Submitter : Ms. Carla Saxton

Date: 04/04/2005

Organization : American Society of Consultant Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-21-Attach-1.TXT

CMS-0011-P-21-Attach-2.DOC

CMS-0011-P-22 **Medicare Program; E-Prescribing and the Prescription Drug Program**

Submitter : Dr. Janet Root **Date & Time:** 04/04/2005

Organization : Utah Health Information Network

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Background

See Pages 1 - 9 of Attachment

Collection of Information Requirements

See page 17 of Attachment

Provisions of the Proposed Regulation

See pages 10 - 16 of Attachment

Regulatory Impact Analysis

See pages 18 - 36 of Attachment

CMS-0011-P-22-Attach-1.PDF

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uhin

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April 4, 2005

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

Dr McCellan,

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act. As a state-wide network engaged in exchanging administrative information for over 10 years, the UHIN Community was deeply involved in the implementation of the HIPAA transactions and we believe there is a lot to be gleaned from that experience

Standards The first HIPAA lesson is the need for true unambiguous standards. While the NCPCP Script is an admirable standard its implementation will be subject to variation if HHS only adopts the *Standard* HHS should adopt a specific implementation guide of the NCPDP Script Otherwise, it is likely that grave differences in implementation will arise and interoperability will become a significant barrier to adoption

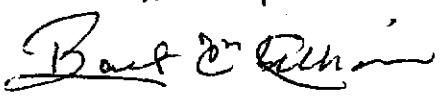
Financial impact. Second, the UHIN Community believes that implementation of these messages will have a significant *financial impact* upon physicians and pharmacists, especially small physician and pharmacy businesses. HIPAA resulted in vendors charging significantly for both HIPAA upgrades and for the ability to exchange messages Several large practice management vendors required their customers to utilize certain exchange entities thereby reducing competition in that market In all likelihood, this will happen again. In all likelihood this will happen again Thus much of the potential economic incentive to adopt the MMA messages will be eroded, particularly for smaller entities It is vital that rural hospitals, pharmacies and providers be protected by this economic impact. Utah is largely a rural and frontier state; we cannot afford to lose these critical access entities.

DEA. Utah is poised to adopt electronic prescribing. One major barrier is the lack of action on the part of the DEA to designate a legal electronic signature mechanism The UHIN Community urges HHS to encourage prompt action on the part of the DEA in resolving this issue.

Privacy The UHIN Community has expressed some doubts about privacy issues that the proposed exchanges may engender, particularly in the exchange of medication history and medical history We understand that payers largely have the right to know both the medication and medical history of their members. However, that right does not extend to pharmacists and physicians. The proposed exchange of medical history from any pharmacy and physician to any other would create the need for these entities to know exactly what patient information could be exchanged and what could not In addition, such an exchange would necessitate the ability to *respond* to an electronic query. This could impose an additional IT burden on pharmacists and physicians

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act We believe this act to be a significant step in moving the entire health care community towards exchanging clinical information which will contribute not only to improving patient care and safety, but also potentially reduce health care costs.

Sincerely,



Bart "C" Killian
Executive Director

Utah Health Information Network

Response to the Medicare Modernization Act Proposed Rules

I. Background

Comment about:

Prescribers may not have access to the latest drug knowledge, do not have a completely accurate medication list or do not have a medical history for their patient, and, may be unaware of potential drug-drug or drug-disease interactions or duplicate therapies

Pharmacists often have difficulty reading handwritten prescriptions and have little or no information about the patient's condition for which the prescription is written May have to contact the prescriber by phone to clarify what is ordered

Mak[ing] changes in the prescription results in delays for the patient and time consuming for the prescriber and the pharmacist

Little or no feedback is given to the prescriber on whether a prescription was filled or refilled

Comment:

There was agreement that the current prescribing process is prone to errors Prescribers do not have easy access to formularies and preferred drug lists; providers do not have easy access to unbiased drug information Usually both formularies and drug information are printed (and are thus mostly unused) Even when a provider downloads them into software like Epocraties, it often takes too much time to use them on an extensive basis Hence use of formularies is usually restricted to the provider's top 2 -3 payers and familiarity with drugs is limited to very common drugs

UHIN providers raised both pro and con points regarding feedback to the provider on whether or not a prescription was filled or refilled While there was agreement that this information may improve quality of care, some physicians are concerned about additional liability and additional uncompensated work However, **physicians are in agreement that they do not want to know whether or not a prescription was filled on every prescription they write** If this information becomes available, they only want to know it about certain prescriptions It is not efficient for them to have this information about every prescription

Pharmacists usually do not have a complete list of drugs the person is taking. Usually their only list of drugs a person is taking comes from their own internal data bases Info on drug-drug interactions from the PBM is spotty at best Therefore most of the drug-drug intervention is primarily driven off the *pharmacists* data base, not the PBMs Will the adoption of these messages assist pharmacists in preventing drug-drug interactions? One important point is that there needs to be a system to rate the potential magnitude of a drug-drug interaction; is it minor, moderate or life-threatening?

There seems to be an assumption that the prescriber will have done any medication history checking prior to the patient presenting at the pharmacy How will the pharmacist know that this has been done? No EDI process is ever 100%; pharmacists need an indicator that medication history has been checked (or not) on incoming prescriptions

Comment about:

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

Comment:

1 Concern was raised about the source of the information on the drug being dispensed

- Would this source of information be neutral or would it be advertising information from the manufacturer?
- Will the drug information data base include negative clinical trials information? Will it include information from the FDA?
- Which data base will be used to monitor potential drug-drug interactions, warnings, and cautions?
- How often will the data base be updated?
- Will all Medicare Part D contractors use the same data base?

The general sense was the different data bases give different information and are more or less reliable

2 Other issues

- Will the PBM be charged with keeping dosage adjustment information? How will they receive this? What about the physicians sample closet –will those types of dosage adjustments be tracked? If yes, how?
- Which message would be used to convey drug-drug interactions, warnings, and cautions?
- Which NCPDP message would be used for drug dosage adjustment information?

Comment about:

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

Comment:
Attention was focused on the last bullet which describes an information exchange of medication history between *payers, prescribers* and *dispensers* as if all three entities could potentially be data sources This particular recommendation does not follow the NCVHS recommendation which limited this exchange to prescribers querying PBMs

There was agreement that an expectation that all three parties might be data sources would dramatically increase the complexity and cost of implementation, particularly for dispensers and prescribers.

There was also concern about managing privacy issues if all three entities became data sources While it is true that if a person holds insurance, there is usually a clause in their contract which states something to the effect that they are allowing the insurer access to their medical information, usually patients who see a need will actively segregate their information so that certain portions of the health care industry do not know all their medical information. However, what if a patient does not want their PCP to know that they had a test for STDs because the PCP is a personal friend of their spouse? While the contract with the payer may require the patient share all medical information with the payer, does it require that the patient share all medical information with ALL their health care providers? There was great concern about the privacy issues such an exchange might open up. While the goal of higher quality care is commendable, should it trump an individuals' right to privacy in all cases?

There was a question about whether large institutions would need to segregate information about inpatient vs ambulatory care. This could be difficult for them to accomplish

Comment about:

Statute: an electronic prescription drug program includes the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed.

"Medication history" refers to drugs that have been prescribed to the individual

"Medical history" relates more broadly to information about the patient's health care and health status (for example, allergies, laboratory test results, and chronic conditions)

Intend to propose standards for communicating medical history at a future date

Comment:

Concern was expressed about how plans were going to accomplish the statute, namely to transmit medical history related to a Part D drug. This will be difficult to impossible because

- Patients often seen providers for more than one reason (particularly patients in this age group)
- Providers often prescribe drugs for off-label use
- Hence there is no link between the prescription and the diagnosis or problem list

There was concern expressed about who was going to do Medication Therapy Management? The physician? The PBM? Who?

Comment about:

"(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed

Comment:

Concerns were raised about who determines what therapeutically appropriate alternatives are

- The group estimated that many drugs are not used for FDA approved diagnoses (off-label use) How will a payer determine what is a therapeutically appropriate alternative if they do not know what symptoms (presumptive diagnosis?) the drug is being prescribed for?
- Given the relatively common off-label use of drugs, how will a payer, whose primary sources of information on a patient are claims, link prescriptions with claim data?
- Given the relatively common off-label use of drugs, how is a plan to link the use of a Plan D drug with a specific portion of a person's medical history? If a drug is being used for off-label purposes how will a 'therapeutically appropriate alternative" be determined?
- What diagnoses code list would be used? Physicians don't use ICD-9 diagnoses for presumptive diagnoses or for true clinical diagnoses
- Who will make the decision about what is 'therapeutically appropriate"?

Pharmacists would like to get information on which brand of a drug is *cheaper for the particular plan*. They may get indications regarding whether it is permissible to substitute a generic but they still don't know WHICH generic to use; they are not told of any pricing arrangements between plans and pharmacy manufacturers

Comment about:

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

Comment:
What is meant by the term *medical history*? What does this encompass? For example, the medical history of a person with asthma might need to involve such factors as triggers, number of recent exacerbations (or a history of exacerbations), etc. Who will make a determination of what constitutes portions of a medical history that are associated with a specific drug?

There was concern about how a PDP could accurately link medical history (presumably derived from claims). Will the PDP be requiring physicians to respond to inquiries about medical history in order to participate with the plan? Responding to an inquiry about a person's medical history could create an enormous burden upon small to moderate sized physician practices Will there be any compensation for this type of work?

What kinds of standards will be used to make the determination that x portion of a person's medical history is linked with a particular Plan D drug? What about medical history being requested from a physician who did not that another physician had prescribed a certain drug? How is the physician going to know what information to respond with?

