drug Benefit final rule is similarly limited to requiring Prescription Drug Plan (PDP) and other Part D sponsors to support and comply with electronic prescribing standards for Part D eligible individuals. However, to be successful, standards for eprescribing and/or Electronic Health Records (EHRs) must be "interoperable" to a large extent. Therefore, in the interest of achieving the ultimate goal of interoperability in health care information data exchange, we support a broad interpretation of the statute, consistent with the aforementioned goal.

Implementation of these eprescribing standards will require the cooperation of numerous healthcare industry participants (including prescribers, payors, PBMs, vendors and pharmacies), as noted by CMS. For example, to access patient medical histories, inpatient and outpatient healthcare facilities must implement the standards. Cooperation will mean, among other things, that these participants become a source of important patient information (i.e., all such parties must share patient data for the program(s) to achieve its purpose of interoperability).

We believe the standards adopted pursuant to Title I of the MMA will have a much broader impact on the prescription industry (and the healthcare industry as a whole) than the "technical scope" set forth in the rule. The practical effect of these regulations is that all electronic prescription systems will have to meet these standards. As a practical matter, PBMs or prescribers are not likely to invest in or take the time to comply with two or more different systems with different standards, one for Part D prescriptions and one or more for others.

2. *The definition of electronic media should be defined to clearly include electronic facsimiles.* In the preamble to the proposed rule, CMS invited comment on whether it should apply the HIPAA definition of "electronic media" to these regulations. We agree that it should apply the HIPAA definition, but believe that CMS should clarify that the term "electronic media," for purposes of the proposed rule, includes prescriptions sent by "electronic facsimile" to a pharmacy. The majority of prescriptions originating from eprescribing applications today are delivered via "electronic facsimile," as opposed to paper facsimiles and electronic data interchange (EDI) transactions. In the interest of uniformity and to avoid inconsistency of treatment, electronic facsimiles should be subject to the same standards as other electronic prescription transmissions.

3. *The foundation standards should be accepted as final standards.* We agree that adequate industry experience exists with respect to the proposed foundation standards such that CMS may adopt the foundation standards as final standards without pilot testing. However, please see the Comment in Section I.F.2. below regarding the use of specific version and release numbers.

4. *The final regulations should include Federal preemption of all other laws or regulations.* As CMS notes, the scope and substance of State activity varies widely among the States. We agree with various commentators that many (if not most) existing State laws were drafted with paper or possibly paper facsimiles in mind and, in fact, contain barriers that could impede the success of standard eprescribing programs. In addition, although we do not see any immediate conflict with the proposed foundation standards, we are concerned that conflicts with State laws will develop as further standards are proposed and implemented. For example, some States set forth with specificity the information that must be included in a prescription, the manner in which the prescription may be sent to the pharmacy, and (depending on the type of drug) whether the prescription can be sent at all. At a minimum, these regulations should clarify that Part D prescriptions may be sent electronically, by facsimile or by data interface exchange regardless of State law to the contrary.

State laws that mandate standards inconsistent with the standards contemplated by these regulations will retard the development and use of uniform eprescribing systems.

5. *The Anti-kickback Statute Safe Harbor and Stark Exception should be broader.* We understand CMS' position that it can only work with the statute as drafted. Notwithstanding, we believe it is important to point out the issues created by the statutory language and the limited safe harbor and Stark exception mandated by the statute. First, the statute requires that the safe harbor and Stark exception be limited to non-monetary remuneration (hardware, software, information technology, etc.) used solely to receive and transmit electronic prescription information. Based on our experience, we believe that dedicating software and equipment solely to a single function – such as eprescribing - is an unlikely business scenario, a waste of resources, and will result in extensive compliance costs and monitoring with limited benefits. Further, we believe that the list of those eligible for the protection of the proposed safe harbor and Stark exception programs would be too limited. The statute provides for a safe harbor and Stark exception for hospitals, group practices and PDP sponsors or Medicare Advantage organizations under specified circumstances in order to encourage implementation of electronic prescribing. We see no reason not to similarly protect laboratory companies or other provider/vendors who have a strong interest in the promotion of health information technology and the resources to assist their customers in its adoption. Indeed, to permit one group of providers or payers to provide eprescribing hardware and software while precluding another group of providers from offering eprescribing software along with their other electronic products will put the latter group of providers at a competitive disadvantage compared to the protected hospitals, group practices, and PDP sponsors. For example, the MedPlus Care360 system already has an eprescribing system that is packaged with the laboratory ordering and resulting system, but which is electronically locked down unless the provider pays for the eprescribing component. The adoption of a broader safe harbor and anti-kickback exception than has been proposed in this NPRM would permit the eprescribing component to become immediately available to thousands of providers at no additional cost to the healthcare system.

B. The NCVHS Process

No comments.

C. Standards Design Criteria

No comments.

D Current Prescribing Environment

No comments.

E. Current E-Prescribing Environment

No Comments.

F. Evolution and Implementation of an Electronic Prescription Drug Program

1. *The criteria are acceptable.* We support CMS's proposal to follow the three criteria set forth: (i) that standards be ANSI accredited, (ii) that the standard generally has been implemented by entities to which the final standard will be applied, and (iii) that the standard is recognized by key industry stakeholders as the industry standard. We agree that the proposed foundation standards are simply a starting point and that many further standards will be necessary to implement an effective electronic prescription drug program.

2. *NCPDP, not CMS, should be the arbiter of what versions of standards are current and compatible.* CMS notes that the NCPDP standards may be enhanced or revised in the future. We agree and, taking that fact into account, believe that references in §423.160 (b) and (c) to a specific "version" and "release" number and date of release introduce a degree of inflexibility into the rule. In fact, CMS acknowledges this issue in the discussion in Section II.E.2 of the proposed rule. Given the likelihood of periodic new versions and/or releases, we do not believe that having to make periodic changes to federal regulations are a practical or wise solution (even through the incorporation by reference update approval process referenced in the proposed rule). We believe a better alternative would be to allow NCPDP to determine which future versions and releases of the standards are considered to be compatible with the "current" version and a reasonable migration period during which certified vendors must continue to support previous versions. If CMS believes (through its own accord or complaints from industry sources) that NCPDP is not applying the criteria set forth in the proposed rule such as ANSI accreditation and wide industry acceptance, it can always "step in" at that time and revise the standards accordingly. This will allow for more flexibility in the industry without the necessity of valuable CMS time and resources yet leave a mechanism in place to protect industry participants in the event NCPDP ceases to be widely accepted as an objective/neutral organization.

3. *We support the current process for standard setting.* We generally support the process that has been utilized by CMS in establishing these foundation standards and propose that the process be continued. That is, public hearings conducted by the NCVHS Subcommittee on Standards and Security should continue to meet and should consider input from a variety of affected stakeholders and constituency groups.

G. Electronic Prescription Drug Program

1. *We support the immediate adoption of the NPI and the unique patient identifier.* CMS invited public comments on the possible use of the NPI as the primary identifier for Medicare Part D transactions. We believe there is general consensus nationally that a national provider identification number/system is necessary and will certainly satisfy the needs of the eprescribing Part D Programs. In our opinion, the discussion and issue then becomes the timing and availability of the NPI for meaningful use. We strongly believe that whatever final decision is made with respect to the NPI, all regulations applicable must be clear and mandate use throughout the healthcare industry.

The proposed rule is silent on an identifier that is even more vital for an effective eprescribing program – the unique patient identifier. Recognizing that CMS proposed and subsequently withdrew this proposed rule, we simply would underscore the necessity for such a unique identifier so that patient records from diverse sources may be properly and flawlessly matched. The adoption and implementation of a unique patient identifier would enable medical records to be matched despite misspelled names, nicknames, initials instead of names, maiden or hyphenated names and changes in address or other demographics - fields that in the absence of a unique patient identifier will have to be used to match patient records both within a provider's own systems and externally.

2. *We support an NCPDP standard for formulary and medication history that is based on the RxHub protocol.* We believe that RxHub has the only currently viable technology to allow providers meaningful access to formulary, benefits and medication history.

3. *We support the characteristics of future standards, as described by CMS, but we are concerned about the ability of providers to comply.* We generally agree with the characteristics that CMS set forth for development of the additional future standards as described in this section. However, we are concerned about the ability of all parties affected by the future standards to comply with them. With respect to medication histories and medical histories in particular, however, there do not exist any regulatory paths by which qualified EHR vendors or providers in the industry can access the data maintained by other EHR vendors or provider systems. As indicated elsewhere in these Comments, electronic prescription programs (as well as EHRs) are heavily dependent upon obtaining patient information from a variety of sources. Without the ability to access the information maintained by these other sources, eprescribing systems and EHR programs will have limited utility. Lack of access to patient information could result in one or a few parties (e.g., health plans or PBMs) developing proprietary systems that are effectively forced upon prescribers and pharmacies. This could have a negative cost impact and competitive effect on the industry.

CMS should ensure that providers receive already-authenticated requests, since individual providers will not have the resources or ability to authenticate every request for records – particularly in "real time." Authentication is an activity that might be a function of the National Health Information Network or RHIOs, but we reserve judgment until a proposal is made upon which we may comment. Furthermore, providers should only be required to fulfill authorized requests that are compliant with the eprescribing standards and which are requests for a disclosure that is compliant with the HIPAA requirements (i.e., for a valid treatment, payment or health care operations purpose and not, for example, a blanket request for data or some other unauthorized request). We are concerned that providers will not have the resources or ability to determine, in "real time," whether each such request is for a valid purpose under HIPAA.

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

We generally support the strategy that CMS has proposed for "phasing in" the implementation of the electronic prescription drug program standards. We believe the

foundation standards will provide a solid starting point for the adoption of eprescribing systems and standards by the industry.

II. Provision of the Proposed Regulation

A. Proposed Change to Scope (Section 423.150)

No further comments beyond Section I.A.1 of these Comments.

B. Proposed Definitions

As noted above in Section I.A.2 of these Comments, we believe the HIPAA definition of "electronic media" should be accepted, but revised to clearly include prescriptions sent by "electronic facsimile" to the pharmacy.

C. Proposed Requirements for Part D Plans

As noted in Section I.A.1 of these Comments, if the objective of the eprescribing rule is interoperability, we believe the statute should be interpreted broadly, consistent with that objective. To the extent consistent with the statute(s), we believe that Part D Plans and other affected parties should be required to respond in a compliant way to compliant eprescribing transaction requests external to the enterprise. Within the enterprise, it should be sufficient if the goals of the eprescribing standards are met, though not necessarily through standard transactions that are purely internal.

D. Proposed Requirements for Prescribers and Dispensers

No comments.

E. Proposed Standards

1. Prescription

No comments.

2. Eligibility

We support the adoption of the ASC X12N 270/271 transaction standards.

F. Compliance Date

No comments.

In summary, we support CMS's proposed rule as described or clarified in these Comments.

- We support CMS' proposal to adopt the foundation standards as final standards, but we have concerns about the ability of providers to conform to future standards without major regulatory changes.

- We recommend CMS adopt both the NPI and a unique patient identifier to avoid errors and mismatches of patient data.
- We support the preemption of all State laws affecting eprescribing to ensure unfettered interoperability.
- We believe that CMS, as authorized by changes in law if necessary, should broaden the proposed anti-kickback safe harbor and Stark exception to allow for free and fair competition and to facilitate the adoption of the eprescribing standards.
- Finally, we believe that the NCPDP should be the arbiter of which versions of the eprescribing standards are considered "current," which versions are c onsidered "compatible" with the current version, and which versions should continue to be supported by "certified" vendors.

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed standards and future standards for eprescribing. Please do not hesitate to contact us should you have any questions about this information or need any further information.

Submitter : **Dr. Alan Reyes** **Date: 04/01/2005**

Organization : **Dr. Alan Reyes**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Sirs:
This bill is yet another unfunded mandate that unnecessarily increases the cost of providing care. Regulators look at requirements like these as if money is meaningless but to those of us trying to provide care with ever shrinking reimbursement,the cost of using yet another special computer service is impractical.Health care is being destroyed one costly mandate at a time, and this is a prime example of wasted care dollars that would go to fund anything and everything except actually caring for patients.

CMS-0011-P-10 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : **Ms. Mary Myslajek** **Date & Time:** **04/01/2005**

Organization : **Ms. Mary Myslajek**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment on this rule. Please contact me at 952-993-3063 if there are any questions.

Issues

Provisions of the Proposed Regulation

Re: CMS-0011-P G. Electronic Prescription Drug Program
+ Provider and Dispenser Identifiers (page 6262 -6263 Federal Register February 4, 2005)

The NPI (National Provider Identifier) should NOT be required on January 1, 2006. Any required use of the NPI should be no sooner than the required use of the NPI on other standard electronic transactions, namely May 23, 2007. Prior to that time legacy numbers should be permitted. Current Medicare provider numbers are available and should be used for the January 1, 2006 implementation of e-prescribing.

At this time, no NPI numbers have been issued. CMS has indicated that bulk enumeration of large segments of providers through associations or employers may not even be an option until late in 2005. Payers and providers in the health care industry confront significant cost and timing issues for the implementation of the NPI.

The focus of implementation timelines has been necessarily on the critical HIPAA transactions for claims, the 837P and 837I and remittance advices, the 835. Requiring the use of the NPI sooner on the e-prescribing transactions presents a hazard and burden for the industry. The hazard is that NPIs will not be readily available. The burden is that duplicate numbering systems will need to be maintained by providers and payers for certain transactions, thus not creating any simplification. Providers need to be able to obtain and implement NPIs in an orderly fashion rather than trying to move one type of transaction ahead of all others.

I urge you not to draw resources away from the methodical concurrent implementation of the NPI for all transactions.

CMS-0011-P-11 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : **Date & Time:** **04/04/2005**

Organization : **American Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0011-P-11-Attach-1.WPD

American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, VA 22314-3563
Phone: 703-739-1300
FAX: 703-739-1321
E-mail: info@ascp.com
www.ascp.com

April 4, 2005

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

The American Society of Consultant Pharmacists is pleased to offer comments on the proposed rule for electronic prescribing to be implemented as a part of the Medicare Part D program.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Consultant pharmacists specializing in senior care pharmacy practice are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illnesses. In their role as medication experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

ASCP's 6,500+ members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

I. Background

A. Statutory Basis

2. State Preemption

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, which will impact their willingness to participate in electronic prescribing.

The interpretation proposed in the NPRM creates a system whereby the prescriber and the electronic 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

These proposed rules also 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 and these state-specific regulations are even more unique for long-term care pharmacies and facilities.