Pharmacists pointed out that the data on the prescribing physician that they receive is often inaccurate. This will further challenge the ability of the PDP to link medical data with prescription data when the prescribing physician data is not accurate

The group strongly recommends *lengthy testing* prior to adoption of any medical history message as well as an *evaluation of the processes* by which the various parties (PDPs, pharmacies, and physicians) might respond to requests for medication history. Because the rule discussion does not mandate the participation of physicians or dispensers there needs to be extensive testing of the implementation of whatever message is chosen and its impact on the ability of physicians and dispensers to respond. However, one criterion for adoption is that the messages not place an undue burden upon the respondent Medical history could pose an enormous burden to implement

Comment about:

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

Comment:

There was concern about the phrase "to the extent feasible". If the messages are not done real time, these messages will not be adopted by physicians or pharmacists. Real time should be defined as less than a 3 second response

One member of the group has been involved at NCPDP for some time. He mentioned that the Formulary and Benefits message is intended to be a batch download to a formulary repository organization. The UHIN group still wants the query to the formulary repository should be less that 3 seconds. However, the actual message being proposed (the NCPDP Formulary download) would not be a 'real time' message. Only the query to the formulary repository would be real time

Physicians often state that they don't want to support the formularies of dozens (sometimes hundreds) of payers. If formulary repository organizations are going to evolve, their use has to be geared towards creating a favorable climate for physicians to use them. For-profit, charge-by-the-query models may face an uphill battle in adoption

Comment about:

These proposed foundation standards are a first step toward a more complete set of standards required for an electronic prescription drug program under the MMA

Additional final standards will be identified, pilot tested, and proposed through separate processes in accordance with the time frames set forth in the statute and will build on these foundation standards

NCVHS recommends that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future

Comment:
Commenters were in agreement that EMRs need to focus on a single standard

There were no comments on State Preemption or on Anti-Kickback or Stark provisions

Comment about:

HHS believes that it is necessary to have a unique identifier for these transactions

The NPI is the preferred option, because it is a standard that many entities will be required to use under HIPAA*

Comment:
UHIN agrees with HHS that these transactions need a unique identifier for prescriber and dispenser. UHIN suggests that HHS stress that EMRs must be able to handle NPI or other types of national identifiers

UHIN recommends that HHS implement the NPI in synch with the HIPAA schedule. The NPI must first be proven to be a workable, low-error system before it should be adopted by clinical systems

Comment about:

ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors

Meets Adoption Criteria

ASC X12N 270/271 are ANSI-accredited standards

the standards are adopted HIPAA standards

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.

Comment:

There was concern about the phrase:

. 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

The primary problem with the current HIPAA 270/271 transaction implementation is that payers are allowed respond with a simple 'yes this person is a member' or 'no this person is not a member' and to not provide any additional information. Payers are also allowed to set up individual web sites using DDE which can have no relation to the 270/271. As a result 271responses to the 270 are often too meager to be of use to providers Or, to obtain a more robust response, the provider has to visit many individual payer web sites which is time consuming and not productive. This has created a state where there is little impetus for providers to use the 270/271 UHIN suggests that the PDPs be required under the MMA to respond with two pieces of information (1) this person is or is not a member of the PDP, and (2) if the inquiry includes the proposed prescription (in NDC), the response include whether or not this particular drug is covered under this persons PDP benefit Also, UHIN suggests that PDPs not be allowed to use DDE for this transaction It is not efficient for physicians to have to visit many web sites to obtain eligibility information The potential offered in HIPAA for this transaction has not been realized *for providers* because of these two issues

Comment about:

Formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub

RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be considered for adoption as an ANSI-accredited standard

We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards

Comment:
The UHIN group was not in favor of including the *Formulary and Benefits*, and *Medication History* Standards as foundation standards for either pharmacists or physicians No one feels that there is sufficient industry experience to justify this approach

Pharmacists do occasionally receive formulary and benefits information but have not had enough experience to recommend forgoing a pilot None of the physicians in the review had ever had this type of information in an electronic form

There was a question about whether reversed/voided prescriptions (prescriptions that were written but not picked up by the patient) would be included in the Medication history Physicians suggested that there could be value in knowing that information

There was concern that, if the RxHub protocols are only now being adopted by NCPDP, how much experience with these messages *in a rigidly standardized form* has the industry truly experienced? Typically when a message has yet to be adopted by an SDO, the implementers of that message tweak it to meet their individual needs. Even when a message has been adopted, there is usually a spread of implementation that more or less conforms to the standard UHIN has no evidence that *Formulary* and *Medication History* Standards have truly been tested in a standardized and widespread fashion

Although UHIN is aware that RxHub and others have used these messages, *we do not believe there is wide-spread industry experience yet*

Comment about:

The standards cover a range of formulary and benefit data, including information on the--formulary (for example, therapeutic classes and subclasses); formulary status (for example, drugs that the benefit plan considers to be "on formulary"); preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another)

Comment:

There were concerns about plans suggesting an alternative therapeutically appropriate drug for off-label use of prescriptions People questioned whether a plan is in a position to suggest therapeutically appropriate formulary alternatives if they do not know the diagnosis (or the presumptive diagnosis). There is a problem with using ICD-9 or CPT codes for diagnoses in this situation. ICD-9 and CPT have largely been developed to bill, not to record detailed diagnoses or presumptive diagnoses However, there is the issue that physicians and hospitals will mostly like be resistant to having to deal with yet another code list (like SNOMED) The group questioned how the PBM might obtain that information. For example, if the diagnosis is pneumonia, the PBM would need to know that it is pneumoccocal pneumonia vs mycoplasmic pneumonia in order to be able to recommend a therapeutic alternative.

There is also the case when a prescription is being used as a therapeutic trial (there is only a presumptive diagnosis) Health care claims only code for diagnoses; they do not indicate if the diagnosis is tentative or firm How would those situations be handled?

There was a question about where information on a drug would originate. Would this information come from the manufacturer? Would additional clinical trial information be included? Would it include FDA information? There is concern about the need for unbiased drug information, with the caveat that people know that the pharmaceutical manufactures fund most of the research on drugs and that, therefore, historically, much of the information on drugs has not come from an unbiased source.

Comment about:

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry

Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs.

Third, the NCPDP SCRIPT Standard transactions we propose for adoption are recognized as the industry standard

Comment:
One of the criteria for by-passing the pilot is:

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

Based on UHIN's experience in implementing HIPAA, UHIN recommends that HHS go further than simply adopting NCPDP Standards; **HHS should adopt specific implementations of the NCPSP Script Standard.** We recently did a detailed review of the SureScripts implementation of the NCPDP Script Standard and while what SureScripts is implementing is in compliance with the Standard, they have created their own interpretation of that Standard. For example, they often do not send elements or segments that are not required in the Standard.

This is going to create a hodge-podge of implementations of the NCPDP Standard. UHIN recommends the HHS adopt specific implementation guides of the NCPDP Standard rather than just the Standard. As we have learned from HIPAA, 'standards' which are relatively permissive get implemented in a huge variety of ways creating deep interoperability issues.

UHIN's other comment about NCPDP Script is that it appears to be designed for a mail boxing type of approach to exchanging information. Will a mail boxing approach meet the real-time requirement specified in the statute? A truly interactive system requires pushing information instantaneously between trading partners. We believe use of the GETMES will encourage many less than real-time implementations.

There is a feeling that while the parts of the NCPDP Scripts messaging standard which are being proposed for adoption as foundation standards have been tested, they have not been equally tested by all three components of the messages in the MMA rule, namely the providers, the pharmacies, and the PBMs.

It is our understanding that the parts of NCPDP Script which are being proposed as foundation standards include *New Rx, Refills, Changes, Cancellations, Formulary and Benefits,* and *Medication History.* UHIN does not feel that the *Formulary and Benefits,* and *Medication History* portions of the NCPDP Script message have been adequately implemented by all the entities who would utilize the final standard. Neither pharmacists nor physicians think that they have adequate experience with these messages to say that they know they will work. They do not think it has been applied in multiple e-prescribing programs with more than one external health care partner to an adequate degree. To our knowledge, SureScripts is the only program which has implemented even the *New Rx, Refills, Changes, Cancellations* messaging standards across many entities and it is our impression, talking from physicians and pharmacists who have participated in the SureScripts implementations that it could be argued that further work needs to be done on these standards prior to adopting them on a widespread basis.

E-Prescribing standards need to be adopted not only message-by-message but also implementer by implementer. One of the biggest mistakes of HIPAA was to mandate that everyone do all the transactions all at once. This approach created a highly chaotic implementation environment mostly to the detriment of the providers. We strongly recommend that HHS adopt a more

measured approach not only to determining the order in which these messages are implemented, but also the entities which would implement them

There was concern raised about whether the PBMs were going to have more voice about treatment for patients The thrust of the MMA act appears to reduce costs by having input into the prescription at the point of writing the prescription. Concern was expressed that this would interfere with quality care tailored to the needs of the individual patient

It was pointed out that pharmacy and prescribers are somewhat at the mercy of their vendors in terms of what they can implement and how fast they can bring it up. It was also pointed out that pharmacists and providers would bear the brunt of the cost of bringing up these systems and yet much of the benefit would be conferred to the PDPs. There were questions about the motivation for providers and pharmacies to participate in these exchanges There is no obvious motivation written into the rule as it currently stands.

UHIN recommends that the messages in with a solid outline (——) in Figure 1 be adopted as foundation standards UHIN recommends that the messages in outlined with a broken line (– – –) in Figure1 be subject to further testing prior to adoption In particular, UHIN recommends that both the Formularies and Benefits and the Medication History message be tested in the arena of making that information available to pharmacists (upon request) Although the model is that the physician makes these inquires prior to the patient presenting to the pharmacy, there is no guarantee that the physician has actually done so; there is no way for the pharmacy to know this activity has occurred.

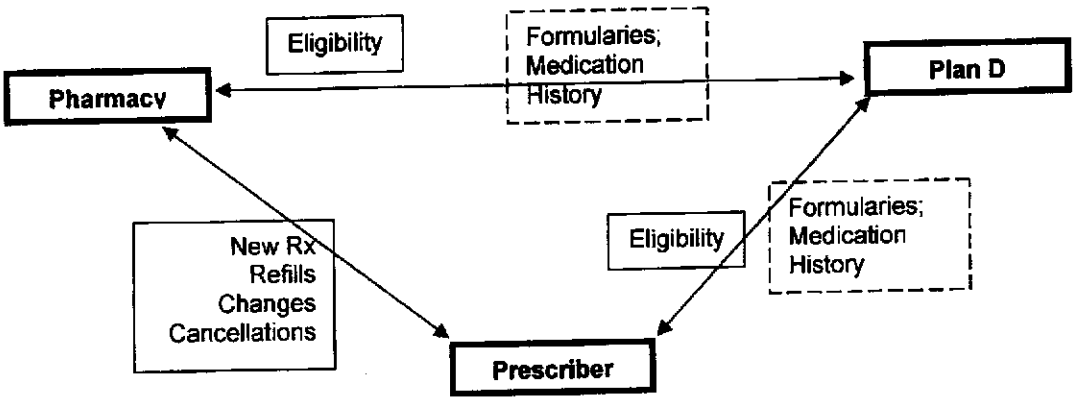


Figure 1 UHIN's recommendations for foundation standards

Comment about:

Except not these parts of NCPDP Script.

the Prescription Fill Status Notification Transaction (and its three business cases

Prescription Fill Status Notification Transaction - Filled,

Prescription Fill Status Notification Transaction - Not Filled,

Prescription Fill Status Notification Transaction – Partial Fill)

These transactions will not be adopted at this time because, there is not adequate industry experience

Comment:

UHIN suggests that the exchange of the Prescription Fill Status Notification Transaction be reviewed for both patient privacy and physician liability issues as well as message functionality prior to adoption Physicians are cautious about any information that might increase their liability burden. If a physician knows that a patient has not picked up a particular medication, what kind of liability does this impose? There is an impression that the liability burden varies from state to state.

Comment about:

NCVHS Testimony.

most health plans/PBMs currently have e- prescribing capability either directly or by contracting with another entity. Therefore, conducting an electronic prescription drug program would not be an additional burden for those plans Since these standards are already in use, we believe the requirement to adopt these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2)

Comment:

There was agreement that the Plan Burden was estimated correctly

Comment about:

- *2003 - 3 1 billion retail prescriptions*
- *Estimate: 2006 as about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan*
- *Estimate 5 and 18 percent of prescribers are conducting e-prescribing*
- *some studies have indicated increased prescriber interest*
- *Predict that MMA will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used.*
- *Predict: the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years*
- *The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of—*
- *Publicity surrounding the Medicare Prescription Drug Program,*
- *More publicity about the benefits of e-prescribing and the experience of prescribers who are participating,*
- *Increased emphasis on health information technology in general,*
- *Potential cost savings to providers using e-prescribing, and*
- *The availability of incentives for participation.*

Comment:
There was agreement that the anticipated 10% annual increase may be overly aggressive Also, if 5 to 18 percent of prescribers are conducting e-prescribing that mean that 95 to 82% are not UHIN feels this is a significant portion of the industry that has not had experience with e-prescribing UHIN recommends a measured approach to implementing the foundation standards.

A concern was expressed about the role of DEA in promoting or inhibiting the adoption of true electronic prescribing Currently the DEAs lack of specification regarding a legally valid electronic signature is holding Utah back from moving aggressively forward in the area of electronic prescribing except for the use of faxes Since the proposed rule clearly does not include faxed prescriptions, the DEA may represent a significant obstacle to the wide spread adoption of true electronic prescribing.

The group commented that the problem with the DEAs lack of action is not that Schedule II drugs constitute a significant portion of the prescriptions – they don't Instead, the problem is that Utah, like most states, wants to develop a *single method* for all electronic prescriptions Until the DEA makes a decision regarding their version of an electronic signature this cannot happen. UHIN recommends that the Secretary encourage the DEA to make a decision and implement their decision prior to the January 2006 implementation date for the MMA foundation standards

There are no obvious cost savings to provider for e-prescribing; e-prescribing may actually slow providers down (i e., take more time)

What is the incentive to participate in e-prescribing? Participants listed several issues that motivate providers towards adopting e-prescribing:

- Ease of use
- Saving time (go home earlier)
- Reduce staff/physician time on prescription issues
- Younger physicians are more likely to adopt (wait until older physicians retire)

Many EMRs only automate the current manual administrative process; they don't have the capability to manage clinical care. There was general consensus that an e-prescribing tool works much better when integrated into a full EMR

There was a suggestion that HHS mandate vendors to comply with certain EMR standards.

Comment about:

More than 8 8 million ADE occur each year in ambulatory care

CITL1 estimates that nationwide adoption of e-prescribing would eliminate nearly 2 1 million ADEs per year prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs.

E-prescribing would promote efficient and effective use of drugs by ensuring that prescribers have up-to-date information regarding advances in drug therapies

Comment:

These statements were quite controversial. There is very little known about ADEs. There isn't really any good information about the number of ADEs per year or the impact of those ADEs on the health care system. The group was somewhat skeptical about the final bullet that e-Rx would promote efficient and effective use of drugs. More studies are needed before these types of statements can be made with some credibility.

Comment about:

Improvements, enabled by e-prescribing programs, will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers.

Comment:

There was some question about the clinical impact of e-prescribing (people cited the recent study showing an increase in certain types of errors in CPOE). People were in agreement that e-prescribing would have a positive impact on problems relating to coordination between pharmacies and health providers; that is, it will be relatively easy to sell office managers on e-prescribing if it can be shown that it improves the workflow in the office. However, it still appears to be difficult to sell e-prescribing to physicians, particularly as a stand-alone tool

Comment about:

Estimate· 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program Because most health plans/PBMs currently have e-prescribing capability, any additional costs associated with hardware/software connectivity would be minimal. The only expense attributable to health plans are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs

Comment:

There was general consensus that this was a valid assessment of the impact on health plans/PBMs People suggested that health plans/PBMs would bear an additional cost to pay for new transaction costs (e g , transactions between prescriber and PBM)

Comment about:

We request comment on our expectation, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. We expect many plans to provide these incentives to prescribers to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. We expect that this will be a transfer of costs from prescribers to health plans, and will neither increase nor decrease the overall impact of implementing an electronic prescription drug program.

Comment:

There was skepticism about whether plans would incur a *substantial* financial benefit from just e-prescribing alone The true benefits to plans are believed to come when providers utilize full EMRs with clinical data analysis capability There was general agreement that a stand-alone e-prescribing tool doesn't bring a lot of value to physicians.

Comment about:

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. We have no basis at this time for estimating the precise timing or magnitude of either gross or net savings We request public comments and information on this topic that we can utilize when revising this analysis for the final rule

Comment:

There was strong agreement with the statement that "we have no basis at this time for estimating the gross or net savings "

Comment about:

Estimate: 5 and 18 percent of physicians and other clinicians are using e-prescribing more than 3 billion prescriptions are written annually

Estimate about 203,000 physician office establishments (~88,061 physicians) The decision to adopt e-prescribing probably rests with the group rather than the individual physician

Expect

e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, magnitude and timing of savings first will have to be demonstrated to many prescribers to induce them to make the "up front" investment in new systems An additional incentive for prescribers to e-prescribe exists, which is the improved patient care that e-prescribing brings

Comment:

There was doubt expressed about the economic benefit e-prescribing would bring to providers. Physicians are most likely to adopt e-prescribing because it saves staff time, particularly on refills and renewals. However, it doesn't seem likely to result in any economic benefit *per se*. The best implementation of e-prescribing is within the context of a full EMR. Stand-alone e-prescribing tools bring very limited value particularly since they are often focused on new prescriptions

Comment about:

We think there are few EMR/e-prescribing vendors are currently using systems that may be in some respects incompatible with these standards We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process. We request comments on whether there are some transition costs attributable to these standards and whether there are steps that we could take to mitigate those costs.

Comment:

People did not agree with the comment "We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process " This is not what happened with HIPAA **Vendors usually charged substantially for these upgrades** Most e-prescribing now is via fax **People expect that there will be substantial cost associated with upgrading to the MMA messages.** In addition to the work to simply connect, there is the internal work to create and manage these messages and their associated data bases

The connectivity will only be effective if providers can connect to a non-profit hub, a RHIO. Without such connections providers will be forced to either connect to many pharmacies or PBMs or to work with for-profit clearinghouses which have proven to be quite expensive on the administrative side

Comment about:

The overall costs of buying and installing systems are several factors including--

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

Expect costs to be defrayed by incentives

We invite comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing

We anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance

Comment:
The group did not see a significant cost savings for prescribers doing e-prescribing. They did envision it as a significant financial investment. The group did see a significant costs savings to pharmacies

Regarding incentives, third party payers appear to be having mixed reactions to the suggestion that they offer incentives to prescribers for e-prescribing. Perhaps of more interest (more potential cost savings) is the Formulary and Benefits message. One provider with an internal e-prescribing tool in place has 95% formulary compliance right now. They don't' envision much ROI for the MMA rules

There were also questions regarding the impact of e-prescribing on ADEs. The group recommended that further studies be done. Very little is known about ADEs

Comment about:

Economic benefits that accrue to prescribers that implement e-prescribing

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

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

Decreased time spent handling prescription renewal requests.

Dramatic time savings that permitted reallocation of nursing and chart room staff

Potential reductions in malpractice insurance

Comment:
The group felt that e-prescribing will have different benefits depending on whether it is part of a full EMR or a stand-alone tool Using a stand-alone e-prescribing tool creates relatively high administrative demands as all the patient information must be entered every time the physician uses the tool to prescribe

People agreed that e-prescribing would result in decreased time in handling prescription renewal requests However, people felt that the economic benefits e-prescribing for new prescriptions was less certain for physicians

Comment about:

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

Comment:

The primary benefits to a physician on e-prescribing may come with increased formulary and generic prescription compliance. Many payers already have systems in place to reward physicians for this. The priority from a physicians perspective is med-med interactions, med-allergy interactions, and then formulary.

One question regarding formulary compliance is whether the plan has a formulary that is structured to increase compliance and whether it is tiered.

Comment about:

Reported benefits.

Reduced time-consuming phone calls to physicians.
Improved accuracy and less time for refill authorizations
Additional time available for patient contact and services
Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).
Improved turnaround time for refill authorizations

Comment:

Pharmacists agree that e-prescribing would result in reduced time calls to physicians, improved accuracy and less time to handle refills. However, pharmacists would not know if a physician had reviewed the current prescriptions a patient was on through the *Formulary and Benefits* message. Pharmacies do have data bases but only of the prescriptions they have filled. It is suspected that there are many people that use more than one pharmacy, primarily out of convenience

It was noted that while physicians and pharmacies bring up these systems, the refill/renewal process will actually *slow down* until the bugs are worked out and people become comfortable with the new routines

Comment about:

Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing

Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.

The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.

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 request additional information on pharmacy impacts.

Comment:

Point 1: The review group had problems with the statement: *Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing*

Many written prescriptions do not reach the pharmacy. The group *does* expect a material change in the volume of prescriptions that reach the pharmacy to fill. The number of prescriptions *written* may not change, but we expect that the number of prescriptions that *reach pharmacies* may increase dramatically. This might pose a challenge to the pharmacies in two ways:

a. It might results in an increase in prescriptions that are filled but then not picked up, which then need to be returned to stock (a very labor intensive process)

b. Patients may come to the pharmacy expecting the prescription to be ready 'immediately' because the physician has said "I've sent your prescription to the pharmacy electronically so it will be ready for you to pick up when you arrive there." In a busy pharmacy it may take over 1 hour to fill any prescriptions regardless of its source. It may be important to manage the expectations of patients

Point 2: The review group had problems with the statement: *Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.*

The group does expect that implementing e-prescribing will have a significant negative economic impact on pharmacies, particularly the small independent pharmacies. Our experience with HIPAA has clearly demonstrated that pharmacies and physicians are usually charged by the vendor for these types of changes. Small business are often more impacted by these charges

Point 3: The review group had problems with the statement: *The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.*

The type of networking that pharmacies currently support is pharmacy to PBM. Most e-prescribing now is via fax, not true e-prescribing. The MMA rule proposes a new connection: that of pharmacy to prescriber. Very few pharmacies are networked to exchange an NCPDP message with a physician; it is a completely different process than faxing prescriptions. **Hence, the costs could be considerable, particularly for small independent pharmacies.**

Point 4: The review group had problems with the statement: *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*

Point 4 basically states that adoption will only occur where there is a good business case for it. If the business case were so obvious, it would have been adopted much sooner. Is it a reasonable

assumption that there will be little/no cost to pharmacies? Probably not It may be voluntary only in the sense that if you do not do it you will go out of business.