D. Current Prescribing Environment

The current prescribing process environment outlined in the proposed rule focuses primarily on the ambulatory setting (e.g., community-dwelling beneficiaries, retail pharmacies and prescribers' offices). The Part D program is indeed an outpatient benefit, but residents residing in skilled nursing facilities and assisted living facilities are considered "outpatients," despite the location of their residence. Many of these residents, actually the majority, will qualify and receive Medicare Part D benefits. Residents in long-term care facilities are among the frailest elderly largely because of their numerous comorbidities. In 2000, a national survey of nursing facilities found that the average nursing facility resident took 8.1 routine medications, and 41.1% took nine or more routine medications. [1]

These long-term care settings have a different prescribing process involving more entities than the typical two parties (pharmacy and prescriber) seen in the ambulatory environment. In fact, there are at least three parties involved in the medication use process in nursing facilities and assisted living facilities:

- Nursing facility staff
- Dispensing pharmacy (or pharmacies)

3. Orders (prescriptions) are usually received in a verbal or faxed format.
4. The nurse enters this order into the resident's medical chart.
5. The nurse then faxes or phones in the prescriber's order to the dispensing pharmacy chosen by that facility/resident.
6. The dispensing pharmacist conducts a prospective medication review by examining potential drug allergy conflicts, drug-drug and other interactions, and other potential medication-related problems. The pharmacy fills the prescription using the NCPDP Telecommunication 5.1 Standard for claim submission. Messages received pertaining to third party coverage, such as formulary information or prior authorization, are considered by the pharmacy and communicated to the facility and prescriber by phone or fax for resolution. Documentation necessary to fulfill these coverage requirements is usually provided by the facility staff, since they have primary access to the resident's medical chart. Although, prescribers and pharmacy staff are also involved in the process.
7. The dispensing pharmacy delivers the medication to the facility where the nurse accepts and notates receipt of the medication. Nursing facilities are required by federal regulation to provide prescribed medications to residents in a "timely manner." Regulations located at Tag F-425 of the State Operations Manual from the Centers for Medicare and Medicaid Services states, "*A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.*"
8. Prescription renewal is documented by the physician when he/she signs each resident's current orders during the recapitulation process, usually occurring every 30 days. For medications warranting refills, this need is either communicated to the pharmacy by the facility or it is automatically refilled by the pharmacy based on the days supply of the dispensed medication.

E. Cu rrent E-Prescribing Environment

The current e-prescribing environment is virtually non-existent in the long-term care industry due to many of the same barriers outlined in the NPRM, including the costs of buying and installing a system, training involved, time and workflow impact, lack of reimbursement for costs and resources, and lack of knowledge about the benefits. However, the distinct difference in the long-term care setting is that all of these potential barriers apply not only to prescribers and pharmacies, but also the nursing facilities. To reiterate the current prescribing environment in long-term care, there are at least three parties involved rather than the two parties currently involved in the ambulatory setting,

While pharmacies rely heavily on computer technology and some are already capable of utilizing e-prescribing due to their use of NCPDP communication standards, many nursing facilities have yet to adopt technology on a large scale other than the one or two computers in their administrative and billing offices. Computer access at nurses' stations is quite limited. In fact, most long-term care facilities still utilize manual charting processes. Therefore, introducing e-prescribing into the long-term care setting will be a challenge. Nonetheless, the closed system created by the nursing facility and limited number of prescribers and pharmacies provides an atmosphere that would enable long-term care to be a leader in e-prescribing if the stated barriers are overcome.

NCPDP, at the request of industry participants, has created a new work group to address these special needs of the long-term care industry. NCPDP Work Group 14 for Long Term Care, in conjunction with the other NCPDP Work Groups, will:

- Guide and advise payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation,
- Support data processing initiatives, and
- Provide 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. Some of these unique needs include the following:

1. The billing offices of the pharmacy and nursing facility communicate residents' billing status to one another, which can change according to the level of care deemed necessary by a resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow coordination of benefits (COB). As outlined previously, there is an increased need for process adaptations and communication between health care professionals in long-term care to assure nursing facilities meet the required federal regulation to provide prescribed medications to nursing home residents in a "timely manner".
2. In the long-term care setting, prescribers and facility nurses often do not know a resident's pharmacy benefit eligibility and coverage, making prior authorization and formulary processes more difficult and time-consuming. The industry has relied on the long-term care pharmacy provider to obtain and provide this information. If this information were made available to prescribers and facility staff at the time of prescribing, much time would be saved by all parties.

3. Medical records for nursing facility residents are located at the nursing facility, not in the physician's office. This causes difficulty when resident information housed in the medical chart is needed by the prescriber or pharmacy. Currently, the information gathering process is often left up to the facility staff.

For these reasons, an electronic health record (EHR) is ultimately needed for e-prescribing to work most efficiently in the long-term care setting.

F. Evolution and Implementation of an Electronic Prescription Drug Program

As a participant of the National Council for Prescription Drug Programs (NCPDP), ASCP appreciates CMS acknowledging NCPDP SCRIPT Standard Version 5.0 as a minimum standard for electronic prescribing programs. It is important to reiterate that this standard is a minimum or a "floor" from which to grow in the future. By naming this standard as the minimum, industry is provided a "floor" that it can support in a timely manner. We feel that this will ensure adoption of electronic prescribing without stifling industry movement to future versions, as business needs arise.

ASCP is in agreement with an NCPDP proposal whereby newer versions are adopted and older versions are retired to allow maximum flexibility for the industry as it upgrades systems. It is important not to negatively impact the long-term care setting by naming an e-prescribing version that the industry is not able to support.

It is expected that long-term care participants of the NCPDP Work Group 14 will be bringing recommendations specific to long-term care to NCPDP for the development of future electronic prescribing standards.

G. Electronic Prescription Drug Program
- **Formulary and Medication History Standards**

As stated above, currently the billing offices of the pharmacy and nursing facility communicate billing status to one another, which can change according to the level of care deemed necessary by the resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow COB and the timely delivery of medications to facility residents. To our knowledge, no current formulary and benefit data standards accommodate these specific needs.

- **Drug Information**

Research suggests that significant inconsistencies exist in the creation of drug information databases utilized in health care software. In addition, the assignment of clinical significance to drug interactions and other drug information is critical to the acceptance and accurate utilization of such facts by health professionals.

In response to the overwhelming number of complaints and errors associated with the multitude of drug information messages in software programs, the United States Pharmacopeia Therapeutic Decisions Making (DTM) Expert Committee formulated a methodology to establish a hierarchy of evidence that defines drug-drug interactions and decides what types of evidence to consider with regard to such interactions. USP and other pharmacy associations have been working with a contracted research team to apply and assess this evidence methodology. In addition, the USP Convention recently passed a resolution pertaining to this issue:

"Evidence-Based Methodologies and Algorithms for Decision Support Used in E-Prescribing and Pharmacy Computer Systems" – USP resolves to work with appropriate stakeholders to continue developing evidence-based methodologies and algorithms for decision support in areas such as drug-drug interactions, and to expand efforts to other alerts and recommendations for use in e-prescribing technologies and pharmacy computer systems. Furthermore, USP resolves to explore the feasibility and advisability of extending this approach to other information domains in the interest of the public health and patient care."

For these reasons, we recommend that any drug information standards developed as a part of the Medicare Part D electronic prescribing program include mandates for evaluating the evidence base, clinical significance, and accuracy of such information. As learned from past experience, an overload of information to providers does not always result in the provision of efficient and effective health care.

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

For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. Including long-term care providers in these pilot projects will help to

identify and define the industry's unique needs and work to promote adoption of electronic prescribing in this setting.

II. Provisions of the Proposed Regulation
B. Proposed Definitions

As mentioned previously, effective electronic prescribing in the long-term care setting must include communication with the nursing facilities where beneficiaries reside. For this reason, we recommend amending the definition of "E-prescribing" to state:

> E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, *nursing facility*, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.

E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information. This definition involves electronic transmission through mechanisms such as the Internet, Extranet, leased lines, dialup lines, private networks, and physical movement of data from one location to another. However, messages that leave or enter a 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. Therefore, we recommend inclusion of a definition for "Non-EDI Messages" to read as follows:

> Non-EDI message means a message that leaves or enters a system (including long-term care facilities and/or pharmacies) as an image, either via fax or email, that are not included in the electronic prescribing standards. This does NOT include handwritten prescriptions that are faxed, but does include legal, electronic prescriptions/orders that are formatted to be electronically received by a fax machine. Due to the nature of such an electronic prescription/order, the prescriber's express authorization and credentials have already been validated and documented prior to transmittal.

IV. Regulatory Impact Analysis
A. Overall Impact

In the March 9, 2005 issue of the *Journal of the American Medical Association*, three articles explored the challenges and benefits of computerized physician order entry (CPOE) systems and clinical decision support systems. It can be easily assumed that these study results will compare with the potential

challenges and benefits resulting from electronic prescribing as envisioned by the Medicare Modernization Act. Researchers found, when widely implemented, a CPOE system "facilitated 22 types of medication error risks." Examples of these errors included:

- Fragmented CPOE displays that prevent a coherent view of patients' medications
- Pharmacy inventory displays mistaken for dosage guidelines
- Ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system
- Separation of functions that facilitate double dosing and incompatible orders
- Inflexible ordering formats generating wrong orders

Researchers found that 75% of staff reported observing each of these error risks, indicating that they occur weekly or more often.

Based on this evidence-based information, it is reasonable to assume that electronic prescribing will cause or potentate new errors while reducing "traditional" medication errors (e.g., those resulting from poor handwriting). These new types of errors will need to be expected and proactively prevented, to the extent possible. It is important to ensure those participating in electronic prescribing programs are aware of the patient safety benefits of such technology while remembering to watch out for new errors that might come forth.

B. Impact on Health Plans/PBMs

The NPRM proposes that "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." To reduce potential confusion, it is important to differentiate health plans from PDPs. Consequences of medication-related problems (e.g., adverse events) resulting in physicians' visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient's medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients' compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term "health plan."

C. Impact on Prescribers

If e-prescribing in the long-term care setting is inconsistent with e-prescribing processes in the community, this could add an unnecessary strain to a

prescribers' practices if they serve both ambulatory and nursing home patients. Prescribers who adopt e-prescribing in their community practice may choose not to work in the long-term care setting unless a similar process is utilized in the nursing facility. It is already difficult for some rural nursing facilities to attract or keep prescribers who are willing to provide services to their residents due to time constraints, liability issues, regulatory requirements, and lack of reimbursement. Compounding these existing issues with e-prescribing inconsistencies could potentially impact the willingness of prescribers to practice in the long-term care setting.

F. Impact on others

The overall impact of electronic prescribing on long-term care nursing facilities and the pharmacies and prescribers serving those nursing facilities is not addressed in the NPRM.

- In the long-term care setting, there is a need to develop technology for a three-way communication between off-site prescribers, long-term care provider pharmacies, and nursing facilities.
- The long-term care setting requires a more complex process utilizing a three-way communication for an e-prescribing model to be successful. For this reason, PDPs, long-term care pharmacies, prescribers, and nursing facilities may incur additional costs beyond those incurred in the ambulatory setting.
- In the nursing facility, there needs to be incentives for the training of nursing staff, which frequently turn over, and the purchase of computers. Most nursing facilities currently have very few computer workstations and still use a manual charting process.
- As discussed previously in the "Impact on Prescribers" section, prescribers who serve both ambulatory and nursing facility patients might be unduly strained if the long-term care setting is excluded from a standardized e-prescribing process.

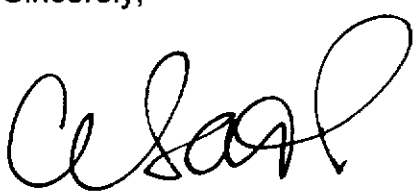
I. Conclusion and Alternatives Considered

In this document, we have identified reasons why the long-term care setting differs from the ambulatory or community setting. For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. We request that CMS prioritize the need for information pertaining to the long-term care industry information as it pertains to electronic prescribing and consider pilot project

proposals from long-term care providers. This will enable identification and definition of the unique needs in this setting. ASCP would be pleased to offer assistance throughout the pilot phase and to provide additional information, as needed, regarding the impact of electronic prescribing in the long-term care setting.

Thank you for your consideration of our comments and suggestions. If you have questions or concerns, you may contact Carla Saxton, Professional Affairs Manager, at the following email address: csaxton@ascp.com, or phone number: (703) 739-1316 ext. 129.

Sincerely,



Carla Saxton, RPh, CGP
Professional Affairs Manager
American Society of Consultant Pharmacists

CMS-0011-P-12 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Mr. James Schuping **Date & Time:** 04/04/2005

Organization : WEDI

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

(See Attachment)

CMS-0011-P-12-Attach-1.DOC

WEDI Comments to E-Prescribing NPRM

April 4, 2005

Workgroup for
Electronic Data Interchange

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

Re: E-Prescribing and the Prescription Drug Program NPRM

The following represent the comments of the Workgroup on Electronic Data Interchange (WEDI) for the Notice of Proposed Rule Making (NPRM) on the Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. This proposed rule is referred to in the Federal Register as 42CFR Part 423.

Following publication in the Federal Register of February 04, 2005, the NPRM was posted to the WEDI web site. Subsequently, WEDI created an E-prescribing Workgroup tasked with the responsibility of formulating a WEDI response to the NPRM. Recommendations created by this workgroup were vetted during an audio cast forum titled the E-prescribing Policy Advisory Group (PAG). The PAG conference call was held on March 15, 2005.

These recommendations, along with comments to the proposed rule received during the PAG call, were presented to WEDI's Board of Directors on March 24, 2005 for their review and adoption as official WEDI recommendations. The following comments are the result of the WEDI Board's deliberations and represent WEDI's official positions on these issues. WEDI believes that the comments set forth in this letter represent the views of a broad coalition in the health care industry and we respectively request CMS to carefully consider these suggestions and recommendations to the proposed rule on E-Prescribing.

Very truly yours,

Mark McLaughlin
Regulatory Policy Analyst
McKesson
Chair, WEDI Board of Directors

Workgroup for
Electronic Data Interchange

Recommendations from WEDI Board of Directors

Medicare E-Prescribing and the Prescription Drug Program CMS-0011-P NPRM (42-CFR Part 423)

This document contains recommendations from the WEDI Board of Directors on the Medicare E-Prescribing and Prescription Drug Program Notice of Proposed Rulemaking.

E-Prescribing NPRM. The Centers for Medicare and Medicaid published a Notice of Proposed Rule Making (NPRM) that proposes regulations on electronic prescribing of drugs and prescription information for participants in the Medicare Part-D Drug Program. *'E-Prescribing'* is given a specific definition in the NPRM. Copies of the NPRM may be obtained at http://www.cms.hhs.gov/medicarereform/. Select **Medicare Part D Electronic-Prescribing Proposed Rule (PDF, 184 KB or Text)** NEW.

Note on organization and format. These notes are divided into two sections: (1) Primary Issues and (2) Additional Issues. Within each section, the notes are in the same sequence as the NPRM, using the same topic numbers and headings. Unnumbered headings are only for the convenience of the reader and are not found in the NPRM. Yellow text boxes are quotations from the NPRM.