Comment about:

Expected benefits

appropriate drug compliance management and Improved medication use,provide information to prevent adverse drug events

improve patient safety by detecting various kinds of prescribing errors, duplicate prescriptions; drug-drug, drug-allergy, drug-disease interactions, incorrect dosage strengths prescribed, problems relating to coordination between health care providers and pharmacies

Drive physicians to appropriate formulary choices.

Comment:
The group did not see how the rule would impact improved medication *use* There did not seem to be any evidence supporting this claim.

From the patient's perspective, most of the benefits are driven by the use of good *decision support* which is tied into data bases on drug-allergy, drug-drug and drug-treatment information The messages which might most impact the patient are the Fill Status Notification messages The group has concerns about this from two perspectives:

1) Will this bring additional liability to physicians?
2) Will patients view it as a violation of privacy?

The one member of the group who has brought up an e-prescribing system noted that they can be quite effective but *physicians must first put in a lot of time tuning them.* For example, physicians may get bombarded with warnings about drug-drug, or drug-allergy interactions many of which may be irrelevant or unimportant to the particular patient. Each physician sets up rules regarding which warnings will actually be presented. This takes time and effort.

Comment about:

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

Comment:

While nothing in the rule creates direct costs there will be many indirect costs to patients There will be a cost to patients to subscriber to the MMA Plan D benefits Patients who subscribe to Plan D benefits who are also covered under Medicaid will lose their Medicaid drug benefits (which may not be beneficial to the patient) The group had heard reports that other senior's plans are also going to drop their drug benefits in favor of the Medicare drug benefits; so there will be a cost to patients for participating in this system

The group did not agree with the claim that there will be a reduction in patient mortality and morbidity There are not enough metrics done at this point to make the claim believable

Comment about:

- *Expect*
  - *Growth of e-prescribing as business potential for healthcare information technology vendors*
  - *Costs associated with e-prescribing and potential business opportunities could be allocated toward new product development.*
- *Question. Impact on entities such as*
  - *pharmaceutical and medical device manufacturers,*
  - *public health organizations,*
  - *research institutions*
  - *academic institutions*
  - *professional lay organizations*
- *We invite public comment on the impact of e-prescribing for these entities*

Comment:

Public Health: the public health potential in this exchange is significant:
Prescription drugs can be used a surrogate measure of several chronic diseases
Pharmacists could send reports to the state's controlled substances data base real time.
Public health will need funding for infrastructure and training to realize this potential.

Research: Research could also benefit significantly as long as patient's privacy is adequately protected

Other entities which will be significantly impacted are rural pharmacies and rural providers, particularly hospitals Rural clinics, (e g , the rural community health centers) often act as the only acute and ambulatory care centers in the community The rule must be structured so that it does not negatively impact these critical facilities

Comment about:

Approximately 95 percent of pharmacy firms, which account for about 51 percent of pharmacy establishments, are small business (1997 Census data)

Estimate that more than 29,000 pharmacy establishments would be considered small entities Includes almost all physicians in private practice

Expect

proposed rule would have an impact on a substantial number of small businesses due to the percentage of pharmacies and providers that are small businesses distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale

However as many as 75 percent of pharmacies already are conducting e-prescribing and 5 to 18 percent of prescribers are using this technology

This demonstrates that it is economically beneficial

Predict 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

Welcome comments on this conclusion and additional information on the small business effects of this proposed rule

Comment:
Most of the e-prescribing currently being conducted by pharmacies is fax, not true e-prescribing. **We believe there will be a significant impact on small pharmacies.** The group is not convinced that e-prescribing alone has been shown to have a positive economic benefit for physicians, particularly those in small businesses. 95-82% of physicians are NOT currently using this technology; therefore we believe the economic case has not yet been made on the physician side

We are unsure what an Initial Regulatory Flexibility Analysis is, but if it could show that small pharmacies and providers, particularly rural pharmacies and providers would be negatively impacted then that should be documented Furthermore, those groups should be protected in the final rule if necessary

We recommend that small pharmacies and providers who work in under served areas be given special considerations in the implementation of this rule. It is critical that these organizations continue to exist We do not believe this rule has adequately taken their special issues into account.

There was an additional concern about the Formulary and Benefits message Rural pharmacies do not always have a particular drug on hand Physicians need to be able to says something to the effect that "I am prescribing this particular drug even though it is not on the formulary because it is the only drug available [without driving 100 miles] to this patient in this location "

Comment about:

- *Small rural hospitals*
  - *small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds*
- *Expect*
  - *Proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay*
  - *Proposed rule would not have a significant impact on small rural hospitals because the e-prescribing provisions are both voluntary and cost-beneficial for prescribers*

Comment:
Most of Utah's rural hospitals (all except 1 have less than 100 beds) have swing-bed licenses and act as long-term care facilities for the local population. This rule will have an impact on these hospitals because an outpatient care service is a significant percentage of their revenue. As we stated above, the group is not convinced that e-prescribing has a positive economic impact, particularly if implemented in a stand-alone setting (i e, not as part of a full EMR) Most of these small hospitals do not have anything approaching an EMR

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

Organization : **Kaiser Permanente**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Thank you for your consideration of Kaiser Permanente?s views. If you need further information or have questions, you may contact Kristin Bear at 626.405.5963.

Issues

Background

Preemption

We encourage CMS to take a more expansive view of federal preemption. The MMA states that provisions promulgated under the MMA preempt any state law that either (a) is contrary to federal standards on e-prescribing promulgated under the MMA or (b) restricts the ability to carry out the e-prescribing provisions of the MMA; and that pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under the MMA. CMS?s proposed interpretation would only preempt state law that is contrary to the MMA standards, not state law that restricts the ability to carry out the purposes of the e-prescribing provisions of the MMA.

Organizations that implement electronic prescribing systems do not adopt two systems: one to comply with federal law and one to comply with state law. Organizations must design systems to comply with the most restrictive standard. Large multi-state organizations must design systems to comply with the most restrictive state standard, resulting not only in financial and administrative burden, but also overall barriers to electronic prescribing. Restrictive state laws that place barriers to electronic prescribing create disincentives to adoption of electronic prescribing programs entirely because organizations cannot create systems that only apply to prescriptions covered by the MMA. If a state law restricts the ability of organizations to implement electronic prescribing under the MMA, then the state statute should be preempted. Where state law stands as an obstacle to accomplishing and executing the full purposes and objectives of Congress, CMS should apply ?implied conflict? preemption to that state law. (See, e.g., Three Affiliated Tribes of Fort Berthold Reservation v. Wold Engineering, 476 U.S. 877 (1986).)

Formulary & Medication History

Kaiser Permanente recommends that any proposed standards for formulary or medication history messaging not be considered as foundation standards to be implemented by January 2006. There is insufficient time for organizations to adopt new technology or modify existing technology to comply with new standards. Adoption in such a short time frame would also be costly and administratively burdensome. Given that standards for these two functions are still in development, Kaiser Permanente recommends that formulary and medication history standards be pilot tested.

Future Standards

Kaiser Permanente recommends that future standards include a standard for electronic signatures, in cooperation with the DEA. We strongly believe that any electronic signature standard must not require Public Key Infrastructure (PKI) technology. Other technology for electronic signatures is more common in existing electronic prescription systems, and any requirement for PKI would impose significant costs on organizations, which would deter adoption of electronic prescribing. A limited requirement for PKI, e.g. for transmission of Schedule II drugs only, does not remedy these concerns. Faced with a choice of adopting potentially cost-prohibitive technology or ?carving out? those prescriptions that require PKI technology for electronic transmission, organizations are likely to maintain paper processes for those prescriptions that would require PKI technology, resulting in a subset of prescriptions that do not benefit from the patient safety and quality of care advancements of electronic prescribing. Other technology for electronic signatures currently in use is secure and reliable in verification of prescriber identity, certainly more secure than currently permitted oral prescriptions, without the unnecessary expense of PKI. Adoption of a standard including PKI would serve as a deterrent to adoption of a complete electronic prescription drug program. Kaiser Permanente recommends that a future standard for electronic signatures be based on the E-SIGN Act definition.

Provisions of the Proposed Regulation

Applicability to Closed Enterprises

Kaiser Permanente strongly agrees with the NCVHS that internal communications within a ?closed enterprise? should be subject to the MMA standards. An integrated organization like Kaiser Permanente, which includes a health plan, pharmacies and a physician medical group in each geographic region where it operates, can implement secure and efficient electronic systems that meet the intent and purpose of the MMA if given the flexibility to do so. Prescription transmissions within a healthcare enterprise can be more easily verified because the enterprise also engages in activities such as credentialing to verify prescribers? licensure and DEA registrations, and utilization review and quality assurance across the enterprise. A closed enterprise can also more closely monitor and enforce the use of security measures, such as use of logon id and password, to better assure the integrity of electronically transmitted prescriptions. Prescribers and dispensers within an organization may also have direct access to Electronic Health Record databases for medical history, medication history, formulary, and eligibility and benefits information. Flexibility in implementation of electronic prescription programs encourages interoperability with EHRs resulting in a more complete electronic system, greater access to information by health care providers, and enhanced patient safety and quality of care.

Further, access to an organization?s own databases should not be considered a ?transmission? of data requiring compliance with these standards. One hallmark of a ?closed enterprise? is a shared health information infrastructure and often shared databases among parts of the enterprise. Access to an organization?s own databases should be outside the scope of the MMA standards.

Requiring organizations to convert their internal systems to MMA standards would not necessarily enhance security of internal transmissions, but would be a

significant administrative burden and cost to the organization, and possibly delay full implementation of an electronic prescription drug program. Organizations that have maximum flexibility to adopt secure electronic systems will be encouraged to expand these systems beyond individual prescribers and medical offices to all parts of the closed enterprise, such as hospitals, skilled nursing facilities, and home health agencies, resulting in better integration of health care information that enables better care.

For consistency, we suggest that CMS adopt a definition of ?closed enterprise? that is similar to the HIPAA definition of ?organized health care arrangement? for purposes of identifying transmissions within an enterprise that would be outside the scope of these rules. Specifically, we suggest that CMS either reference the HIPAA definition of an ?organized health care arrangement? or adopt the following definition:

A ?closed enterprise? is

1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider that share a common electronic health information system;
2. An organized system of health care in which more than one covered entity (as defined by HIPAA) participates and in which the participating covered entities:
a. Hold themselves out to the public as participating in a joint arrangement; and
b. Participate in joint activities that include at least one of the following:
i. Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; or
ii. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; and
c. Share a common electronic health information system

Submitter : Dr. M.Ruiza Yee

Date: 04/05/2005

Organization : Dr. M.Ruiza Yee

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The effective date for e-prescribing standards should be extended. The final standards formulated may be skewed as it was developed by pharmacy industry members. Also, the standards do not support the Medicare Prescription Drug, Improvement and Modernization Act (MMA) requirements.There should be more pilot testing.

Submitter : Dr. Janis Chester

Date: 04/05/2005

Organization : American Association of Practicing Psychiatrists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The regulation will put patient privacy at risk by forcing more physicians to become covered entities under HIPAA, and by encouraging the use of unsafe electronic communication systems.

Issues

Background

There are two problems with this proposal for electronic prescribing. (1) It forces all physicians who engage in electronic prescribing to become covered entitites under HIPAA and (2) it ignores the fact that nation's electronic information systems are highly vulnerable to hacking and corruption.

With respect to HIPAA, the Amended Privacy Rules allows the release of personal health information without patient consent for the purposes of treatment, payment and health care operations. This is allowed in spite of the fact that the Department of Health and Human Services has noted, 'the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. More than anything else, the relationship between a patient and a clinician is based on trust.' HIPAA legalizes violation of this trust which is prohibited by professional ethics. Therefore increasing the number of physicians who are covered entities under HIPAA will increase the number of patients who are at risk to have their privacy legally violated.

With respect to the lack of security with the use of electronic prescribing, the findings of the President's Information Technology Advisory Committee show that electronic information systems are highly vulnerable to hacking and corruption, the vulnerabilities are increasing at a rate of 20% a year, and the vulnerabilities cannot addressed without redesigning the information systems from the ground up to build in security measures. 'Cyber Security: A Crisis of Prioritization' (February 28, 2005).

Provisions of the Proposed Regulation

Proposed regulations will increase the number of physicians who are covered entities under HIPAA. This will put patient privacy at risk.

Regulatory Impact Analysis

The regulation will put patient privacy at risk.

Collection of Information Requirements

see above

Submitter : Mr. Elliot Stone

Date: 04/05/2005

Organization : Massachusetts Health Data Consortium

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

MHDC convened a meeting of its membership representing providers, pharmacy benefit managers, payers and e-prescribing vendors to coordinate a Massachusetts community response to the NRPM. Please see the attached response which includes the comments made by the group and recommendations on specific issues, as well as factors in lessons learned from the MedsInfo-ED project.

CMS-0011-P-26-Attach-1.DOC

Massachusetts Health Data Consortium, Inc.

MHDC Response: CMS-0011-P - Electronic Prescribing and the Prescription Drug Program

SUBMITTED BY

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INTRODUCTION

Massachusetts Health Data Consortium (MHDC) welcomes the opportunity to respond to the CMS proposed rules for e-prescribing. Founded in 1978 by the state's major public and private health companies, MHDC's mission is to "lead the development of a comprehensive data system to address the health information needs of the Commonwealth for the purpose of improving health care and health." Massachusetts, long recognized as a world class center of medical excellence, is also recognized for its innovative use of state-of-the-art healthcare IT.

MA-SHARE, LLC was established by MHDC in 2003 as a vehicle to advance the introduction and deployment of clinical data exchange (CDE) in Massachusetts. MedsInfo-ED, a patient safety initiative that makes available patients' dispensed drug history from multiple data sources to emergency department clinicians, is MA-SHARE's first clinical data exchange project. This project is the first step towards the development of an Rx Gateway which will support end-to-end e-prescribing. In addition, MedsInfo-ED helped to identify critical "lessons learned" that could present barriers to successful e-prescribing. These lessons ranged from technical to regulatory to procedural issues; some of which could be easily resolved through existing collaborative efforts while others will require amending current state legislation.

In mid-March, MHDC convened a meeting of its membership representing providers, pharmacy benefit managers, payers and e-prescribing vendors to coordinate a Massachusetts community response to the NRPM. The following response includes the group's comments and recommendations on specific issues, as well as factors in lessons learned from the MedsInfo-ED project.

BACKGROUND

Definition of Electronic Media

Faxed Prescriptions: The MHDC members discussed whether a prescription that originates electronically from an e-prescribing tool (e.g., EHR, CPOE or stand-alone e-prescribing application) with a computer-generated fax of the prescription sent to the pharmacy that was then printed on paper is an electronic prescription subject to these rules. The group consensus was that dropping a prescription to paper (printing a faxed prescription) is *not* e-prescribing. In addition, there needs to be a standard for the information that is conveyed in a faxed prescription and how it is presented. MHDC recognizes that creating a fax standard is beyond the scope of this Rule. However, we recommend that a committee should be established to explore fax prescription standard formats. A pilot could explore the fax issues and move this issue forward. In the interim, the SureScripts standard for faxed prescriptions could be used as a potential starting point for establishing standards for faxed prescriptions.

Scope of Preemption, specifically State Preemption

Restricted Access to Sensitive Medication Information: Pre-emption of state regulations that limit access to or transmission of prescription information is critical to accelerating the adoption of e-prescribing. For example, federal and Massachusetts state laws restrict access to sensitive drug information that indicates the treatment of AIDS/HIV, mental health disorders and substance abuse. Clinicians need access to a comprehensive medication history, specifically sensitive drug information which might be difficult to accurately ascertain from the patient. The information about these sensitive drugs is particularly important when treating a patient and prescribing other medication, and is directly related to patient safety. Until this restriction is lifted for treatment purposes, sensitive drugs are not included in drug-drug interaction checking (DUR) and clinicians risk prescribing new medications that will have an adverse drug interaction with the patient's current medication regimen. A (more) complete medication history allows clinicians to be proactive versus reactive.

Cumbersome Consent Processes: In addition to preventing access, some state regulations impose a consent process that creates a cumbersome, if not impossible, workflow process to obtain real-time access to medication history. Massachusetts state insurance regulations require that additional written consent be obtained in advance before a health plan can release information related to AIDS/HIV treatment, and before indemnity carriers, including Blue Cross Blue Shield, can release information related to mental health treatment. These regulations, enacted before legislators and the healthcare industry envisioned payer data being used for direct patient care in real-time, limit access to the patient's medication history.

E-Prescriptions for Controlled Substances Not Allowed: The prohibition of electronic prescriptions for controlled substances (i.e., the requirement of a handwritten or "wet" signature) is another example of a regulatory barrier to e-prescribing. The group estimated that 15 to 20% of prescriptions are for controlled substances. Each time a prescriber is required to write a paper prescription over an electronic prescription, there is a risk that he or she will abandon the electronic e-prescribing solution entirely. The industry needs to explore ways to protect the integrity of prescriptions for controlled substances while allowing them to be electronically transmitted.

Partial Solutions Thwart Adoption: Bottom line, any state or federal regulation that engenders a partial solution (e.g., the ability to view a partial medication history or electronically submit certain types of prescriptions) will discourage e-prescribing adoption. Pre-emption of these regulations will address these local regulatory barriers.

Criteria to Access "Adequate Industry Experience"

While MHDC concurs with the criteria for accessing adequate industry experience, we believe that the relatively low adoption of e-prescribing nationwide warrants conducting a pilot to "test run" the formulary and medication history standards prior to their being named foundation standards. A pilot would help identify areas for improvement, review interoperability, and confirm ability to provide medication history across pharmacy benefit manager data sources.

Standard Evolving and Setting Process

Standards Update Process: The group was concerned that if the standards were modified to accommodate technical changes or correct technical inconsistencies without an open public comment process, that this could be an issue for e-prescribing. MHDC recommends that the standards development organization (SDO) responsible for a standard be the body that determines if an update to the standard is minor, requiring no comment period beyond the normal internal process of the SDO. The experience in adopting changes to the HIPAA transactions for minor corrections has shown that the full Federal rule-making process is cumbersome and results in delays that impede industry use of named standards.

Drug Identification Schemes: MHDC also suggests that a coding scheme be adopted for drug identification that can be used for clinical representation. Such a code set could be adopted as a standard through the National Library of Medicine, in the same manner that was used for SNOMED codes. The industry needs to accelerate the development of RxNorm for general distribution. It is imperative that the e-prescribing standards meet the clinical requirements of prescribers.

Eligibility 270/271 Transaction: MHDC believes that the industry also needs to focus on the 270/271 Eligibility transaction, which is an essential building block for reliable clinical data exchange. There are still issues with the implementation of the 270/271 eligibility transaction after HIPAA transaction standards went into effect. For example, MedsInfo-ED — MA-SHARE's early-stage clinical data exchange initiative that provides dispensed medication history to ED clinicians — uncovered a difference in interpretation regarding the data used for the 271 response that affected the ability of clinicians to verify patient data from approximate data matches. The 271 response should return demographic data on file with the PBM (i.e., data source being queried) and not simply echo the 270 request data (i.e., original patient search criteria). This is important because some PBMs use probabilistic matching such that Smith and Smythe are considered a match.

Such differences between data entered and data returned need to be displayed for users to identify inexact matches, and inform the requesting clinician of the possibility of a false positive match and data integrity issues, or simply the need to verify the patient and misspelling errors in the search criteria entered. It should be noted that any time a user begins to suspect the veracity of information presented by an e-prescribing application (or any other healthcare information system), the risk of clinician abandonment increases. It is very challenging to turn around a negative perception of a clinical data exchange project.

MHDC recommends that language be included in the Final Rule to help reduce such conflicting interpretations. The language should state that usage clarifications and explanations issued by the authoring body in the standards development organization are to be recognized as normative for the standards named for e-prescribing.

Avoid Multiple Sets of Standards: The MHDC members briefly discussed the risk of one set of named standards for Part D beneficiaries and another set for other classes of patients. The general consensus was the industry is not likely to adopt two sets of standards because of the time and expense involved in the standards setting effort. The group felt strongly that only one set of standards be promulgated for all patient classes to help reduce the cost barrier associated with standards compliance, and to encourage e-prescribing adoption by providing a single solution for multiple situations.

MHDC Recommends Piloting Standards: Piloting the various named standards provides an opportunity to fully evaluate the standards implementation and make modifications before the standards are widely deployed. RxNorm is still in its nascent stages of development and could use more refinement before it can replace the current (imperfect) drug coding schemes. There may be other, similar 270/271 implementation issues like those identified by the MedsInfo-ED project, that will impact e-prescribing that would be discovered through piloting the named standards. MHDC believes that the relatively low adoption of e-prescribing nationwide warrants conducting a pilot to "test run" the named standards.

Use of NPI and/or Alternatives

The use of the NPI should not be accelerated for e-prescribing. The group believed that the healthcare industry could not absorb accelerating the NPI; most entities will not be ready before the regulations go into effect May 2007. The industry should continue to use the current numbering scheme for e-prescribing.

Formulary, Benefit and Medication History Standards

MHDC believes that at the present time, there is no widespread agreement on a single standard for formulary and medication history. However, adoption of such standards should be accelerated and be included as foundation standards. We welcome the suggestion that the RxHub formulary standards be submitted for evaluation and adoption by NCPDP. By seeking broad industry input that includes a focus on the clinical use of these standards, clinically-oriented standards for formulary and medication history can be developed.

Clinicians noted that formulary messages should support the e-prescribing process by alerting clinicians if a drug is off formulary or requires prior authorization by the payer. Marketing messages from pharmaceutical companies promoting one brand of drug over another included in a formulary transaction were perceived to hinder the e-prescribing process and stand in the way of the physician-patient relationship. These types of messages should not be allowed by the standard.