SECTION 1: PRIMARY DISCUSSION ISSUES

I. Background

A. Statutory Basis

Topic 1

2. State Preemption

> We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well. (F.R. page 6259)

WEDI Recommendation:

WEDI believes that federal preemption should be taken to a broader level than just Medicare Part D and should apply to paper as well as electronic prescriptions.

WEDI further believes that discrepancies in state board of pharmacy rules and regulations are a significant barrier to electronic prescribing and insert unnecessary costs into already thin margins.

Retail pharmacies must rely on electronic switch vendors, who have to assign high-level staff members to educate, petition, and obtain clarification and as well as lobby state boards of pharmacy (BOP) in certain circumstances, at considerable and unnecessary cost to the industry. (In its testimony in December 2004, the National Association of Boards of Pharmacy testified that all 50 states permitted electronic prescribing yet in its February 2005 Newsletter, SureScripts said that just 37 states were "good to go.")

Mail service and specialty pharmacies, as well as pharmacy benefit managers, must aggregate and reconcile different state rules, and ensure compliance with the specific rules applicable in the state in which the pharmacy filling each prescription operates.

Physicians rely on their software vendors, who must monitor board of pharmacy rules and modify their software systems to comply with them. The cost of a 50-state legal review, monitoring and software modification is absorbed by either the software company, or pushed back to physicians in the form of higher software costs.

Therefore:

- WEDI recommends Federal preemption of contrary state board of pharmacy (BOP) rules and regulations relative to electronic and paper prescriptions so that paper and electronic rules are complementary and synergistic.

- WEDI recommends that Federal preemption apply to all Medicare electronic and paper prescriptions, not just those covered under Medicare Part D.

    - WEDI recommends that Federal preemption have the same strong safeguards achieved by the states. In his December 8, 2004 testimony to NCVHS, the National Association for Boards of Pharmacy's Executive Director, Carmen Catizone, PharmD, said "NABP and the states are not opposed to federal pre-emption, but you have to make sure things occur with pre-emption. You have to look at why the states have certain requirements in place. ... If you go with a very broad federal pre-emption that eliminates all the states' safeguards, what we would ask is that you put in place very stringent safeguards that mimic the states." WEDI agrees with Dr. Catizone.

- WEDI recommends that HHS review all 50 states BOP rules and regulations and determine a set of rules and regulations that will mimic the states' safeguards then consistently apply them to all states. Furthermore, keeping up with changing technology is a challenge for the states. WEDI believes modifications to BOP rules and regulations would be handled more efficiently at a

federal level. However, WEDI is concerned that Federal preemption that will reconcile BOP rules of the 50 states is highly complex and will take considerable time; therefore, WEDI recommends that the deadline for implementation of this aspect be in 2009. WEDI recognizes that this recommendation is out of scope for the NPRM. WEDI will draft a separate communication to HHS about this issue

Topic 2

F. Evolution and Implementation of an Electronic Prescription Drug Program

Process for evolution of standards:

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. (F.R. page 6261)

WEDI Recommendation:

WEDI recommends that a true private sector approach through ANSI accredited SDOs for standards development for e-prescribing is needed, with the federal government participating 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 what has been experienced with the HIPAA administrative transactions standards.

In addition, WEDI 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. Further, a responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain the vocabularies. WEDI does not believe that it is necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

G. Electronic Prescription Drug Program

Topic 3

Versioning of standards

Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at §162.1101 through §162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. (F.R. 6261)

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. (F.R. page 6267)

WEDI Recommendation:

WEDI recommends that (i) HHS adopt minimal version levels of the standards, (ii) HHS depend on existing SDO enhancement processes for newer versions, and (iii) health care organizations be permitted to use newer versions provided there is backward compatibility. WEDI recommends NCVHS hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such change to HHS. If NCVHS considers the change to be substantive, as described in Federal Register Page 6267 above, HHS would issue a NPRM within 90 days. If the change is not substantive, it would waive notice and comment.

WEDI is concerned about any possible divergence between HIPAA standard transactions and the same transactions, such as the 270/271 eligibility inquiry, that are employed in this NPRM. WEDI 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. WEDI also recommends consideration of implementation phases rather than requiring all transactions by a single date. Consideration should be given to adequate piloting and testing.

Topic 4

Use of National Provider Identifier

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.

(F.R. 6263)

WEDI Recommendation:

WEDI believes standard identifiers are extremely important for these transactions. It makes the following recommendations:

- WEDI recommends that the NPI be the primary identifier for prescribers and dispensers.
- WEDI recommends that current identifiers be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access, are available.

- WEDI recommends that the required date for use of NPI in transactions in this NPRM must not be sooner than the required date for use of NPI in HIPAA transactions. WEDI is concerned that there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before NPI can be mandated. The NPRM date of January 2006 is unattainable because of non-availability of these NPI system capabilities. The NPI should not be required until the May 2007 deadline.

- WEDI is also concerned that legacy identifiers had capability for transaction routing that may not be provided by NPI or other data elements in standard transactions. This problem must be researched and resolved. Most likely the solution is will be with data in the transactions and thus no change to NPI rules.

Topic 5

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:...
>
> (F.R. 6263)

WEDI Recommendation:

WEDI recommends that the formulary benefit and medication history messaging standards currently being developed should go through rigorous pilot testing prior to the release of a final rule by HHS.. Vendors should be factored into the regulations and encouraged to bring products to market that can assist physicians in complying with the statutory requirements prior to compliance dates. Because pharmacies and pharmacy benefit managers must have their systems operational in order to allow physicians to send test prescriptions that comply with new standards, the final regulations should provide for staggered implementation dates. Most physicians must rely on their vendors to provide them with the tools necessary to comply with the electronic prescribing program. Strong government leadership is critical to rapid and seamless conversion.

WEDI urges HHS to make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. 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 an extremely difficult task of trying to resolve inter-governmental differences from across the Federal government in the Addendum to the Electronic Transactions and Code Sets rule. The additional time it took to resolve those differences left inadequate time for the various vendors to work with their customers (the provider and payer communities) 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.

Topic 6

Medication history standards[1]

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 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. (F.R. 6263)

WEDI Recommendation:
As similarly described in "*Process for evolution of standards*" above, WEDI recommends private sector development and maintenance of standards and that modifications and enhancements to standards not be hindered by extensive rule making processes.

WEDI is 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 privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in

[1] Medication History transactions involve all entities in the healthcare arena (prescribers, pharmacies, payers, RHIOs, etc) and the patient.

responses to requests for a listing of a patient's drugs, or his or her medical history within a certain timeframe, are likely to be highly complex. WEDI recommends that the framework of the requisite controls be designed and explained.

WEDI is concerned that the current models for retrieving prescription and medical history is still underdevelopment and incomplete. For example, patients often utilize multiple pharmacies which makes the patient's full 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 rather to rule out a diagnosis, and a record of the outcome is not recorded.

II. Provisions of the Proposed Regulation

E. Proposed Standards

2. Eligibility

Topic 7

> 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[2]. ... (F.R. Page 6266)

WEDI Recommendation:

- **Adopt ASC X12N 270/271 where Appropriate**. For eligibility inquiry and response, the HIPAA Transactions and Code Sets rule adopts the NCPDP Telecommunication Standard for pharmacy inquiry and the ASC X12N 270/271 for physician and other provider inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

[2] A clarification: Although the NCPDP Telecommunication Standard is EDI and was named in HIPAA, it is not based on EDI for EDIFACT and ASC standards.

- **Plans should be encouraged to respond with more than "yes" or "no".** WEDI and the Council for Affordable Quality Healthcare (CAQH) are working together to improve the quality of the 271 eligibility response from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. In the current HIPAA 270/271 eligibility transaction a health plan may either give detailed benefit information or simply give a "Yes, this person has coverage", or "No, this person does not have coverage". Physicians need more detail than yes/no and they need the information in a more consistent manner. At a minimum, plans should respond whether the patient is covered and provide 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. WEDI recommends that E-prescribing standards support the findings of the WEDI/CAQH project.

  The goal of the WEDI/CAQH project is to encourage all health plans to respond to eligibility questions based on business rules established by the industry that are agreed to by health plans in concert with other key stakeholders, such as, healthcare providers, vendors, and X12. While this effort is just beginning planning has been in process and CAQH initiated the process in January.

- **Adopt NCPDP Implementation Guide for Standard Card.** In 1997 NCPDP adopted an Implementation Guide based on the INCITS 284 standard for a health care identification card for prescription drug plans. The NCPDP Implementation Guide complies with regulations mandated in more than two dozen states. INCITS 284, revised for NCPDP in 2004-2005, is designed to support health care identification for any type of health plan. To avoid conflicting card standards, WEDI recommends that HHS adopt the NCPDP Implementation Guide as the standard for the Medicare Part D Pharmacy ID Card Standard.

IV. Regulatory Impact Analysis

Topic 8

We invite public comment on our expectations for prescriber participation. (F.R. Page 6268)

WEDI Recommendation:

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 2006-2012 with a slightly lesser cut in 2013. Concurrent with these cuts, the costs of 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% less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to assist in the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment WEDI believes it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless this technology provides an irrefutable, tangible benefit both to their patients and their practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of electronic prescribing's promise of improved efficiency, patient safety and health care quality.

WEDI believes that e-prescribing offers significant financial and other benefit potential to providers. But that case may not appear compelling to many providers in the healthcare financial environment between now and 2014. WEDI recommends that CMS fund development of analysis and educational documentation which will ease the financial case for providers.

SECTION 2: ADDITIONAL ISSUES

I. Background

Topic 9

A. Statutory Basis

> In the context of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and code sets (TCS) requirements, a covered entity that conducts a covered transaction using electronic media must comply with the applicable transaction standard. Electronic media is defined under HIPAA to include both electronic storage media and transmission media, including the "internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media." (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards. (F. R. page 6256)

WEDI Recommendation:

WEDI supports this definition.

WEDI recommends that the e-prescribing final rule should apply the HIPAA Security rules to the e-prescribing transactions.

Topic 10

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

WEDI Recommendation:

From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. We urge that the final standards are flexible and scalable in an effort to encourage adoption from small to large health care organizations as well as low to high-volume prescribing physician specialties. Electronic prescribing standards must allow for basic stand alone electronic prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. 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 management software and electronic medical record systems when making an investment.

projects, education, surveys, and developing financial models, in accordance with WEDI's statutory advisory role.

In some cases, pilot projects may be indicated, not just for non-foundation standards with which there has not been adequate industry experience, but also for any standard already demonstrated but being proposed for use in new circumstances.

Topic 13

CMS Approach

> 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. (F.R. Page 6264)

WEDI Recommendation:

WEDI applauds this approach and fully supports it.

WEDI believes interoperability with many clinical terms is also very important. For example, some terms may be used differently in a hospital setting than in 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, efficiency, facilitation of 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.

II. Provisions of the Proposed Regulation

Topic 14

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. (F.R. Page 6265)

WEDI Recommendation:

WEDI recommends that the definitions above be written in more generic terms without the reference to Part D. P art D restriction should be included in the applicability rules. WEDI believes e-Prescribing regulations and voluntary efforts based on regulations are likely to evolve to Medicaid and other plans; therefore, definitions should not be restricted to the single initial plan.

GE.JSP&R_OBJECT_ID=090F3DDD8001063D
Los Angeles

WEDI E-Prescribing Committee

Lynne Gilbertson	National Council for Prescription Drug Programs
Bob Beckley	SureScripts, Inc.
Jean Narcisi	American Medical Association
Anthony (Tony) Schueth	Point-of-Care Partners, LLC
Peter Barry	Peter T Barry Company
James Schuping	EVP/CEO, WEDI
Mary Ryan	Medco Health Solutions, Inc.
Mark McLaughlin	McKesson; Chair, WEDI

CMS-0011-P-13 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : **Ms. Anne Marie Bicha** **Date & Time:** **04/04/2005**

Organization : **American Gastroenterological Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment for complete letter. Thank you.

The notice of proposed rule-making proposes that ?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.? It is important to differentiate health plans from prescription drug plans (PDPs) to reduce potential confusion.

Consequences of medication-related problems (e.g., adverse events) resulting in physicians? visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient?s medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients? compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term ?health plan.?

Please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

CMS-0011-P-13-Attach-1.DOC

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April 4, 2005

Mark McClellan, MD, PhD
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: E-Prescribing and the Prescription Drug Program; Proposed Rule

Dear Dr. McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

The AGA appreciates the ability to comment on the proposed rule for E-Prescribing and the Prescription Drug Program. We recommend clarification on the issue below for the final rule.

The notice of proposed rule-making proposes that "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." It is important to differentiate health plans from prescription drug plans (PDPs) to reduce potential confusion.

Consequences of medication-related problems (e.g., adverse events) resulting in physicians' visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient's medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients' compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term "health plan."

Thank you for consideration of our comments. If we may provide any additional information, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

Sincerely,

Emmet B. Keeffe, MD
AGA President

CMS-0011-P-14 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Mr. Barry Gershon **Date & Time:** 04/04/2005

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-0011-P-14-Attach-1.RTF

GlaxoSmithKline (GSK) appreciates the opportunity to comment on the proposed regulations pertaining to eprescribing. GSK is a global pharmaceutical company that provides therapies that help patients with a variety of serious diseases such as asthma/allergy, HIV, diabetes, mental health, and cancer as well as prevent disease through active vaccine and smoking cessation programs. We have ongoing experience with a variety of health systems, both private and public and hope that our perspective on eprescribing will be useful as CMS continues to implement this important advance in pharmaceutical therapy.

GSK believes that implementing eprescribing has the potential of greatly improving the pharmaceutical care provided to patients but also, if systems are not designed and implemented carefully, has the potential to compromise patient care. Our overriding principle that guides our approach to this issue is that any eprescribing system should exist primarily to serve the medical needs of the patient.

In general, GSK applauds the deliberate approach taken by CMS in the development of an eprescribing program. We are encouraged that CMS is developing eprescribing standards through an open, public review and comment process. We encourage CMS to continue this process as eprescribing evolves and standards require updating. We are offering no specific comments with regards to technical matters, but we encourage CMS to ensure that the new eprescribing system incorporates the following dimensions:

Patient Safety: Be designed to ensure patient safety (e.g. helping to avoid adverse drug-to-drug interactions), improve the quality of care, promote the efficient delivery of prescription drugs, and facilitate communications between patients and physicians.

Clinical Judgment: Support the clinical judgment of physicians (and other prescribers) by ensuring their autonomy with respect to drug therapy decisions. Preserving the physician's ability to select the right therapy for a patient is critical to preserving the physician-patient relationship and achieving quality medical care.