When the standard for medication history is issued, that standard should provide explicitly for all drug information, including sensitive drug information to be reported to a clinician. This provision should preempt any local laws prohibiting such information from being included in medication history.

The healthcare industry should expect that the various stakeholders will collaborate to establish standards that will best suit the clinical requirements of prescribers. A concurrent pilot of proposed standards will assist in developing and refining appropriate standards. Such pilots can be readily undertaken in Massachusetts. Rx Gateway, MA-SHARE's next clinical data exchange project, will support end-to-end e-prescribing including checking for formulary compliance and drug-drug interaction by obtaining access to medication history.

PROVISIONS

Use Standards within the Enterprise

MHDC urges that there be no requirement for enterprises to use standard e-prescribing transactions when the data is exchanged within the enterprise. While organizations with

large closed systems may easily adopt the named standards for internal use, other organizations should not be required to modify internal systems. We believe that there would be no benefit to patient care or ease of use in requiring the named standards to be used for internal data exchange. In addition, requiring remediation of internal transaction systems could be unnecessarily expensive for enterprises, and further discourage e-prescribing adoption.

IMPACT ANALYSIS

Health Plan e-Prescribing Incentive Programs Impacts on Plans and Providers

MHDC would like to underscore that incentives, either by rule or other inducements, be put in place to encourage prescribers to implement e-prescribing tools. Since the Rule does not mandate that e-prescribing be adopted, health plans, pharmacy benefit managers, dispensers, and other entities may incur large costs to implement with little usage. In the interest of patient safety as well as administrative savings, universal adoption should be encouraged and accelerated.

GENERAL COMMENTS

Suggestions for Improvements

Privacy and the Minimum Necessary Information Requirement: MHDC acknowledges that while the Rule needs to address privacy concerns, electronic prescriptions should not be subject to the administrative burdens imposed by HIPAA. Specifically, all data sent in the SCRIPT transaction, even if marked optional in the standard, is "necessary" for the prescription process and is information exchanged between covered entities for treatment purposes. Therefore, the Rule should state that all data in the SCRIPT messages named under this Rule are considered to meet the Privacy standard of the minimum necessary information and no additional document is required by covered entities when the transactions are exchanged between covered entities.

Electronic vs. Digital Signatures: The group consensus was that there is not enough industry experience with public key infrastructure (PKI) technology to use digital signatures for e-prescribing, especially at the individual prescriber level. Furthermore, PKI requires significant administrative overhead to establish and maintain digital signatures. MHDC recommends that the electronic signature from faxed document is sufficient for faxed prescriptions, and an equivalent authentication process other than PKI be established for end-to-end e-prescribing.

Date: 04/05/2005

Submitter : **Mr. Gregory Weishar**

Organization : **PharmaCare**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Background

See Attachment.

Regulatory Impact Analysis

See Attachment.

Collection of Information Requirements

See Attachment.

Provisions of the Proposed Regulation

See Attachment.

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

Date: 04/05/2005

Submitter : Mr. Brian Bamberger

Organization : MediMedia USA, Inc

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-0011-P-28-Attach-1.DOC

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 D rug Program NPRM (42-CFR Part 423) – Comments

Dear Centers for Medicare and Medicaid Services:

MediMedia appreciates the opportunity to comment on the Medicare Prescription Drug Benefit notice of proposed rule-making (NPRM).

MediMedia Information Technologies is a division of MediMedia USA, a $250 million publishing company. One of the world's leading providers of healthcare communication, educational materials and services, MediMedia is an *independent* international company with a reputation for t he quality and i nnovation of i ts products, and the s trength of it s t ruly global representation.

We own and distribute the InfoScan Formulary Database, which contains more than 3,400 health plan, PBM, PPO and self-insured employer formularies. In addition to most of the plans associated with Rx Hub and CAQH, we represent many of the smaller plans and PBMs who have thus far chosen not to affiliate with those organizations.

We have been providing a formulary database to electronic health records (EHR), computerized physician order entry (CPOE) and ePrescribing software companies since 1994. O ur clients inc lude W ebMD's M edical Manager, GE M edical's M edicaLogic, Cerner, NextGen, Misys and others – a veritable a "who's who" of mature health care information technology providers.

I. Background (F. R. page 6257)

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.

MediMedia Recommendations:

Our p resident, Brian Bamberger, w as o n t he t ask g roup t hat r esponded to t he NPRM on behalf of NCPDP. We agree with NCPDP's comments on preemption.

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

MediMedia Recommendations:
We agree that E-prescribing is a complex process, and that there are different levels of technology. A possible misperception is that most technology solutions have the ability to perform patient eligibility checks. In reality, most do not.

There are many challenges associated with eligibility checking. On the physician software side (ePrescribing, EHRs and CPOE systems), there is a larger percentage than we believe CMS realizes that are legacy systems and do not have electronic connectivity outside the group practice or enterprise setting. Upgrades have been slower than expected because of the costs.

Systems that have electronic connectivity have just two choices today: (1) RxHub or (2) direct to a health plan or PBM. While plans and PBMs are proficient at eligibility checking in the claims world, many are not yet ready to transmit information that would accommodate linking to formulary and benefit information. Of note, *only two of the three RxHub founders* provide eligibility information.

The way the majority of prescribers link to formulary is as follows: the ePrescribing, EHR or CPOE system demographic information – including health plan – from the practice management system (PMS). The pre-loaded formulary has a plan name. When the formulary plan name and the plan name coming from the PMS match, the prescriber is linked to the formulary. The prescriber isn't aware of any of this, as it all takes place behind the scenes.

We think that it is important that CMS understands this prior to moving forward with the Part D program. We describe the best way to address this later in our NPRM response. In summary, we recommend that PDPs be required to provide a formulary identifier on their benefit cards.

(F.R. page 6263)
We propose the following critical characteristics for formulary and benefit data standards:

MediMedia Recommendations:
Even though we have greater marketshare than RxHub, we were willing to work with them to enhance their proprietary formats to make a contribution to the marketplace. As the proposed formulary & benefits standard moves through the NCPDP accreditation process, we continue our support. We think that the combination of the industry experience gained from RxHub proprietary formats and collaboration of different stakeholders meets the characteristics that are critical to becoming a formulary standard.

That said, we do think there are components of the formulary and benefits formats that are redundant, such as the preferred alternatives list.

We are also not comfortable with the proposed standard's treatment of prior authorization. For example, while each drug has a 100- and 200-character text field, the resource link is at the benefit level. We believe that it should be available at the drug level so that a link to prior authorization information can be provided.

For very appropriate reasons, many fields are optional (conditional). We agree with this approach so that plans can have maximal flexibility. However, for CMS to extract the greatest benefit from the formulary & benefit standards, we recommend that CMS require its PDPs to provide specific information.

One example that would provide value to CMS and prescribers is prior authorization. When a PDP requires prior authorization of a medication, the PDP should be required to provide an indication -- a flag -- through the formulary and benefit standard so that the prescriber understands that a pre-authorization request is required. Nearly as important are notes that provide a sense of PDP's rules, and the previously mentioned resource link. In our experience, if CMS does not require PDPs to 1) make available a flag, 2) summarize rules in the form of notes and 3) supply a URL link to prior authorization plans, only a small percentage of them will provide this information.

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).

MediMedia Recommendations:

We support the proposed foundation standards without pilot testing.

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

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.

MediMedia Recommendations:

While we support NCPDP SCRIPT as a foundation standard, we agree with CMS's proposed exception of not requiring SCRIPT within the enterprise. As noted in the preamble, our clients tend to be the "who's who" of clinical software companies, many of which are enterprise systems' vendors. As such, we believe we have a handle on ePrescribing in the enterprise environment.

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.

MediMedia Recommendations:

As we noted in Background, E. Current E-Prescribing Environment (F.R. page 6260), eligibility transactions are not common in ePrescribing. The largest volume of eligibility checks for linking patient to formulary is through RxHub, and there are also some eligibility transactions that go directly to some plans. However, not every plan or PBM wants to go through RxHub for many reasons. Some are concerned for competitive reasons. Others are not ready to take on the costs. Still others are apprehensive of an entity gaining that kind of leverage.

In general, physicians utilizing ePerscribing, CPOE and EHR software applications that do not connect to RxHub have had an exceedingly difficult time identifying a patient's formulary.

To facilitate linking the formulary to the patient, we recommend that the "issuer field" on the NCPDP's "Pharmacy ID Card Standard" include an ability to include a formulary identifier, and that CMS require its PDPs to use it for this purpose.

The field is available to describe the issuer and we recommend than an issuer be required to have an identifier for each formulary being offered. Using this field to identify not only a health plan but the specific formulary the patient is using would allow physicians to quickly identify the list of drugs being used for the formulary including preferred, non-preferred, prior authorized and prescribing limitations from third party databases such as ours.

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.

MediMedia Recommendations:

Requiring the eligibility transaction without requiring the formulary indicator on the pharmacy ID card will have the unintended consequence of either forcing all ePrescribing players to go through RxHub or another not-as-yet established player. The impact of this on PDPs will be substantial, and may not be in the best interest of the industry.

In the absence of the standardized ability to adjudicate prior authorization electronically, the formulary and benefit standard should be modified to accommodate prior authorization information, and PDPs should be required to provide a (1) prior authorization flag, (2) summary of rules and (3) URL linking the prescriber to the plan's prior authorization forms.

Sincerely,

Brian Bamberger, President
MediMedia Information Technologies.

Submitter : Mr. Robert Marotta

Date: 04/05/2005

Organization : WebMD Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Background

See Attachment

Provisions of the Proposed Regulation

See Attachment

Regulatory Impact Analysis

See Attachment

CMS-0011-P-29-Attach-1.DOC

WebMD

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April 5, 2005

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

Re: Comments of WebMD Corporation regarding 42 CFR Part 423; Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

To Whom It May Concern:

WebMD Corporation ("WebMD") commends the Centers for Medicare and Medicaid Services ("CMS") for its leadership in convening health care industry stakeholders in the effort to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"). In this regard, WebMD welcomes the opportunity to respond to certain provisions of the proposed rule.

By way of introductory background, WebMD is comprised of three business units, each of which is a national leader in providing health care information services and technology solutions for participants across the health care continuum:

- WebMD Health, with more than 20 million visitors a month, is the nation's leading consumer-focused health care information Web site. WebMD Health is also the leading provider of personalized, co-branded health and benefit management web sites for use by approximately 15 million beneficiaries of large c orporations a nd health p lans. These websites enable consumers to become more educated and pro-active in choosing health plans, treatments, and care providers. Additionally, WebMD Health's Medscape service is the leading destination on the Web for physicians and other health professionals. The site has over 500,000 physician visits per month and, in 2004, Medscape members completed more than 800,000 CME credit hours making Medscape the leading online source for continuing professional education.

- WebMD Business Services is the health care industry's leading clearinghouse for electronic health care transactions, processing over 2 billion transactions per year. More than 300,000 medical and dental providers, 5,000 hospitals, 36,000 pharmacies and

laboratories and 600 information system software vendors rely on WebMD Business Services to connect to nearly 1,200 commercial and governmental health care plans.

- WebMD Practice Services is the leading national provider of integrated physician practice and clinical management systems, supporting thousands of practices sites nationally.

Due to the nature and scope of these operations, WebMD is committed to promoting the development and adoption of interoperable health care information services and technology solutions, including the adoption of standards for electronic prescriptions. Accordingly, WebMD supports and participates in the activities of the eHealth Initiative and such standards development organizations as ASCX12, Healthcare Information and Management Systems Society ("HIMSS"), HL7, NCPDP and other national and state organizations to promote electronic data interchange. Given its connectivity infrastructure and the extent of its installed electronic health technologies, WebMD is committed to working with CMS toward achieving the adoption of standards for an electronic prescription drug program under Title I of the MMA.

General Comments

WebMD supports the adoption of the definitions proposed at 42 CFR 423.159(a) and the "foundation" standards (*i.e.*, standards for which pilot testing is not required) proposed at 42 CFR 423.160, to include:

- NCPDP SCRIPT Standard, Version 5.0, as delimited, for communicating a prescription or prescription-related information between prescribers and dispensers.
- ASC X12N 270/271, Health Care Eligibility Benefit Inquiry and Response, for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.
- NCPDP Telecommunication Standard Guide, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

Specific Comments

I. Background [*FR*, 6256]

A. Statutory Basis [*FR*, 6256-6259]

- Electronic Media [*FR* 6257]

WebMD does not object to the proposed use of the definition of electronic media found at 45 CFR 160.103 to determine when a prescriber is electronically transmitting prescription information in a manner that must comply with the proposed standards for an electronic

prescription drug program under the MMA, which amended Title XVIII of the Social Security Act ("Act").

2. State Preemption [*FR*. 6258-6259]

Based on a close reading of the MMA, WebMD concurs with the Department of Health and Human Services' ("HHS") proposed interpretation that the preemption provision of Section 1860D-4(e)(5) of the Act has effect only with respect to prescriptions and prescription-related information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically under the MMA's e-prescribing program. However, WebMD believes that the preemption provision, even if narrowly interpreted, will still have the practical effect of establishing "field preemption." WebMD submits that the effect of establishing e-prescribing standards for the Medicare Part D drug program will be comparable to the impact of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") on state pharmacy laws and regulations.

In brief, OBRA 90 amended Medicaid to require pharmacists (a) to obtain, record and maintain individual patient profile information for Medicaid beneficiaries, (b) to perform prospective drug utilization review before filling prescriptions for Medicaid beneficiaries, and (c) to offer to discuss the unique drug therapy regime of each Medicaid patient when filling their prescriptions. To comply with OBRA 90 and, more importantly, to rationalize practice standards, the States amended their respective pharmacy laws and regulations to require pharmacists to provide the mandated services not only to Medicaid beneficiaries but also to all patients, regardless of payment source.

In sum, WebMD believes that, even in the absence of HHS broadly interpreting the MMA's preemption provision, state policy makers, with few exceptions, will not require dispensing pharmacists to comply with one set of e-prescribing requirements for Medicare Part D individuals and another set of requirements for the rest of the population. At the same time, WebMD would not suggest that the process of bringing state e-prescribing laws into conformity with the standards established under the MMA will be seamless, timely or transparent. The e-prescribing industry will continue to face many tests and challenges in complying with applicable state law.

The first test of the practicality of HHS' proposed interpretation of the MMA's preemption provision will be how states react to the e-prescribing definition proposed at 42 CFR 423.159(a):

> *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.

WebMD is not aware of a single state that has adopted an "e-prescribing" definition as broad as the one HHS has proposed. More importantly, WebMD has identified at least fourteen

states that specifically require electronic prescriptions to be transmitted directly to the pharmacy, with no intervening person having access to the prescription.[1] Historically, the vast majority of such prohibitions were adopted to ensure that pharmacy benefit managers did not gain access to prescriptions electronically transmitted between prescribers and pharmacies for purposes of either "steering" prescriptions to mail service pharmacies or initiating therapeutic substitution activities. While direct transmission requirements would not affect prescriptions transmitted directly over the public telephone network, these requirements, applied literally, prohibit the use of e-prescribing networks to route prescriptions from prescribers to pharmacies, to ensure that prescriptions contain all information required by law in the proper format, or to maintain a copy of a prescription transaction for transmission receipt audit purposes.

WebMD urges HHS to prepare to undertake an educational campaign in cooperation with the National Association of Boards of Pharmacy to educate policy makers at the state level of the implications of the e-prescribing standards adopted under the Medicare Part D drug program.

C. Standards Design Criteria [*FR* 6260]

Section 1860D-4(e)(3)(C) of the Act specifies that e-prescribing standards be designed so that they (a) do not impose an unreasonable administrative burden on prescribers and dispensers; (b) are compatible with standards established under Part C of Title XI, standards established under Section 1860D-4(b)(2)(B)(i) of the Act and general health information technology standards, and (c) permit the electronic exchange of drug labeling and drug listing information (RxNorm) maintained by the Food and Drug Administration ("FDA") and the National Library of Medicine ("NLM").

WebMD relies on the products of two commercial database vendors for the drug labeling and drug listing needs of its e-prescribing products—First Databank and Wolters Sklewer. Both vendors have advised WebMD of a concern that RxNorm may be incomplete.

WebMD suggests that, prior to implementing the RxNorm mandate, HHS should ensure that RxNorm's content is validated for completeness. Further, HHS should ensure that the NLM develop a translation table between RxNorm and the commercial database publishers. Such an approach would enable the point-of-care e-prescribing software community to achieve the goal of normalizing drug labeling and drug naming while avoiding the costly process of redesigning existing systems that interface with RxNorm.

F. Evolution and Implementation of an Electronic Prescription Drug Program. [*FR* 6261]

The MMA establishes a timeline for adopting the standards required by the Act to implement the e-prescribing program requirements under Medicare Part D. Section 1860D-

[1]Arkansas, Delaware, Georgia, Hawaii, Iowa, Kansas, Massachusetts, Michigan, Mississippi, Montana, Virginia, Washington, West Virginia and Wyoming. Additionally, in June 2004, the Pennsylvania Board of Pharmacy proposed rules that would prohibit any intervening person from having access to an electronically transmitted prescription. The Pennsylvania rule making is now pending.

4(e)(4)(A) of the Act requires the Secretary to adopt initial, uniform e-prescribing standards no later than September 1, 2005. Section 1860D-4(e)(4)(C)(i) requires the Secretary to conduct a pilot project to test the initial standards between January 1, 2006 and December 31, 2006. However, Section 1860D-4(e)(4)(C)(ii) does not require pilot testing for any initial standard for which there is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. Further, the Act requires the Secretary to conduct an evaluation of the pilot project and submit a report on the evaluation to Congress not later than April 1, 2007. Finally, Section 1860D-4(e)(4)(D) requires the Secretary to promulgate final standards not later than April 1, 2008.

At 70 FR 6261, HHS explains its criteria for identifying those standards for which pilot testing would not be required (*i.e.*, "foundation" standards for which there is "adequate industry experience") and invites comment not only the criteria but also on (a) how to establish a process to evolve the proposed foundation standards and additional standards (b) how to determine an appropriate implementation sequence that is consistent with the Administrative Procedures Act and other legal requirements, and (c) the role of standard setting organizations and the National Committee on Vital and Health Statistics ("NCVHS").

WebMD believes that the criteria proposed by HHS for determining "adequate industry experience" for the purpose of identifying and adopting those standards for which pilot testing will not be required pursuant to Section 1860D-4(e)(4)(C)(ii) are appropriate and defensible. The criteria include the following:

- The standard is American National Standards Institute ("ANSI") accredited.
- The standard 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.
- Key industry stakeholders have recognized the standard as the industry standard.

WebMD also believes that the criteria reflect and support the critically important role of ANSI-accredited standard-setting organizations in producing appropriate standards for the MMA e-prescribing program. WebMD would also note that the NCVHS process established by the Act has amply demonstrated that standard settings organizations, particularly the National Council for Prescription Drug Programs ("NCPDP"), are responsive to industry and governmental recommendations. Moreover, the criteria outlined above preserve NCPDP's ability—as a voluntary, consensus-based organization—to balance the recommendations of e-prescribing software vendors, the pharmacy industry, prescribers and NCVHS.

G. Electronic Prescription Drug Program. [*FR* 6261]

HHS has requested comment on three proposed standards to support the Medicare Part D e-prescribing program: provider and dispenser identifiers; formulary and medication history;

and medical history transmission. HHS has also requested public comment on any other standards that should be considered for adoption that do not appear on the chart at 70 FR 6262.

- Proposed Use of the National Provider Identifier ("NPI") [FR 6262-6263]

HHS proposes at 70 FR 6262-6263 to adopt the NPI as the primary identifier for dispensers and providers for the e-prescribing program under Medicare Part D because it is the standard that covered entities will be required to use under The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). However, HHS notes that it may not have the capacity to issue NPIs to all covered providers by January 1, 2006, the effective date of the Medicare Part D drug program. HHS also notes that NCVHS has recommended that HHS allow the use of the NCPDP Provider Identifier Number for dispensers and the NCPDP HCIdea® for prescribers in the event that the NPI cannot enumerate covered providers in time for implementing the e-prescribing program under Medicare Part D.

WebMD supports the use of the NPI for Medicare Part D e-prescribing transactions, once it becomes available. In the interim, WebMD supports the use of the NCPDP Provider Identifier Number for dispensers. For prescribers, however, WebMD strongly recommends the use of Drug Enforcement Agency ("DEA") registration numbers until the NPI is available. While the DEA may not approve, virtually every payor, every e-prescribing software vendor, and every pharmacy system currently uses DEA numbers to identify prescribers. Conversely, NCPDP HCIdea® is not a complete database, and it has not been widely adopted by stakeholders. Moreover, both prescriber and pharmacy systems would require modification to support the use of NCPDP HCIdea®. Because systems will eventually have to be modified to support the NPI, it would be costly and shortsighted to require systems to be modified twice to accommodate the NCVHS interim proposal.

- Formulary and Medication History Standards [FR 6263-6264]

WebMD supports the adoption of RxHub's formulary and medication history standards by the NCPDP. Once these standards have been recognized by the NCPDP and ANSI-accredited, we support their adoption for formulary, benefit and medication history messaging as foundation standards.