As noted in the legislative history to the MMA, commercial messaging that attempts to inappropriately influence the physician's clinical decisions, should be prohibited. In addition, there should be standards for the evaluation of product information – both for products on formulary an off. Ideally, those standards should require that the information be balanced, clinically and scientifically sound, and not supplant economic considerations for the clinical needs of individual patients.

It is important that the system include information about whether prescriptions were filled by the patient – including the timing of refills. That information should be available to the prescribing physician. This will enable physicians to track each patient's compliance with medically necessary therapies and change the patient's prescriptions according to patient behavior, counsel the patient about the benefits of maintaining compliance with a therapeutic regimen (and the dangers of non-compliance), or both.

Patient Privacy: Ensure adequate security and privacy measures to maintain the privacy and confidentiality of patient information.

Patient/Physician communication regarding access to appropriate care: Provide physicians with the information needed to discuss drug therapy with the patient at the point-of-care. In addition to appropriate information about the prescribed drug, the physician should also be able to provide information to the patient about the exceptions and appeals process that would allow patients to access needed medications. An eprescribing system should enable the patient to receive immediate notice of the right to request an exception or appeal, and the information required to do so. To help the physician work with the patient, the data provided to the physician should also include information pertaining to the patient's specific drug plan sponsor, including changes in the patient's plan sponsor.

Further, just as formulary information will be readily available and automated through the eprescribing system, so should the ability of providers to implement a prior authorization process to expedite the ability of patients to receive appropriate pharmaceutical products. An expedited prior authorization process will aid in striking the right balance between formulary restrictions that encourage the appropriate use of resources and exceptions that ensure that patients with specialized medical needs have assess to the best medications.

In addition to system characteristics that directly effect patient care, eprescribing can improve quality of care in a broader manner through an evaluation of the health care system. While eprescribing involves pharmaceutical therapies, in concert with medical records and claims databases, it also facilitates the identification of savings to the entire health care system gained by appropriate drug therapy. For example, providing appropriate drugs can reduce inpatient admissions or other costly medical procedures, which results in cost savings throughout the health care delivery system.

Such analyses require that all legitimate researchers have access to the data, properly masked to assure patient confidentiality.

We hope that this perspective will be useful as CMS continues to develop standards for the eprescribing system required by the MMA. Please feel free to contact GSK with any questions or requests for additional information.

Yours truly,

Barry Gershon
Director, Public Policy
GlaxoSmithKline

CMS-0011-P-15 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Mr. Mick Kowitz **Date & Time:** 04/04/2005

Organization : ZixCorp

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Background

See Attachment

Collection of Information Requirements

See Attachment

Provisions of the Proposed Regulation

See Attachment

Regulatory Impact Analysis

See Attachment

CMS-0011-P-15-Attach-1.DOC

CMS-0011-P-15-Attach-1.DOC

CMS-0011-P-15-Attach-1.DOC

CMS-0011-P-15-Attach-1.DOC

CMS-0011-P-15-Attach-1.DOC

zixcorp

April 5, 2005
To: Centers for Medicare & Medicaid Services
Re: Response to CMS-0011-P

Zix Corporation respectfully submits its comments on the CMS proposed rules for e-prescribing.

As a leading vendor for e-prescribing and prescription management services, we are pleased that the government has realized that this technology is a viable, beneficial service for the healthcare community and support measures creating standards and policies for the industry. We believe these actions will help foster widespread adoption of e-prescribing and contribute to significant cost savings and reduction of medical errors.

ZixCorp's position in the healthcare marketplace has given our company close affiliation with many of the stakeholders involved in the proposed CMS rules, including payors, pharmacy benefit managers, hospital associations, and the physicians and medical office staff who are most directly affected. Our e-prescribing application is currently certified with RxHub and SureScripts. We are the e-prescribing vendor for the country's largest e-prescribing initiative in Massachusetts. We are also the technology behind MedsInfo-ED, a patient safety program of the Massachusetts Health Data Consortium (MHDC) that offers point-of-service access to dispensed prescription history information in emergency rooms, and which utilizes many of the proposed standards.

Our comments are based on real-world experience in this emerging e-prescribing market. We also operate and maintain a SysTrust-certified data center for millions of users of our e-prescribing and secure e-messaging applications that serves as the trusted hub of connectivity, predominantly for the healthcare industry. Thank you for giving us the opportunity to voice our opinion on this very important proposal. If you'd like to know more about ZixCorp you can visit our Web site at http://www.zixcorp.com/ or feel free to contact us.

Sincerely,

Rick Spurr
CEO, President, and Chief Operating Officer

zixcorp

eHealth
Solutions

ZixCorp® Responses

CMS-0011-P

Prepared for

Department of Health and Human Services

Submitted By:
Zix Corporation
2711 N. Haskell Ave., Suite 2300
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Contact Person:
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Phone: 513-701-6009
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Date: April 5, 2005

Table of Contents

1.0 RESPONSE FORMAT

ZixCorp responses reference the Department of Health and Human Services, Centers for Medicare & Medicaid Services document, 42 CFR Part 423 [CMS-0011-P], RIN 0938-AN49, Medicare Program: E-Prescribing and the Prescription Drug Program (01-17master.pdf) and comment on the proposed rule.

2.0 BACKGROUND

2.1 Statutory Basis

2.1.1 State preemption: scope of preemption, specifically relevant State statutes, page 17

ZixCorp makes a great effort to understand State regulations regarding the e-prescribing process. In general, we agree with the proposed scope of State law preemption as outlined in CMS-0011-P, i.e., the preemption applies to State law provisions that conflict with Federal e-prescription drug requirements that are adopted under Medicare Part D.

In particular, it is ZixCorp's position that the preemption should apply to Medicare and Medicaid prescriptions, as the States have varying and disparate rules and regulations relating to prescriptions for Medicare and Medicaid patients. Monitoring the changes to these disparate rules and regulations requires significant effort, as does implementing the required software changes to develop and support different versions of the e-prescribing software and system.

Furthermore, it is our position that Federal standards developed for Part D transactions should be broadly applicable to all e-prescription transactions. Not to do so would be to require the e-prescribing industry to adhere to a patchwork of multiple standards at different levels of jurisdiction.

2.2 Evolution and Implementation of an E-prescription Drug Program

2.2.1 Criteria to assess "Adequate Industry Experience", pages 28-29

ZixCorp agrees that the stated criteria to assess "Adequate Industry Experience" — American National Standards Institute (ANSI) accreditation, proven implementation success, and recognition by stakeholders — establish a good initial framework for validation. These factors serve to support a degree of technical experience and viability but do not immediately indicate proven commercial viability or value-delivery enablement. We would recommend the addition of indicators related to user acceptance such as utilization metrics and total attributable business/transaction volume.

Although ANSI standardization is desirable, we also suggest that the existence of multiple implementations based on alternative industry standards or a consistent group of standards, which may lead the ANSI process, should be considered equivalently valid, in the presence of earlier achievement of the other criteria.

2.2.2 Process used to evolve currently adopted and additional standards, page 30

ZixCorp supports the Administrative Procedures Act; however, in an emerging market it is difficult to enforce a public offering of documents that to date have only been viewable

through organization membership. Groups such as the National Council for Prescription Drug Programs (NCPDP) provide access to their standard documents through NCPDP membership, as does RxHub® through contractual membership.

We support making documents that deal with format and standard rules and changes available in a timely manner. Currently some of these documents change without appropriate public knowledge and their publication in the *Federal Register* would level the playing field.

Additionally, we recommend that the Federal government adopt a similar process as that used by standards-setting organizations such as ANSI and Health Level Seven® (HL7) for proposing, specifying, changing, and approving standards.

2.3 e-Prescription Drug Program

2.3.1 Use of National Provider ID (NPI) and/or alternatives, page 37

As recently as mid–February, NCPDP released the HCIdea® identifier for dispensers. This concept is new and adds to the complexity faced by e-prescribing companies and transaction hubs in building identifiers. Currently, there is no single source for mandated identifiers and we would support a national identifier for providers, dispensers, and dispensing organizations.

Every "hub" might reference these identifiers but they typically implement provider directories that incorporate their own unique identifiers as well. The regulations should establish a transition period for these new identifiers and mandate that the new identifiers be used between partners by the end of the transition period.

2.3.2 Formulary, benefit, and medication history standards, pages 37-41

ZixCorp currently uses the RxHub Formulary and Benefit protocols as part of its system implementation. It is our opinion that this standard meets the National Committee on Vital and Health Statistics (NCVHS) requirements for inclusive information.

However, this standard relies upon the representative National Drug Code (NDC) supplied by the pharmacy benefit managers (PBMs) or health plans, a complicated variable. It is our recommendation that drug identifier standards be included, whether RxNorm or NDCs (excluding Universal Product Codes (UPCs) from re-packagers or PBMs).

2.3.3 Identify required standards, page 41

ZixCorp agrees that the listed standards should be required to support an e-prescribing program. Today, while many of the organizations we interact with formally state that they comply with the standards, in fact, they impose additional requirements above and beyond the standard.

As our written testimony of May 24, 2004, to NCVHS indicated, we have been asked to implement wrappers and add fields to these standards beyond the ANSI accreditation stipulated in the NPRM, which results in additional development and quality assurance time. To avoid this in the future, we recommend that the standards approved through ANSI accreditation be adhered to precisely.

ZixCorp currently supports the NCPDP SCRIPT standard 5.0 and the ASC X12 270/271/997/TA1 transactions. Additionally, we support the current implementation of the

RxHub formulary file and the pending NCPDP drug history transaction. Also, ZixCorp has been required by many partners to make modifications by adding the aforementioned SOAP wrappers and other XML wrappers.

2.4 Summary of Status of Standards for an e-Prescription Drug Program

2.4.1 Proposed and currently used standards, page 43

The proposed standards are from the NCPDP SCRIPT standard Version (5.0), ASC X12N 270/271, and NCPDP Telecommunications Standard Version (5.1). ZixCorp recommends that the regulations explicitly state that in conjunction with using the 270/271 transactions, the 997 and TA1 message and error transaction be used to communicate routing, format, and error messages.

The reason for this inclusion is to promote the use of the true ASC X12N standard instead of transaction authentication and error processing through XML wrappers such as SOAP and other non-standard wrappers.

From our experience in implementing the transaction set with multiple plans and PBMs, many have non-standard implementations of the X12 transactions. This causes an increase in our development costs and time-to-market readiness.

2.4.2 Strategy for phasing-in implementation of an e-prescription drug program, page 43

ZixCorp agrees that a phased-in approach is appropriate in this marketplace. The adoption of future standards will depend greatly on the concept of a national patient identifier, drug utilization standards for EHR, and other unknown datasets.

It is our position that SCRIPT standard and ASC X12N 270/271 transactions are central to the effective implementation of e-prescribing. As prior authorization standards and other standards become available, the industry will adopt them appropriately based on the Administrative Procedures Act.

2.4.3 Approach to interoperability, page 45

ZixCorp's opinion is that interoperability between EHR systems and e-prescribing systems is critical to the growth and long-term adoption of e-prescription technology. Many physicians will eventually perform e-prescribing tasks through EHR systems, however, for the foreseeable future (3-5 years) e-prescribing systems will be the fastest and most cost-effective approach for transmitting prescriptions electronically — especially for smaller practices. When the time comes for practices to migrate to EHR, interoperability will be essential to the practice and the standards will assure a smooth transition. However, until that time, EHR vendors should be required to comply with the stated e-prescribing standards in the same manner as e-prescribing systems to maintain continuity in the industry.

The ZixCorp e-prescription system is an open-interface architecture. We enable bi-directional HL7 integration and client-side integration of our application. We provide data to third-party sources such as PBMs, health plans, and other point-of-care solutions including practice management software and EHRs.

It is our opinion that basic core integration can be achieved by specifying required standards. It is our opinion that over the next two years industry standards will become apparent by necessity and will make implementation of the new rules easier.

ZixCorp supports the current approach to interoperability to gain insights and determine next steps. If vendors implement their system architectures correctly, this approach will be achieved and should not adversely impact current implementations.

3.0 PROVISIONS

3.1 *Proposed Definitions*

3.1.1 *Electronic media, page 47*

Electronic media are defined and expressed with the conceptual notion that all electronic media are transmitted through "wired" connections. This definition is flawed because it does not address the issue of prescription information that is created at the point of care on devices that are wirelessly connected. In fact, more than half of the prescription information created at the client device for the electronic transmission of prescriptions is sent via a wireless network connection.

Information management is often addressed at a server farm where data is manipulated and then transmitted to third-party dispensers; however, the information is created and moved electronically from the point of care via wireless communications. This is not addressed in the document, yet the Medicare Modernization Act of 2003 specifically identifies the protection of patient rights as one of the purposes of the Act.

ZixCorp therefore recommends that the section dealing with network protocols that would exist in a wired network be expanded to include reasonable best practices for securing wireless communication.

3.2 *Proposed Requirements for Part D Plans*

3.2.1 *Use of e-prescribing transaction standards within the enterprise, page 49*

Organizations must be able to interact with one another to ensure patient safety and reduce medical costs. ZixCorp's opinion is that this philosophy is inherent within any healthcare organization.

In many cases, healthcare facilities also work with internal vendors (i.e. their own staff) that are required to interoperate. While we would expect that standards make it easier for facilities to internally integrate disparate systems, we do not recommend that an organization be required to adhere to standards internally.

If third-party vendors are brought into these facilities, they will most likely have implemented the e-prescribing standards. If the facility has already built an internal system that communicates to the third-party system through a custom interface, converting to the standards could be a financial and time-consuming burden on the facility.

Our position is that internally created systems should not be mandated to communicate using the standards if an interface already exists and is operational. If the internal systems are communicating to other internal systems, they should not be required to implement the standard. Any externally facing interface should be required to comply with the standards.

3.3 Proposed Standards

3.3.1 Adopt ancillary prescription messaging and administrative transactions in NCPDP SCRIPT, page 55

ZixCorp's suite of NCPDP SCRIPT implementations includes all SCRIPT standard transactions and ancillary transactions. While implementation is slightly different among transaction hubs and individual pharmacies accepting these transactions, it is our opinion that they are business-based differences that still meet the core definition of these transactions.

There most likely is adequate industry experience based on existing implementations and therefore these transactions would not require pilot testing.

3.3.2 Coordinate eligibility update process when e-prescribing and HIPAA standards are the same, page 59

We recommend that CMS reference the relevant HIPAA standard so that the standard will be updated automatically in concert with any HIPAA standard modification.

4.0 IMPACT ANALYSIS

4.1 Overall Impact

4.1.1 Expectations for prescriber participation, page 66

ZixCorp's position is that the key to prescriber participation in e-prescribing programs is an integrated approach that encourages the vendor, prescribers, regional payors, and PBMs to collaborate on all aspects of prescriber recruitment, deployment, and retention in local healthcare communities.

The estimate of growth in e-prescribing of 10 percent per year is reasonable, but is contingent upon incentives or sponsorships for physicians to e-prescribe. These incentives or sponsorships should be borne by the payors, since they have the greatest financial benefit from e-prescribing, but other parties, including physician organizations, pharmaceutical companies, and other entities may be willing to provide them. Another incentive might be reduction in malpractice premiums. Without these incentives, or a Federal mandate, it is unlikely that physicians will adopt e-prescribing at the estimated rate.

Publicity surrounding e-prescribing and the Medicare Prescription Drug Program will no doubt heighten prescriber awareness of benefits and options. We recommend that the Federal government commission studies around the individual e-prescribing solutions and publicize the results to the prescribing community.

4.1.2 Cost and saving estimates, page 71

Our opinion is that e-prescribing provides measurable benefits to physicians, patients, pharmacists, health plans, and pharmacy benefit managers. Of these, health plans and PBMs generally benefit the most financially.

Health plans and PBMs benefit by improved generic dispensing rates, formulary compliance, and mail order utilization. Formulary and generic improvements achieved with e-prescribing vary by plan benefit design but generally are 1-4% or more per year over

traditional prescribing. In addition, mail order rates are improved as the physician is reminded of this benefit when available. Mail order improvement rates also vary by plan benefit design and are generally 1-3% or more per year. Actual dollar amounts related to these savings vary by drug purchase price and market.

Health plans and PBMs also benefit from improved formulary compliance by better drug purchasing power as related to drug rebates. These rebate amounts vary widely based on many criteria including member group distribution (union, Medicare, etc.), market coverage, and drug volumes. In addition, health plans benefit from potentially reduced medical costs as a result of reduced adverse drug events. In one of the few studies to examine medical cost changes with e-prescribing, a Tufts Health Plan analysis showed a 19.3% reduction in medical cost increase as compared to a control group.[1]

Benefits for physicians include substantial time savings, specifically around the renewal process. Two separate studies showed approximately two hours of savings per physician per day (Tufts Health Plan Pilot Program[2] and Newton-Wellesley Case Study[3]). The physicians saved time because of fewer phone calls from pharmacies, health plans, and patients; calls were reduced because physicians had drug formulary status and patient medication lists on their e-prescribing devices.

Patients react positively to their physicians using advanced technology to care for them and are pleased to have their prescriptions waiting for them when they arrive at the pharmacy.

Pharmacists are more efficient in fulfilling prescriptions received electronically because the prescriptions are more legible and require fewer callbacks for clarification. The prescriptions are also less likely to have drug interaction alerts or require pre-certification, as the physician was aware of these issues at the point of prescribing.

4.2 *Impact on Health Plans/PBMs*

4.2.1 *Health plan costs and financial benefits, page 72*

It is ZixCorp's position that health plans, as the primary financial beneficiaries of e-prescribing, should bear the initial financial burden of sponsoring key physicians who treat a large share of their members. After the physician has been enjoying the efficiencies of e-prescribing for a period of time, the physician should pay any ongoing fees to continue access to e-prescribing.

Health plan full service sponsorship costs are above $1,500 per physician. This covers all costs of implementation, training, and retention for the first year. The financial benefits to health plans are primarily through improved formulary compliance, generic dispensing rate improvement, and an increased utilization of mail order services. The exact amount of these benefits varies due to many factors including plan benefit design, market share, covered lives, and local market competition.

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[1] Tufts Health Plan Pilot Program, Zix Corporation, 2003.

[2] Tufts

[3] Newton-Wellesley Internists Case Study, Zix Corporation, 2004.

It is our opinion that in general, plans can save approximately $40 every time a drug is switched from a non-preferred formulary or off-formulary drug to a generic.[4]

Additional savings may also accrue through reduced medical costs as a result of fewer adverse drug events. The cost of these adverse drug events varies by the severity of event as well as any co-morbidity factors with the patient's health. It is not uncommon for these adverse events to involve any or all of the following: office visit, ER visit, hospitalization, and lab tests.

The per-physician cost for a health plan to sponsor e-prescribing or to provide incentives to e-prescribing is modest compared to the potential savings from helping physicians to prescribe more cost-effective medications. However, the cost savings will not accrue if physicians decline to utilize the technology because they are unwilling or unable to bear the modest cost burden. Therefore, health plans should be actively encouraged by CMS to provide sponsorship and incentives for e-prescribing implementation.

4.2.2 *Health plan gross or net savings (after subsidizing prescribers to adopt e-prescribing), page 73*

It is ZixCorp's opinion that health plans should see a complete return on their sponsorship investment for subsidizing prescribers within the first 12-18 months after those physicians are fully implemented. Health plans will continue to receive financial benefits during subsequent years as those physicians continue to utilize e-prescribing.

Furthermore, our opinion is that health plans would additionally benefit should they receive favorable tax considerations for investments in e-prescribing programs. Specific e-prescribing grants would enable smaller or not-for-profit health plans to sponsor physicians. These incentives are key in the development of e-prescribing in small markets.

4.2.3 *Health plan e-prescribing incentive programs impact on plans and providers, page 74*

It is our opinion that health plan-sponsored physician incentive programs can be effective when structured appropriately. Health plans should incent physicians to use e-prescribing programs rather than give the physician funds for implementation. In this way, physicians are encouraged to use the e-prescribing system and benefits accrue to the health plan, physician, and other stakeholders in the prescription process.

4.3 *Impact on Prescribers*

4.3.1 *Transition costs related to e-prescribing standards, page 76*

It is ZixCorp's position that e-prescribing usage costs for proven e-prescribing applications should not increase as a direct result of the new standards requirements since proven vendors have already implemented many of these standards. Much of this has been fostered by the standards bodies and the various transaction hubs.

[4] Pharmacy Benefit Managers: Tools for Managing Drug Benefit Costs, Quality, and Safety, prepared for Pharmaceutical Care Management Association by Health Policy Alternatives, Inc., August 2003.

Vendors that have not implemented these transactions will need to go through certification processes with the different transaction hubs that will help facilitate and normalize the implementation of the standards. They could incur more costs to update their systems and may need to pass these costs on to their users or sponsors. Additionally, many vendors may find it difficult to implement these standards. Once implemented, however, the benefits within the industry become far greater to them and everyone. While it may take longer to go through the process of implementing these transaction sets, in our opinion that is an achievable goal.

4.3.2 *Health plan e-prescribing incentive programs, page 77*

Health plans are currently in various stages of evaluating e-prescribing programs, some of which involve incentives. Most often, these programs are structured so as to offer higher incentives with higher e-prescribing use. Currently programs such as Bridges to Excellence as well as several programs offered by Blue Cross Blue Shield of Massachusetts reward physicians for improving care, usually by implementing and using e-prescribing or EMR technology in their practices.

We anticipate that as e-prescribing program results are more widely known, health plans will be more aggressive in implementing these programs, which include incentives for continued use. Physicians who use the systems for all of their prescriptions should be rewarded with higher incentives relative to others who use e-prescribing systems for only some of their prescriptions.

4.3.3 *Provider savings, especially solo and small group practices, page 78*

It is ZixCorp's opinion that smaller physician offices are at an economic disadvantage compared to larger offices in terms of their ability to purchase e-prescribing and especially EMR systems. Their smaller size, however, can work to their advantage. They are more nimble and generally not as risk-averse as are some larger offices. This makes them better suited to 1) make a decision to adopt e-prescribing more quickly, 2) implement the e-prescribing system in less time (smaller offices have fewer office staff and are often easier to schedule for training) and 3) because of their size, they often can't afford the more elaborate EMR systems making the efficiency, time savings, and relatively low monthly cost of e-prescribing to be a particularly good fit.

Several studies[5] have shown a significant time savings with e-prescribing of approximately two hours per physician per day. This benefit of increased efficiency is especially important to smaller offices with fewer internal resources and in our estimation far outweighs the nominal monthly access fees.

4.3.4 *Provider cost – benefit information, page 79*

Medical offices benefit from e-prescribing by reduced pharmacy call volume, and larger offices may even benefit more — we estimate that with the higher volume of avoided calls, larger offices may actually be able to redirect or eliminate resources dedicated to processing pharmacy calls.

It is ZixCorp's position that the initial costs for implementing an e-prescribing system should not be borne by physicians. Health plans and/or PBMs should, as the primary financial

[5] Tufts Health Plan Pilot Program, Zix Corporation, 2003, Newton-Wellesley Internists Case Study, Zix Corporation, 2004, Framingham Pediatrics Case Study, Zix Corporation, 2004.

beneficiaries of e-prescribing, bear that initial cost. However, after the first year, the physician should pay for any monthly access fees or for additional physicians who join the practice. ZixCorp charges a small monthly access fee to physicians after the first year of use.

Physicians do have a disruption cost and learning curve associated with implementing e-prescribing. They usually need four to six weeks to fully incorporate e-prescribing into their daily routines and an additional eight to twelve weeks to realize the full benefits with respect to practice efficiency, personal productivity, and cost savings. In addition to reduced pharmacy phone calls, physicians benefit from potentially better medical outcomes and knowing that prescribing electronically is safer for their patients.

Our position is that the e-prescribing adoption success rate is directly tied to the ability of the physician to use the system for all or for the majority of their patients. Therefore, CMS should not try to implement an e-prescribing solution that enables providers to only prescribe for Medicare Part D beneficiaries, since it will likely fail.

4.4 Impact on Pharmacies and Other Dispensers

4.4.1 Pharmacy impacts, page 81

It is ZixCorp's position that pharmacists will greatly benefit from the efficiencies of e-prescribing. Studies have shown that pharmacists are very satisfied with e-prescribing rating it 4.67 on a 5-point scale where 5 = very satisfied.[6] In addition, this study reported that pharmacists saved an average of almost an hour a day. This study covered faxed e-prescriptions.

Currently most e-prescriptions being sent to pharmacies are sent via fax. This hampers the ability for both providers and pharmacists to track information and prevents efficiencies that utilization of an electronic process would promote. It is our opinion that full EDI to the pharmacy management system will further increase the value for pharmacists.

The major impact of EDI on pharmacies is the ability to receive electronic transmissions, which reduces the risk of losing paper prescriptions and eliminates the paper trail in the pharmacy. Additionally the electronic transmission of both renewals and new prescriptions increases transactional integrity in the pharmacy and reduces duplicate data entry.

4.5 Impact on Others

4.5.1 Impact of e-prescribing on healthcare information technology vendors, page 82

ZixCorp is a trusted provider of secure Internet services and applications. The PocketScript e-prescribing solution is one of the premier products in the marketplace. Yet because so many plans, pharmacies, and PBMs still do not support the proposed transaction standards, integration with our partners has required a great deal of development work and its associated cost.

We agree that the growth of e-prescribing provides business potential for healthcare information technology vendors. In addition, we estimate the cost to healthcare technology vendors will vary depending on the extent to which they have already adopted the

[6] Tufts Health Plan Pilot Program, Zix Corporation, 2003

recommended e-prescribing standards into their products. The impacts should generally be minimal because these standards were taken from the industry itself.

4.5.2 *Impact on other healthcare organizations, page 82*

It is ZixCorp's opinion that as e-prescribing continues to grow beyond its current adoption levels of 8-18%, other companies with interests in pharmacy or healthcare will necessarily be drawn towards it.

- Pharmaceutical manufacturers will likely invest in ways to promote their products because of the efficiency inherent in delivering their product messages directly to the physician.
- Medical device manufacturers such as makers of diabetes monitoring equipment will integrate their products with e-prescribing devices and offer physicians broader information for prescribing and therapy decision-making.
- Health content providers will also be aggressive in marketing their information products to e-prescribing vendors.
- Disease management information providers will devise ways to integrate their targeted medication compliance and protocols into point-of-care e-prescribing devices.
- Specialty pharmacies will promote e-prescribing to certain specialists to better enable them to send specialty prescriptions to their mail order facilities for fulfillment.
- Medical organizations will become engaged with e-prescribing, possibly certifying certain vendors on behalf of their members.
- EMR and EHR vendors will begin to incorporate proven e-prescribing systems into their suite of offerings. This interoperability will allow physicians a true evolutionary path from e-prescribing through EMR and EHR while enabling them with more choices for their e-prescribing tool.

4.6 *Impact on Small Business*

4.6.1 *Impact on small entities regarding initial regulatory flexibility analysis, page 85*

We do not disagree with the conclusion stated in the proposed NPRM relating to the impact of the NPRM on small entities.

4.7 *Effects on States and Federalism Statement*

4.7.1 *Input from states concerning State law preemption, pages 87-88*

Our views relating to the scope of State law preemption are stated above in response to section 2.1.

4.8 Conclusion and Alternatives Considered

4.8.1 Suggestions for improvements, pages 88-90

ZixCorp congratulates CMS on the process and questions laid out in CMS-0011-P, which present a very well-thought-out proposal for the implementation of e-prescribing to Part D entities.

It is our opinion that upon review of these comments, the Committee will recognize that a pilot of "real world" quality will be of tremendous value. The pilot must be administered in such a way as to allow e-prescribing vendors, pharmacies, and PBMs to follow their existing implementation strategies.

End of document

CMS-0011-P-16 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Ms. Kelly Lavin **Date & Time:** 04/04/2005

Organization : American Osteopathic Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-16-Attach-1.DOC

Department of Government Relations

AMERICAN OSTEOPATHIC ASSOCIATION

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D.O.s: Physicians Treating People, Not Just Symptoms

April 5, 2005

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

Via: http://www.cms.hhs.gov/regulations/ecomments

Re: Medicare Program; E-Prescribing and the Prescription Drug Program (02/04/05 Federal Register)

Dear Dr. McClellan:

Thank you for the opportunity to provide comments on electronic prescribing (e-prescribing) and the Medicare prescription drug program (Part D). The American Osteopathic Association (AOA), which represents the nation's 54,000 osteopathic physicians, practicing in 23 specialties and subspecialties, supports ongoing efforts to develop and implement health information technologies (HIT).

The AOA is committed to advancing the utilization of technology in the practice of medicine. E-prescribing offers a unique opportunity to improve the quality of patient care and increase the efficiency in the disbursement of prescriptions.

The rapid development of medical informatics is changing the face of the healthcare delivery system. It is imperative that these technological advances occur through a deliberative process in which physicians and other interested parties are able to provide input and ultimately shape the end product. If done with careful deliberation and consideration for the various issues that arise with implementation, e-prescribing and HIT have the potential to be a driving force in enhancing the quality and efficiency of the healthcare delivery system.

In July 2004, the AOA House of Delegates created seven principle guidelines on e-prescribing. These seven guidelines serve as a framework for the development and adoption of electronic prescribing standards and technology. Application of these principles will assist our physicians in providing the highest possible level of care to our patients:

1. **Safety**: The units used to prescribe electronically should clearly show safety alerts. These alerts should be distinguishable from advertisements. In our opinion, advertisements adversely impact efficiency and offer no clinical benefit.