- Medical History Transmission Standards [FR 6264]

WebMD understands that HHS is not statutorily authorized to propose or adopt standards for the transmission of a patient's medical history until after the Secretary adopts final standards for the Medicare Part D e-prescribing program. The delay is appropriate because such standards will necessarily have to comply not only with HIPAA privacy and security requirements but also with the interoperability standards envisioned by the establishment of a National Health Information Network facilitated by HHS' Office of the National Coordinator for Health Information Technology.

In addition to the three standards addressed above, WebMD respectfully urges HHS to adopt a standard that provides guidance regarding how a prescriber's drug product selection instructions may be communicated in an electronically transmitted prescription under the Medicare Part D drug program.

- Standard for Communicating Prescribers' Drug Product Selection Instructions.

With a few exceptions, state pharmacy laws do not provide specific guidance for how prescribers' drug product selection instructions are communicated in electronically transmitted prescriptions, whether transmitted computer-to-computer or computer-to-facsimile machine. Clearly, the existing requirements for written prescriptions cannot be applied to electronic prescriptions. Where handwritten signatures and/or handwritten instructions are required, applicable electronic commerce law[2] makes such requirements unenforceable. Further, even though bit-mapping technology can be used to replicate handwritten signatures and instructions (to include handwritten initials, check marks, and abbreviations), few, if any, vendors employ technology that meets the implicit requirement that such handwriting be created contemporaneously with the creation of the prescription. Finally, bit-mapping technology cannot be employed in electronic prescriptions transmitted computer-to-computer because the SCRIPT standard format does not support graphical images.[3]

Additionally, state pharmacy laws require a wide variety of terminology and formats to communicate drug product selection instructions. With respect to the former, for example, the following phrases are required among the states: "Do Not Substitute"; "No Drug Product Selection"; "NDPS"; "Dispense as Written"; "DAW"; "Brand Necessary"; "Brand Medically Necessary"; "Medically Necessary"; and "May Not Substitute." With respect to the latter, some states have also required two, discretely labeled signature lines or boxes of a specific size with labeling requirements in or on which prescribers are expected to insert a check mark, an abbreviation, or their signatures in their own handwriting.

In sum, requiring electronically transmitted prescriptions to comply with the same requirements for communicating drug product selection instructions in written prescriptions is neither reasonable nor enforceable. To accommodate the requirements of electronic commerce law and the limitations of electronic prescribing technology, HHS should adopt standards to provide specific guidance to pharmacists on how drug product selection instructions may be separately addressed in electronically transmitted prescriptions.

The SCRIPT standard provides such guidance for computer-to-computer transmissions. For prescriptions that are electronically transmitted between the prescriber's computer and the pharmacy's facsimile machine, however, WebMD respectfully recommends that HHS adopt a

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[2] The Uniform Electronic Transactions Act, which has been adopted by 45 states and the District of Columbia, and the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. §§7001-7006, 7021, and 7031.

[3] In prescriptions formatted according to the SCRIPT standard, drug product selection instructions are transmitted as numeric values: "Ø" for substitution permitted and "1" for substitution not allowed by prescriber. See SCRIPT Standard Format Implementation Guide, Version 5.0 (May, 2004).

separate standard for communicating the prescriber's drug product selection instructions. WebMD would support a standard that would require the inclusion in the prescription of the phrase "Brand Necessary" or any other mechanism that clearly indicates the prescriber's intent to prohibit drug product selection.

H. Summary of Status of Standards for an Electronic Prescription Drug Program. [FR 6264]

WebMD believes that HHS has adopted a sound strategy for phasing in the implementation of a Medicare Part D e-prescribing program. Indeed, given the strict timeline imposed by the Act for the adoption of e-prescribing standards and the criteria HHS has proposed for identifying foundation standards, the standards proposed in the current rulemaking are the only standards HHS could possibly adopt prior to the January 1, 2006, the effective date of the Medicare Part D drug program.

WebMD also concurs with HHS with respect to the strategy the agency envisions for ensuring that future standards (to include DUR, dosage adjustment, and the availability of lower cost therapeutic alternatives) are interoperable with emerging standards for Electronic Health Records ("EHR"). Further, by adopting foundation standards that are ANSI-accredited and have industry experience, the HHS strategy will facilitate interoperability with later industry-adopted standards for EHRs, across software and hardware products. WebMD is active in several organizations involved with the development of EHR standards, including HL7, and will work to ensure that the interoperability goals are achieved.

II. Provisions of the Proposed Regulation. [FR 6264]

B. Proposed Definitions. [FR 6265]

WebMD commends HHS for incorporating the definition of "electronic media," as found in 45 CFR 160.103, into the proposed definition for "e-prescribing." As a result, the proposed definition not only supports the most common means of electronically transmitting a prescription but it also ensures that prescribers will be able to transmit prescriptions electronically to virtually every pharmacy in the U.S. under the Medicare Part D e-prescribing program.

For example, prescribers using WebMD's e-prescribing software electronically transmit some 200,000 prescriptions per month. All such prescriptions are formatted in the SCRIPT standard and transmitted via an e-prescribing network to the pharmacy specified by the patient. However, 63% of these prescriptions are destined for pharmacies that are not technologically capable of receiving a SCRIPT-formatted prescription. As a result, the original SCRIPT-formatted content of the prescription must be reformatted at the network into a graphical image so that the pharmacy's facsimile machine can receive it via a point-to-point transmission over telephone lines.

WebMD would note that other e-prescribing software vendors have taken slightly different but equally compliant approaches to transmitting computer-to-facsimile prescription

transactions. In all such transmissions, the common element is that the electronic prescription never takes physical form in the prescriber's office prior to transmission.

C. Proposed Requirements for Part D Plans. [FR 6265]

HHS requests comment on whether Part D plans should be required to use the standards for e-prescribing transactions within their respective enterprises. WebMD believes that, consistent with the goal of achieving national interoperability for health information transactions, it is essential for all covered parties to support a single standard for prescription transactions: the NCPDP Script Standard.

Recognizing that many Part D plans have already invested significant funds to enable HL7 messaging for e-prescription transactions within their enterprises, WebMD recommends that such Part D plans be grandfathered in at the time of adoption of final standards, provided that the data in such systems is available for interchange with external systems in the required format. Part D plans that implement e-prescribing systems within their enterprises after the adoption of final Medicare Part D e-prescribing standards should be required to comply with the SCRIPT Standard.

E. Proposed Standards.

As noted above, WebMD believes that the proposed standards for prescriptions and eligibility transactions meet the criteria of being ANSI-accredited standards for which there is adequate industry experience. Accordingly, WebMD supports their adoption as foundation standards in the proposed regulation and concurs that entities with e-prescribing programs should be required to comply with such foundation standards, if adopted, by January 1, 2006.

1. Prescription. [FR 6265]

Concerning the proposed adoption of a foundation standard for the transmission of prescription and prescription-related information, HHS has proposed adoption of all SCRIPT Standard transactions (*i.e.*, business processes) save for the Prescription Fill Status Notification Transaction and its three business cases, on the ground that the latter set of transactions lack adequate industry experience, based on testimony before the NCVHS. WebMD concurs and therefore supports the adoption of the limited set of SCRIPT Standard transactions. Further, WebMD believes that the NCPDP transactions that HHS has identified as ancillary messaging and administrative transactions do not require pilot testing.

IV. Regulatory Impact Analysis. [FR 6268]

A. Overall Impact. [FR 6268-6269]

WebMD believes that, while the adoption of e-prescribing standards by HHS will provide critical guidance to the software industry, such standards will do little or nothing to spur physician adoption of e-prescribing practices. WebMD's experience, to date, is that less than 5%

of active clinicians are using e-prescribing software products. While the number of e-prescribers has dramatically increased in the last 18 months, this increase is primarily due to physician adoption of integrated EHR systems. In an integrated EHR, the e-prescribing module is a component of the full system, and the prescription writing process becomes a critical component of the workflow of patient treatment.

WebMD believes that, to achieve higher than the modest 10% annual growth that HHS predicts, cost savings experienced by other stakeholders must be shared. The organizations achieving the most dramatic cost savings are the payors, through better drug regimen compliance, improved patient outcomes, fewer adverse drug events and hospitalizations, better utilization management, and increased generic substitution.

Based on WebMD's field experience marketing e-prescribing systems, WebMD has concluded that, at best, prescribers view creating and issuing prescriptions electronically as time and cost-neutral within the patient treatment process. They believe this instinctively, in spite of data to suggest that, even if it takes a few more seconds to issue a prescription electronically, the savings in deferred phone calls is substantial. Prescribers believe that since health plans, among all stakeholders, stand to accrue the largest share of the financial benefits derived for the adoption of e-prescribing practices, these organizations should provide compensation to prescribers who adopt e-prescribing practices.

While prescribers are primarily concerned with patient health and safety, they are also small business owners. Accordingly, they are averse to discretionary investments that do not yield a return on investment. WebMD believes that "pay for use" is necessary to dramatically increase physician adoption of e-prescribing practices.

WebMD also believes that other incentives, such as payments to subsidize the costs of hardware and software, while well intended, are misguided. Without an ongoing revenue model, prescribers will take advantage of "one time" incentives but have no commitment to utilize the technology going forward.

D. Impact on Pharmacies and Other Dispensers. [FR 6271]

Based on marketplace experience, WebMD does not believe that 75% of the 57,208 pharmacies in the U.S. are online and receiving SCRIPT-formatted prescriptions. Although a substantial number of pharmacies have signed contracts with e-prescribing networks, and while some chain drug store operations are nominally EDI-capable, the number of pharmacies that are actually receiving computer-to-computer prescription transactions is much smaller. For example, WebMD provides e-prescribing systems to prescribers in 39 states. Of the 200,000 prescriptions these prescribers transmit electronically each month, 63% must be re-formatted from SCRIPT for transmittal to the pharmacy's facsimile machine.

WebMD believes that, as the number of prescribers who issue prescriptions electronically grows, more pharmacies will enable SCRIPT-compliant technology because it is operationally more efficient than computer-to-facsimile transactions and, more importantly, it enables

electronic prescription refill transactions. While WebMD believes that the pharmacy industry is committed to embracing SCRIPT-compliant prescription transactions, HHS should not underestimate the costs, logistics, and training required to migrate to that capability. However, as noted above, the proposed "e-prescribing" definition ensures that electronically transmitted prescriptions under the Medicare Part D drug program can be delivered for the foreseeable future to virtually every pharmacy in the U.S. with little or no additional expense to the pharmacy industry.

If you have any questions regarding this matter, or desire further clarification or information, please contact me.

Respectfully submitted,

Robert D. Marotta
Senior Vice President

Submitter : Ms. Kristin Lewis

Date: 04/05/2005

Organization : Tufts Associated Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Due to work required and cost to update e-prescribing systems and applications, we recommend that there be a clear review process for any proposed changes to the standards and that all parties be given at least one year to accommodate and implement any changes to the e-prescribing standards.

Issues

Background

Standard Evolving and Setting Process. In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. CMS invites 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. Specifically, CMS invites comment regarding the role of industry standard setting organizations and the NCVHS.