2. **Privacy**: Privacy of the patient must be protected. Information on patients' medications should be current, comprehensive, and compliant with standards set forth in the "Health Insurance Portability and Accountability Act" (HIPAA).
3. **Transparency**: All third party involvement in an electronic prescribing system must be clearly identified.
4. **Design**: The development of any system must ensure that the physician-patient relationship is protected to ensure that doctors in conjunction with their patients dictate the care, not computer software. In addition, the system must be designed in a manner that ensures that new health care errors are not introduced into the health care delivery system.
5. **Integration**: Systems should be proven and integrated into existing health information technology. E-prescribing can be an important component of a larger electronic medical record.
6. **Scalability**: Any standards should be broad-based and applicable to all health care delivery systems.
7. **Timing**: Standards should be implemented in a manner that allows software vendors and physicians adequate time to become compliant. In addition, we strongly advocate for broad testing of technologies and standards to ensure efficiency and effectiveness.

The AOA stands ready to work with you on the development of e-prescribing standards and technologies that are designed and implemented in a manner that enhances the quality of care our patients receive and assists with the efficiency of delivering health care services. E-prescribing offers great potential if all interested parties remain part of the process.

The AOA understands that physicians are not required to write prescriptions electronically. According to the proposal, physicians and other 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 transmitted electronically.

While the AOA agrees e-prescribing potentially increases safety and efficiency and could lower the costs of health care, we do not believe that this should become -- at any time -- an unfunded mandate on physicians. For this reason, we support the establishment of grant programs that will assist physicians, especially those in small group or solo practices, with the capital investments associated with HIT. For practices that are not yet electronic, the cost is a barrier.

Osteopathic physicians represent 18 percent of all physicians practicing in small towns and rural areas with populations of 10,000 or less, and 22 percent of all physicians practicing in communities of 2,500 persons or less. Financial incentives must be created to offset the cost of initial investment particularly for physicians and other health care providers practicing in lower income, rural and underserved areas.

Our comments to the proposed rule are as follows:

BACKGROUND
A. Statutory Basis

The AOA is working to ensure that physicians have the ability to afford new health technologies. Physicians, especially those in small practices, are facing financial difficulties with funding their own technologies. Providing a safe harbor under the Anti-kickback statute and an exception under the Stark law for certain non-monetary remuneration related to e-prescribing information technology items and services would help greatly to break down the monetary barrier that prevents technology adoption.

We look forward to the separate publication of rulemaking for the Stark Exception, as well as the new safe harbor under the anti-kickback statute, which will be proposed by the Office of the Inspector General (OIG). We urge CMS and the OIG to release proposed rules as soon as possible. We ask that the exception and safe harbor pre-empt any state law that would be seen as a barrier to adopting e-prescribing and HIT technology.

PROVISIONS OF THE PROPOSED REGULATIONS
C. Proposed Requirements for Part D Plans

The AOA questions why closed networks would be exempt from the standards. Allowing such an exemption would contradict the universality of protocol adoption. If a closed network must convert from HL7 to NCPDP SCRIPT to communicate prescriptions to community and retail pharmacies, as well as be able to receive prescription transmittals via NCPDP SCRIPT from outside enterprises, then wouldn't it be appropriate to use NCPDP SCRIPT inside the network as well?

In addition, allowing such an exception to the rule will only complicate the following of other rules. Under HIPAA, the transaction requirements apply to both closed and open environments. Since both rules are encompassed around patient information, consistency would be favorable.

E. Proposed Standards

The AOA found an inconsistency in the Proposed Rule regarding the Prescription Fill Status Notification Transaction. According to the preamble on pg. 6265, the Prescription Fill Status Notification Transaction and its three business cases are excluded from the foundation standards due to inadequate industry experience. However, on page 6266, it states "the NCPDP SCRIPT Standard transactions we propose for adoption have been used extensively for messaging between prescribers and retail pharmacies for new prescriptions, prescription refill requests, **prescription fill status notifications** and cancellation notifications, as part of the Consolidated Health Informatics Initiative." We would appreciate a clarification on whether industry experience exists.

If the first statement is correct and there is no significant industry experience in the area of Fill Status Notification Transaction, then it should in turn be part of a pilot project to gain the experience. A Fill Status Notification could serve as a quality tool for physicians. Many patients are non-compliant with physician recommendations, including prescriptions. Having the mechanism of viewing when and if a prescription is filled can play a major role in the quality of care that the patient receives.

IMPACT ANALYSIS
C. Impact on Prescribers

While the AOA believes that e-prescribing is a helpful tool in improving the quality of patient care and increasing efficiency, primary care physicians who oversee the care and medication provided to their patients by other physicians plays a greater role in significantly reducing the potential problems of overmedication, under-medication, and/or harmful drug interactions.

In addition, having only osteopathic and allopathic physicians prescribe or supervise prescriptions written by non-physicians clinicians is important step in significantly reducing the problems of inappropriate drug use and/or harmful drug interactions. The AOA supports shared responsibility among patients, caregivers, and physicians to ensure appropriate drug use.

CMS and stakeholders must be cautious in their expectations regarding e-prescribing. A U.S. Pharmacopeia study found that medication errors attributable to computerized prescribing are increasing. E-prescribing mistakes accounted for almost 20% of all hospital and health system medication errors in 2003. "Computer entry errors were the fourth leading cause of medication errors in U.S. hospitals and health systems," according to USP.

CONCLUSION
Putting Patients First—Patient Centered Quality Care is the AOA's theme. We believe that one of the fundamental principles of patient centered quality care is the ability of patients in our care to have access to appropriate drug therapies. We realize controlling costs is an important factor, however, access to appropriate treatments must be the primary focus. Promoting the use of cheaper drugs could prevent the selection of appropriate treatment protocols, which directly affects the patient's health. We hope that as CMS develops its policies on e-prescribing, the main focus will be ensuring access to appropriate treatments while improving the quality of patient care and safety.

***

The AOA appreciates the opportunity to comment on the proposed e-prescribing rule. We look forward to working with CMS in the future on this and other issues of concern to the osteopathic medical profession. If you have any questions, please contact Kelly Lavin, AOA Regulatory Analyst, at 202-414-0140.

Sincerely,

George Thomas DO

George Thomas, DO
AOA President

CC: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

CMS-0011-P-17 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : **Bruce Kelly** **Date & Time:** **04/04/2005**

Organization : **Mayo Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Issues

Provisions of the Proposed Regulation

See attachment

CMS-0011-P-17-Attach-1.DOC

CMS-0011-P-17-Attach-1.DOC

MAYO FOUNDATION

Mayo Foundation
1025 Connecticut avenue NW, Suite 1012
Washington DC, 20036
202-327-5424 Fax: 202-327-5426

Office of Government Relations

April 4, 2005

Centers for Medicare and Medicaid Services

Re: CMS-0011-P
Medicare Program: E-Prescribing and the Prescription Drug Program

On behalf of Mayo Clinic I am submitting comments in response to the notice of proposed rulemaking cited above.

Mayo Clinic is a multi-specialty group practice with major sites in Rochester, Minnesota, Jacksonville, Florida, and Scottsdale and Phoenix, Arizona. We see patients from all over the country at each of our sites, and accordingly our comments will focus primarily on the ramifications of the rule on a large, national, multi-specialty academic health center.

Mayo supports the movement toward broad use of electronic transactions in healthcare. We have moved within our own institution to an electronic medical record, and we believe the widespread use of better electronic records and information technology is absolutely necessary for the future of healthcare. We also support the concept of interoperability to allow electronic communications among different systems in a seamless manner.

The proposed rule establishes several basic standards to be adopted for the Medicare electronic prescribing system, and we support the adoption of these standards, which were developed through a consensus process. Our comments will focus on the broader issues raised in the NPRM of how the electronic prescribing system will evolve and the appropriate roles within that system for the various parties involved.

We believe the model for the system needs to be built with the patient and the patient's physician or other prescribing healthcare professional (prescriber) at the center. This is the point where issues of medical appropriateness, patient medical and medication history, drug interactions, and allergies are dealt with and resolved. It is also the opportunity for the prescriber, with the patient present, to make decisions about possible generic substitution and the necessity of using off-formulary drugs in the individual case. Therefore, this should be the starting point for the electronic system. If the prescriber has covered all these issues with the patient, the need for interventions downstream will be obviated. The system should be built around this patient-prescriber focal point. The prescriber should have access at this point to whatever information is available through the PBM, rather than having the PBM be the focal point for information after the medication has already been prescribed. In addition, the information exchange between the prescriber and PBM must be limited to the information necessary to make appropriate medical and cost effectiveness decisions, without the insertion of any messages that could be construed as the marketing of a particular drug.

The patient-prescriber focal point model will require a system that is user friendly, and one that practitioners will be willing to embrace. It must be pilot tested for not only technical functionality, but also ease of use, effectiveness of communications, time required to complete the prescribing process, and potential problems of information handoffs from prescriber to PBM and pharmacy. The model must make the prescriber's job easier, and be seamless to the patient. The process must also eliminate repetitive flagging of the same issue after the prescriber has signed off on a prescription. The prescriber and patient should have to deal only once with these flagged issues.

In the case of centers such as Mayo Clinic, the system must also be nationwide. We will likely see Medicare patients enrolled in every drug plan in the nation. The ability to deal efficiently with all plans will be a necessity, with the same criteria needed as described above. This will require uniformity of systems to access information among the drug plans. For example, standardized models will be required for patients and prescribers to navigate formularies and access other information held by different PBMs.

In order to achieve the objectives we have outlined, we strongly urge that this system be developed incrementally, with pilot testing of all elements. While technical standards may seem straightforward in theory, or even in local settings with a limited number of parties involved, in the real world of mobile patients and multi-state providers, plans, and pharmacies, there is huge potential for unintended consequences. The pilot testing is needed to assure that standards are both technically and practically (in a real clinical setting) useful and efficient. What will make or break this system are not necessarily the standards themselves, but the ability to have workable procedures and policies to make effective use of the standards. Many details need to be addressed, such as which issues will trigger alerts, how those alerts will be displayed, how workflow will be affected, who will maintain and update medication and allergy lists, how will organ dysfunction be captured, and many other critical questions. Reality testing will be crucial for achieving a workable system.

We also urge your attention to making sure this system is compatible with electronic patient records already being used by many hospitals and medical groups (including Mayo Clinic). We already are dealing with an electronic environment, and this new system should not be constructed outside of the existing electronic world. Focus should be on use of existing data standards to insure interoperability and portability of this type of information. The system should also be constructed with HIPAA privacy concerns built into the model. With patient drug information, and eventually medical history, being housed in this system, it will be imperative to protect patient privacy.

Thank you for your consideration of these comments. For further information I can be reached at 202-327-5424.

Sincerely,

Bruce M. Kelly

Bruce M. Kelly
Director of Government Relations
Mayo Clinic

CMS-0011-P-18 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : David McLean, PhD **Date & Time:** 04/04/2005

Organization : RxHub

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-18-Attach-1.DOC

RXHUB™
Where the Prescribing Industry Connects

April 4, 2005

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 Notice of Proposed Rule Making (NPRM) [42-CFR Part 423] - Comments

Dear Madams/Sirs:

RxHub is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

At a time when society is focused on a rise in medication errors, increasing costs, and the need to provide benefit to our seniors and most needy, electronic prescribing holds the most promise for relief. RxHub was founded in 2001 by the three largest pharmacy benefit managers (PBMs) to advance the acceleration of electronic prescribing—electronically delivering real-time access to patient medication history and formulary and benefit information at the point of care. We have learned that electronic connectivity between payers, physicians, and pharmacies is essential to improving patient safety and containing health care costs. We have successfully demonstrated this through:

- building a secure, private connectivity infrastructure able to handle high transaction volume,
- building an open, standard means to share prescription drug benefit information with all participants in the prescription delivery team,
- facilitating the adoption of open, uniform standards, and
- forging industry-wide alliances and participation.

Today, clinicians use this information to make more informed and safer prescribing decisions, reducing medication errors at every point of care. We are working with over 40 participants (and growing), generating over 1 million transactions per month, demonstrating more than adequate industry use and acceptance. Each one of these transactions represents a patient visit with one or more possible prescriptions.

RxHub strongly supports the development of standards for electronic prescribing, and we have actively participated in the process of the National Committee for Vital Health Statistics (NCVHS) leading up to the release of the NPRM. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to the passage of the Medicare prescription drug bill, and we believe Congress intended to achieve true standardization of electronic prescribing for the benefit of the nation's health care.

BACKGROUND

Commenting on: Statutory Basis- Definition of Electronic Media (F. R. page 6257)

According to the NPRM, "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."

RxHub Recommendation:

This rule seems to include (but does not specifically mention) **electronic faxes**, since those transmissions were created in an electronic format, then transmitted electronically. Since electronic faxes are electronic media, they could also considered electronic prescriptions, per the interpretation of the definition on page 6273 of the NPRM (section 423.159):

> *E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.*

Electronic 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." However, electronic faxes do not comply with the proposed standards, as they do not utilize the NCPDP Script standard, and could not be used to e-prescribe under the NPRM as currently drafted. Furthermore, electronic fax software does not support the communication of eligibility or formulary and benefit information, which e-prescribers are required to support.

RxHub would recommend that given the number of entities currently utilizing electronic faxes, and given an accelerated timeframe for implementing the e-prescribing program under MMA, that HHS may want to include a transition period in the Interim Rule during which those entities could continue to utilize electronic faxes for the electronic transmission of prescribing information.

Commenting on the following Sections:

I. A. Background/Statutory Basis (F. R. page 6257
I. F. Background/Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)
II. Provisions for the Proposed Regulation (F.R. page 6265)

Also relates to I. H. Background/Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. page 6264)

RxHub Recommendation:

Standards Approval Should Not be Dependent upon ANSI Accreditation

For the development and implementation of standards under the e-prescribing program, the NPRM offers for comment three criteria to give meaning to the statutory requirement that a candidate 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 (demonstrated interoperability); 3) the standard is recognized by key industry stakeholders as the industry standard (no competing standards to cause potential confusion). 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."[1]

While we support the goal of leveraging the capabilities, experience, and broad industry participation of ANSI-accredited organizations in the quest for identifying standards, we are also concerned about including ANSI accreditation as a threshold requirement. To the extent the NPRM is intending to require that any standard, whether it is a "foundation[2]," initial or future standard, be 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.

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[1] 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.

[2] 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.

Congress Mandated Standard Setting Responsibility be Retained by HHS

Congress mandated that the process to follow in approving standards for the e-prescribing program does not consist of ANSI accreditation as the sole determinant. The basis for Congress' intent to have a broader set of criteria utilized is because there is no standards development organization today that has representative participation from all the requisite industry stakeholders. To give great clarity on this important point and the need for a broader process, MMA specifically requires that all industry stakeholders as enumerated in the statute need 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.

Relying on industry standard setting organizations creates a risk that parties with particular agendas or ulterior motives can usurp the process, preventing any standard from getting passed, despite broad consensus and/or the lack of any alternative standard for a given transaction type. NCPDP traditionally has enjoyed significant participation from the pharmacy stakeholders. The physician community, critical to the success of the e-prescribing program, is a primary 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. [1]

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.[2] However, this specific provision 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 be 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 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.

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[2] 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).

In addition, the ANSI accreditation process is, as acknowledged by the NPRM, a time consuming process and 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 ambitious 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.

We recommend that HHS not implement a requirement that all standards (foundation, initial or future) be certified by an ANSI accreditation consistent with the requirements of MMA. HHS should 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.

Support for Adoption of RxHub Protocols as Foundation Standards Under Two Criteria

As an example, of standards that do not need to go through the ANSI accreditation process, we point to the RxHub protocols (the Protocols[1]) for formulary/benefits information and for medication history to be adopted as foundation standards. The Protocols 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 Protocols 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 Protocols 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. 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 Protocols meet the two criteria demonstrating adequate industry experience, resulting in approval as foundation standards.

RxHub has submitted the Protocols 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 Protocols 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.

Commenting on:
Background: Statuary Basis/ State Preemption (F.R. page 6259)
Provisions: H. Effects on States and Federalism Statement (F.R. Page 6272)

We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenter 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.

RxHub Recommendation:
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, predictable, national scheme, physicians and pharmacist will be uncertain as to their obligations 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 software technology 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. "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.

CMS stated in the preamble to the NPRM that "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 figure out how 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 all this 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 standards for electronic prescribing are 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
- 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 standards 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 the proposed approach of 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.

Commenting on: Evolving and Standard Setting Process (F.R. page 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.

RxHub Recommendation:
In terms of addressing future standards under the e-prescribing program, there are two important issues raised under the NPRM: 1) whether to configure at this point in time a predetermined formula for all standards that may be proposed in the future; and 2) whether all future standards will be approved if they meet a single criterion, ANSI accreditation.

We are concerned about the issues identified in the foundation standard-setting process as they apply to future standards and ask for restraint from imposing at this time a detailed regulatory process for future standards that may be precise in process but short-sighted in consequence. 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. It should not impose at this point in time an ANSI accredited standard setting process as the sole requirement for approval, particularly given the need for broader consensus building, neutrality and participation by all industry stakeholders.

Accordingly, we recommend that HHS not issue a predetermined formula to approve future standards until and unless needs for this are clearly identified beyond a successful implementation of the foundation and remaining initial standards.

As needs for future or evolving standards become clear, HHS is authorized to provide guidance from time to time on an ongoing basis. Such guidance may address matters related to the standards that remain within the scope of MMA and impact the maintenance of "backward compatibility" among e-prescribing program participants.

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

Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at §162.1101 through §162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. The standards must be designated to enable transmission of basic prescription data to and from prescribers and dispensers, a well as the transmission of information about the patient's drug utilization history, possible drug interactions, the drug plan and cost information.

RxHub Recommendation:
RxHub supports the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers. This transaction set supports real-time mode lookup, sending a request to the appropriate benefits administrator for additional

information and including the patient's Cardholder information as well as links to the benefit information for accessing formulary and benefit information, medication history and processing the drug claim. In addition, this standard transaction set can support COB by informing the prescriber that the individual is covered under multiple plans.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patent's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction be piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

RxHub notes that eligibility request 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. Consequently, RxHub recommends 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.

Commenting on: Table of transactions (F.R. page 6262).

The key NCVHS recommendations concerning functions related to interoperable electronic exchange of information and whether they are included in the NPRM are summarized in the table page 6262.

RxHub Recommendation:
Remove function titled "Exchange of medication history, and medical history for e-prescribing program" from the table as this is covered in two distinct functions one of which is currently being addressed: Medication History and the other which will be subject to future NCVHS hearings: Medical History.

Commenting on: Provider and Dispenser Identifiers (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.

RxHub Recommendation:

Currently, RxHub supports the use of the NCPDP Provider ID for pharmacy providers and the DEA number for physicians. We also create a unique ID for each physician/location/Point of Care vendor combination. RxHub plans to support use of the NPI once it becomes available.

However, there will need to be a transition period in order to move to the industry's use of the NPI while the industry is still supporting other identifiers. RxHub supports and encourages the use of pilot projects using the NPI in 2006. Adoption of NPI in e-prescribing program should not be required until May 2007 deadline, only if there is adequate industry experience in the use of the NPI and acceptable business practices are available for distribution of the NPI file to the industry. Until that time, the current identifiers should be supported.

We recommend that the Interim Rule affirms 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

Commenting on: Provider and Dispenser Identifiers (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.

RxHub Recommendation:
RxHub and the industry currently support the use of the NCPDP Provider ID for identifying dispensers. We would support the use of NCPDP HCIdea for identifying prescribers if the industry moves in that direction. It is important that the same identifiers be used for both Medicare and non-Medicare prescriptions.

Commenting on: Formulary and Benefit Coverage Information 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

RxHub Recommendation:
The e-prescribing industry has sufficient experience with the standards currently being used by RxHub and its many partners for formulary and benefits information and medication history to be named as foundation standards. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing industry, clearly demonstrate adequate industry experience with the RxHub standards for formulary and benefits information and medication History. RxHub has submitted these standards to NCPDP to be worked through the approval process for becoming ANSI-accredited standards. There have not been significant changes made to the submitted formats and therefore these standards should be named as foundation standards which will not cause additional rework on behalf of those entities already utilizing these formats in their current e-prescribing transactions.

The Medication history standard is currently being balloted with the NCPDP membership, and the formulary and benefits information standard has been submitted to NCPDP and upon approval will be taken to ballot. RxHub anticipates that these standards will be approved but the outstanding question is timing of the final accreditation.

We support adoption of the RxHub standards for communication of formulary and benefits information and medication history information between health plans/PBMs and physicians via their technology vendors. We believe these should be adopted in the final rule as final standards. We do not believe it is necessary for these standards to be validated by an ANSI-accredited organization, given that the participants in the industry that are doing electronic prescribing have effectively adopted these as their "de-facto" standards for communication of this type of information, and that the industry has extensive experience in the use of these standards. The vast majority of electronic prescribing solution providers and each of the three largest PBMs (representing over 150 million lives) are using these transaction sets today and have been for several years.

Commenting on: 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. (SPL discussion)

RxHub Recommendation:
RxHub plans to support new drug information standards as they are approved and become available.

Commenting on: 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).*

RxHub Recommendation:
RxHub supports naming NCPDP SCRIPT and ASC X12N 270/271 as these foundation standards. Minimum standard is what is indicated in the NPRM as the "floor" with the assumption that higher versions are acceptable.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB)

responses as it is only designed to handle verification of a patent's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction is piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

Commenting on: Standards for Interoperability (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.

RxHub Recommendation:
Standards for e-prescribing and EHRs can be implemented independently, as there is no value to curtailing the momentum that is already building in the industry today around e-prescribing. EHRs are very broad reaching and may be implemented at different times or addressing different business cases. RxHub considers e-prescribing as a vital component of the EHR application. E-prescribing is available today and is being used. We support addressing interoperability between different standards in order to more easily integrate healthcare applications and functionality. Future features and functions should be incorporated into the whole continuum of care, but it is our strong recommendation not to postpone what is available and in use today

II. PROVISIONS

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

The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with electronic prescription drug program standards relating to covered Part D drugs, for Part D enrolled individuals once final standards are effective. Effective January 1, 2006, Part D sponsors would be required to have an electronic prescription drug program and would be required to support electronic prescribing, once standards are in place.

RxHub Recommendation:
RxHub agrees and supports the recommendations from NCVHS.

Commenting on: (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.

RxHub Recommendation:
RxHub agrees with the recommendations from NCVHS.

Commenting on: 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.

RxHub Recommendation:
RxHub agrees with the conclusion as recommended by NCVHS to not adopt these at this time due to inadequate industry experience and business case use.

Commenting on: (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

RxHub Recommendation:
RxHub agrees with the naming of NCPDP SCRIPT as a foundation standard, however, not all messages in the information exchange have been proven to have adequate industry experience. In addition, not all messages (e.g. Get message and Password Change) are required in all business models. Therefore we agree with naming all messages within the SCRIPT Standard, but not requiring all messages to be supported.

Commenting on: 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.

RxHub Recommendation:
RxHub supports naming NPDPD SCRIPT and X12 270/271 as foundation standards.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patent's cardholder status for a specific

benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction is piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

IV. REGULATORY IMPACT ANALYSIS

Commenting on: Prescriber Participation Expectations (F.R. Page 6268)

We invite public comment on our expectations for prescriber participation

RxHub Recommendation:
Please see RxHub's response at ***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259).***
There is a consistent and growing body of knowledge about the factors that, until now, have impeded the emergence of e-prescribing on a nationwide basis. One major factor is the reluctance of physicians to adopt new e-prescribing technologies.[1]

One way to overcome physician inertia is to provide incentives for them to adopt the new electronic technologies needed for e-prescribing. This is a mandate on HHS as a part of President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335, issued April 27, 2004.

It could be cost-effective for some plans or pharmacy benefit managers to provide electronic devices and software to physicians without charge as an incentive to encourage their adoption of e-prescribing practices. The NPRM notes (p. 6270) that, "One of the barriers to early adoption 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, we expect a steady increase in the number [of] electronic prescribers."

The NPRM makes clear (p. 6269) that pharmacy plans and pharmacy benefit managers are likely to find it cost-effective to provide incentives to encourage e-prescribing: "We expect many plans to provide these incentives [i.e., financial incentives and technical assistance] to prescribers to offset the prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing."

As the NPRM also points out, a major impediment to the provision of these needed incentives is the existence of federal and state laws prohibiting kickbacks and physician self-referrals. The NPRM states that HHS will address these impediments by issuing a proposed rule to create an exception under Section 1877 of the Act (the "Stark law") for incentives relating to e-prescribing and that the department's Inspector General is considering how best to establish a safe harbor under the federal Anti-Kickback statute.

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[1] "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.

The Government Accountability Office points out that state law is prevalent in this field: "Many states have laws analogous to the federal self-referral and anti-kickback laws, some of which are stricter or have fewer exceptions, or both."[1] However, the proposed rule fails to preempt or otherwise address these conflicting and burdensome state laws.

Commenting on: A. Overall Costs & Savings Impact (F.R. Page 6268)

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.

RxHub Recommendation:

Americans made more than 823 million visits to physicians' offices in 2000[2] and according to the National Association of Chain Drug Stores (NACDS); four out of five patients who visit a doctor leave with at least on prescription.[3] Close to 4 billion prescriptions will be written in 2006, as prescription medications are used by over 65 percent of the U.S. population in a given year.[4] It is our opinion that with this significant volume, even a small improvement in quality attributable to electronic prescribing would translate into significant healthcare cost savings--and hospitals, pharmacies, health plans and purchasers all stand to gain form an accelerated adoption of this technology. RxHub delivers via its industry adopted "de-facto" standards relevant patient information and clinical knowledge to the prescriber, thus reducing the likelihood of a medication error. This change in approach represents a fundamental overhaul to our national prescription error prevention system, and the safety implications are staggering: CITL estimates that nationwide adoption of electronic prescribing will eliminate nearly 2.1 million adverse drug events annually in the United States.[5] This same study projected a savings of $27 billion annually with widespread adoption of electronic prescribing

Commenting on: B. Impact on Health Plans/PBMs Cost & Financial Benefit (F.R. Page 6269)

We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans.

RxHub Recommendation:

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[1] Government Accountability Office, *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, GAO-04-991R, August 13, 2004, p. 47.

[2] Pastor PN et. Al. Chartbook on trends in the health of Americans. Health, United States, 2002. National Center for Health Statistics. 2002

[3] The chain pharmacy industry profile. National Association of Chain Drug Stores. 2001

[4] Agency for Healthcare Research and Quality. MEPS Highlights #11: distribution of health care expenses, 1999.

[5] Center for Information Technology Leadership. The value of computerized provider order entry in ambulatory settings, 2003. This study also reported that over 8.8 million adverse drug events (ADEs) occur each year in ambulatory care, of which more than 3 million are preventable. The widespread adoption of e-prescribing would prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 ADEs annually.

Cost or, perhaps more accurately, a lack of documented cost/benefit analysis, has been one of the primary barriers to adoption thus far. Furthermore, there are costs involved in supporting electronic prescribing that the industry may not be prepared to absorb, transaction fees in particular.

It is important to distinguish the costs associated with supporting electronic prescribing functionality according to the standards to be adopted from the transaction costs associated with conducting electronic prescribing. While some of the larger PBMs have implemented electronic prescribing capabilities and have historically supported the transaction fees associated with providing formulary and benefit information for electronic prescribing, it isn't clear, particularly given how the PBM market is evolving, that payment of these fees by PBMs can or will continue, and there is a lack of precedent for other parties in the chain paying these fees directly. The market will have to sort out where the value from electronic prescribing accrues, and allocate fees accordingly. It will be important for the anticipated pilot tests to carefully measure where and to what extent value accrues from electronic prescribing, in order to better inform the market as to how these costs should be allocated.

One way to reduce the costs associated with providing electronic prescribing technologies to the market will be to implement a single, national set of standards for all electronic prescribing, so that technology vendors do not have to incur inordinate expense in researching and keeping up-to-date on the evolving federal and state regulatory schemes, and developing systems to comply in each jurisdiction in which they operate.

Commenting on: 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.

RxHub Recommendation

It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new versions of the standards must be predictable and timely (in industry time speed) to not negatively impact the movement of the industry to new business functions and needs.

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

RxHub Recommendation:

We agree that the impact of electronic prescribing will have a positive influence on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance. E-prescribing with the development of common standards and streamlined communication between physicians, patients and pharmacy will encourage accelerated adoption based on the value proposition that will be demonstrated. Patients will have the added ability to take a more proactive approach and responsibility for the health care they receive. Electronic prescribing practices will enable patient's to track their medication use to assist in efforts to improve compliance and also allow physicians to monitor risk of abuse by prescriptions obtained through multiple providers and pharmacies.

Commenting on: F. Impact on Technology Vendors & Others (F.R. Page 6271)

We have no estimates for these types of costs and invite public comment from healthcare information technology vendors and others on the impact of e-prescribing.

RxHub Recommendation:
It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. There is a healthy competition and advancement of the industry today as a result of the requirements stated in the MMA. The process of migrating to new versions of the standards must be predictable and timely (in industry time speed) to not negatively impact the movement of the industry to new business functions and needs.

Commenting on: (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.

RxHub Recommendation:
RxHub supports the adopting the formulary and benefit standard and medication history standards as a functional equivalent standard in the final rule and we encourage the piloting of these standards to continue demonstrating and validating what is currently successfully implemented in the marketplace today.

CONCLUSION
RxHub has built a national network that connects all the key stakeholders in the medication prescribing process which includes physicians, pharmacies and payers, thus playing a key role in improving the lives of patients and lowering costs for everyone concerned. Our leadership and success at forging participation and industry alliances has facilitated the development of standards where none existed and the promotion of standards already in industry use.
Functioning as the definitive "national exchange network" for electronic prescriptions—from delivery of relevant information at the point of prescribing for informed decision making through the transmission of the prescription electronically to the pharmacy of patient's choice; has significantly impacted physician adoption.
RxHub will continue to support and assist CMS in the acceleration of adoption in the use of health information technology to achieve better quality outcomes, improved efficiency and reduction on overall healthcare costs.

Sincerely,

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Submitter : Mr. David Karmol **Date:** 04/04/2005

Organization : American National Standards Institute (ANSI)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-0011-P-19-Attach-1.DOC

File Code: **CMS-0011-P**

42 CFR Part 423

Medicare Program: E-Prescribing and the Prescription Drug Program

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

Comments of the American National Standards Institute (ANSI)
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Our submission is divided into two parts, preliminary remarks designed to frame our comments, and comments on the proposed rule itself.

1. PRELIMINARY REMARKS: Description of the U.S. voluntary standards system and the role of the American National Standards Institute (ANSI)

With respect to this proposed rule, the Congress specifically recognized the value of using standards from ANSI-accredited standards developers when it passed the Health Insurance Portability and Accountability Act of 1995. At Sec. 1171(80), Congress chose to define a Standards Setting Organization as one that is accredited by the American National Standards Institute. This recognition and acknowledgement is reflected in the proposed rule.

In the healthcare sector, the American National Standards Institute's Healthcare Informatics Standards Board (ANSI HISB) provides an open, public forum for the voluntary coordination of healthcare informatics standards among all United States standard developing organizations. Every major developer of healthcare informatics standards in the United States participates in ANSI HISB. The ANSI HISB has 27 voting members and more than 100 participants, including ANSI-accredited and other standards developing organizations, professional societies, trade associations, private companies, federal agencies and others.

Because we find that the standardization system, and its terminology, remains a mysterious and sometimes confusing realm, we begin our submission

with the following introductory remarks to provide a basic description of the system that produces standards, and the role that ANSI plays in the system.

The voluntary standardization system in the United States is the most effective and efficient in the world. For almost 100 years, this system has been administered and coordinated by the private sector through ANSI, with the cooperation of federal, state and local governments. ANSI does not write standards; it serves as a catalyst for standards development. The Institute is a unique partnership of industry; professional, technical, trade, labor, academic and consumer organizations; and some 30 government agencies. These members of the ANSI federation actually develop standards or otherwise participate in their development, contributing their time and expertise in order to make the system work.

ANSI has accredited hundreds of standards developers to develop American National Standards across a range of industry sectors. Thousands of individuals from companies, organizations (such as labor, consumer and industrial groups), academia, and government agencies voluntarily participate and contribute their knowledge, talent and efforts to the standards development process.

ANSI determines whether standards developed by ANSI-accredited standards developers meet the necessary procedural criteria to be approved as American National Standards. The document that sets forth these criteria is entitled the *ANSI Essential Requirements: Due process requirements for American National Standards* (also known as the *ANSI Essential* Requirements). ANSI's approval of standards as American National Standards is intended to verify that the principles of openness and due process have been followed and that a consensus of all interested parties has been reached. In addition, ANSI's procedures provide for the opportunity for any interested party at any time to make a claim that an American National Standard is contrary to the public interest, contains unfair provisions or is unsuitable for national use.

The voluntary consensus standards development process has proven its effectiveness across a diverse set of industries and in federal, state and local government processes. These industries include (but certainly are not limited to) telecommunications, medical devices and systems, heavy equipment, agriculture, fire protection, information technology, petroleum, textiles, automotive, aerospace, banking and household appliances. There are now approximately 10,000 ANSI-approved American National Standards that address topics as diverse as dimensions, ratings, terminology and symbols, test methods, interoperability criteria, product specifications and performance and safety requirements. These standards development efforts continue today and are being applied to new critical areas such as the environment, healthcare and homeland security.

ANSI is the official United States member body representative in two non-treaty international standards organizations: The International Organization for Standardization (ISO) and, through the United States National Committee, the International Electrotechnical Commission (IEC). In the conformity assessment area, ANSI accredits organizations that certify that products and personnel meet recognized standards. In addition, through a joint program, ANSI and the American Society for Quality (ASQ) accredit organizations that register quality and/or environmental management systems conforming to the ISO 9000 and/or ISO 14000 series of standards.

In fulfilling its roles and responsibilities, ANSI continues to pursue its mission to "[e]nhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and safeguarding their integrity." In summary, ANSI ensures the integrity of the U.S. voluntary consensus standardization system by serving as (1) an open, national forum for standards-related policy issues, (2) the recognized accreditor of standards developers, ISO Technical Advisory Groups (TAGs) and certain certification programs, and (3) a primary source of information and education on standards and conformity assessment issues.

a.) ANSI Processes and Procedures[1]

As the only accreditor of U.S. standards developing organizations, ANSI ensures the integrity of the voluntary consensus standards development process and determines whether standards meet the necessary criteria to be approved as American National Standards. The goal of standards development within an ANSI-accredited process is to develop a document in an open and balanced process that represents a consensus of materially affected interests. Due process is critical when it comes to determining if that consensus has been fairly achieved. Accordingly, ANSI requires that a draft proposed standard be appropriately circulated (both to the consensus body and the public at large) and that an attempt is made to resolve all negative comments. If a duly constituted consensus body implements its ANSI-accredited procedures and then votes on and approves the proposed document after reviewing all unresolved negative comments and any substantive changes to the text, consensus has been achieved and due process has been satisfied. This process also requires that before any standard with objections is approved as an American National Standard an appeals process must be available and any appeals concluded. This basic formula has been the hallmark of the ANSI process for decades, and it has garnered widespread respect and acceptance.

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[1] The ANSI procedural requirements for accrediting standards developers and for designating American National Standards are available on ANSI Online at <http://public.ansi.org/ansionline/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/ER2003.doc>

If a standard is developed according to ANSI requirements, there should be sufficient evidence that the standard has a substantive reasonable basis for its existence and that it meets the needs of materially affected and interested parties. If a vote on a standard was or is somehow perceived as having been subtly manipulated, any person or entity who participated in the standards development process – whether a voting member of the consensus body or a public commenter – can appeal the decision. The grounds for an appeal to ANSI include procedural issues that relate to a lack of compliance on the standards developer's part with ANSI's Essential Requirements. Issues raised in a procedural appeal may include such concerns as a lack of balance on the consensus body, dominance by any person or entity, inadequate response to a negative comment (again whether from a voting member of the committee or a public commentator), and restraint of trade concerns. The appeals process, and the requirement that all consensus bodies seek to have representatives from a balanced group of stakeholder interests, assures that no one interest can manipulate the process unfairly. The ANSI system is designed so that contrary evidence proffered by opponents of the standard must be properly addressed and responded to or else the standard will fail to achieve ultimate approval.

In addition, proper procedures are of little value if they are not followed in practice. As a result, in addition to the review ANSI undertakes when a standard is submitted to it for approval as an "American National Standard," the Institute also has implemented a mandatory standards developer audit program. The program is designed both to verify an accredited standards developer's compliance with current ANSI requirements and to provide guidance on more efficient or effective ways to address various aspects of the standards development process.

While all American National Standards must be developed in accordance with these basic hallmarks of the ANSI process, accredited developers may satisfy these requirements in innovative ways and rely extensively on electronic communications. If there is a ready consensus by the interested parties on a proposed standard, the standard can meet the procedural requirements for, and be approved as, an American National Standard in a matter of months.

b.) <u>The Public-Private Partnership</u>

While the term "public-private partnership" has been in vogue in Washington in recent years, it has been a reality for ANSI since our creation. In fact, ANSI was founded in 1918 by a group of private sector organizations and government agencies that recognized the need to have a forum in which they could address common concerns. As a private sector organization with many government members, ANSI has a strong tradition of working cooperatively with government as well as industry, organizations, and consumer interests.

ANSI is a private sector organization in which many government representatives are active at all levels, from its Board of Directors to the committees that promulgate, maintain and implement the procedures pursuant to which standards developers are accredited and American National Standards are developed and approved. Government representatives participate in ANSI delegations addressing international standardization policy issues, thereby strengthening the U.S. voice in international standardization negotiations.

When Congress enacted the National Technology Transfer and Advancement Act of 1995 (NTTAA)[2], it specifically and strongly encouraged the participation of the U.S. government, and state and local governments in the development of voluntary consensus standards. It was the clear intent of Congress that federal employees play an active role in the development of standards that will be used in regulation, procurement, and trade. This action by Congress confirmed a basic principle of the U.S. standardization system—that standards-setting is a partnership process in which government and the private sector are equal partners.

In recognition of the benefits of private standards development, the Office of Management and Budget ("OMB") has for nearly a decade directed all federal agencies to incorporate, "in whole, in part, or by reference," voluntary consensus standards for regulatory and other activities "whenever practicable and appropriate," thereby "[e]liminat[ing] the cost to the Government of developing its own standards." 63 Fed. Reg. 8545, 8554-8555 (Feb. 19, 1998) (revision of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," October 20, 1993).

The importance of the private-public partnership was reaffirmed in a series of laws enacted by Congress in recent years, including these:

- Consumer Product Safety Improvement Act of 1990
- The National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)
- Telecommunications Reform Act of 1996
- FDA Modernization Act of 1997

Each of these laws reinforced the principle that the Federal government should rely heavily upon private sector standards, and that the government should participate actively in the development of those standards and the development of policy regarding U.S. standardization objectives.

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[2] Op.cit.

2. COMMENTS ON THE PROPOSED RULE

Issue Identifier: BACKGROUND

ANSI strongly supports the decision made by CMS to issue foundational standards for e-prescribing and the prescription drug program. ANSI believes that the issuance of these rules and adoption of these standards will have a significant effect on the adoption and use of e-prescribing throughout the healthcare system.

Further, ANSI agrees with the background section definitions and choice of criteria for the adoption of foundation standards, and the assumptions made about standards that meet the proposed criteria.

As an editorial matter, it should be noted that some of the references to standards "accredited" by the American National Standards Institute are not correct, and should be changed for clarity. On pages 28, 39, 40, 55, 90 various references are made to standards being "American National Standards Institute accredited," "ANSI-accredited," "accredited by ANSI," and "not accredited by ANSI." In the nomenclature of standards development and approval, the organization that sponsors or hosts the development of standards may be "accredited" by ANSI if the organization's process meets *ANSI's Essential Requirements* for the development and approval of American National Standards. A standard that is developed by an ANSI-accredited standards developer and processed in accordance with ANSI's requirements may be submitted for "approval" as an American National Standard. In summary, organizations should be described as "accredited" by ANSI, standards should be described as "approved" by ANSI.

On page 39, among others, there is a reference to "ANSI-accredited standards development organization." This is a correct and accurate designation, and need not be modified.

Consistent use of this nomenclature will make the proposed language understandable and accurate. The reason for this distinction is that a standards organization may be accredited by ANSI, as required in HIPAA for its standards to be considered, while the organization may publish standards that are not processed through ANSI, and have not been approved as American National Standards.

We agree with, and endorse the criteria proposed to assess whether there is adequate industry experience with respect to proposed standards. With

respect to this issue, we believe that this is achieved by virtue of the fact that an ANSI-accredited standards developer in connection with an American National Standard must comply with the criteria established in the *ANSI Essential Requirements*. These requirements can be found on the ANSI website, at http://www.ansi.org/standards_activities/domestic_programs/overview.aspx?menuid=3

We agree with the selection of criteria for foundational standards in each of the areas addressed in the "Background" section. In particular, we wish to comment on the first criteria for assessing adequate industry experience for foundational standards, that "the standard is American National Standards Institute accredited (sic). We propose this criteria because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to address, and effectively respond to, industry needs."

ANSI believes that its process, which provides that any standard that is approved as an American National Standard must be the result of an open and transparent process, and must be produced by a consensus from a body that is balanced between users, producers, regulators and other affected interests, and is not dominated by any one interest category, is designed to assure that the resulting standard will meet the needs of materially affected and interested parties. While the consensus process does not guarantee unanimity, it does assure that all views are considered, and that contrary views are taken into account. We believe the ANSI process does provide assurance to the Department that standards selected which meet the criteria of ANSI approval will have industry recognition, will demonstrate industry acceptance and implementation, and will reflect the needs of multiple stakeholders.

In endorsing this criteria, ANSI does not mean to imply that the ANSI approval of a standard is the only way to assure industry acceptance and usage of a standard, but that ANSI approval is a useful and recognizable shorthand for determining those qualities, without further in-depth review.

ANSI is working with its accredited standards developers to arrange for the availability of all standards proposed for adoption in this rule, as well as future rulemakings related to e-prescriptions, to be available for purchase or acquisition at terms set by the publisher, and instantly downloadable from the ANSI website at: http://webstore.ansi.org/ansidocstore/default.asp

Since each standard constitutes the intellectual property of the sponsoring standards developing organization that issued the standard, ANSI cannot guarantee that all of the standards proposed for adoption will always be available through the ANSI website. However, it is our goal to maintain such availability to the extent possible. It is also our intention to develop a package of all of the standards referenced in the rule and bundle such standards for the convenience of users and healthcare providers interested in utilizing such standards.

Submitter : Carolyn Gingras **Date:** 04/04/2005

Organization : Lifespan

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-20-Attach-1.TXT

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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
Dear Centers for Medicare and Medicaid Services:
I. Background (F.R. Page 6261 - 6264)
G. Electronic Prescription Drug Program
Provider and Dispenser Identifiers. The MMA Does not expressly direct the Secretary to require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions. However, the NCVHS found that it was important to address the issue of provider identifiers for various e-prescribing standards it reviewed and, more generally, for an electronic prescription drug program. We agree. After assessing a number of candidate identifiers, the NCVHS further recommended the use of the National Provider Identifier (NPI)) as the primary identifier dispensers and prescribers once it becomes available.
Lifespan Response
We believe that a required unique prescriber identifier is vital to the success of e-prescribing. However, using the NPI as it currently exists does not address the reality of prescribers with multiple locations. We are currently utilizing e-prescribing in our environment, which is made up of physicians that do rotate through many locations. We are currently struggling with the routing of transactions because of one identifier that is being used for our physicians. Although the vendor can support multiple identifiers, the pharmacy systems that we deal with cannot handle this situation at this time

Sincerely,

Response to CMS-0011-P NPRM
Page PAGE 2