Submitter : Ms. Kristin Lewis

Date: 04/05/2005

Organization : Tufts Associated Health Maintenance Organization

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Foundation standards should not include marketing messages from pharmaceutical companies promoting one brand of drug over another included in a formulary transaction.

Issues

Background

Formulary, Benefit and Medication History Standards. CMS sets out the characteristics the Agency will consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicits comments on those characteristics. CMS further solicits comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards.

Submitter : Ms. Kathryn Kuhmerker

Organization : NYS Department of Health

Category : State Government

Date: 04/05/2005

Issue Areas/Comments

GENERAL

GENERAL

Other Comments

Federal Medicaid law mandates that a prescriber certify in their own handwriting that a brand-name drug is medically necessary for a particular recipient. NYS has several means to promote the dispensing of generic drugs. For example, the NYS Board of Pharmacy mandates generic substitution for prescriptions filled in NYS and the NYS Medicaid program also requires prior authorization for a brand-name drug when a generic equivalent is available.

Prescribing for Medicare recipients with dual-eligible status, for secondary billing purposes, would still need to meet the above Medicaid program's 'brand medically necessary' requirements. As CMS has oversight over both the Medicare and Medicaid programs, clear guidance is needed from CMS to all state Medicaid programs regarding how the requirement for 'brand medically necessary' in the prescriber's own handwriting can be accomplished through electronic prescribing. As this is a national issue, we suggest a change in federal law regarding certification in a prescriber's own handwriting or at a minimum development of a standard for electronic prescribing consistent with state mandatory generic programs/laws and federal laws to meet the intent of the 'brand medically necessary' requirement.

New York State would like to participate in the pilot testing of e-prescribing that will take place during the 2006 calendar year. As part of its efforts to reduce fraudulent prescribing, New York State initiated an Official Prescription Program that prevents alteration of paper prescriptions. In conjunction with that effort, the State is encouraging prescribers to use e-prescribing to prevent theft of these Official prescriptions, and as a means to further reduce fraud.

NCVHS has not advanced to HHS any recommendations for standards pertaining to exchange of medication history and medical history for the e-prescribing program. New York State recommends the use of existing systems where they exist.

HHS is considering use of the NPI for Medicare Part D e-prescribing transactions, and is looking for alternatives to NPI, especially in the short term. New York State supports the use of the NPI, as well as use of State issued professional licenses and Provider Identifiers, to identify e-prescribers.

Thank you for the opportunity to comment.

Issues

Background

The NYS Medicaid program is generally supportive of the proposed electronic prescribing rules provided that appropriate, flexible standards and patient safeguards are developed. This proposed rule may have a sweeping impact on all third party payers and result in standards adopted by all third party payers.

Background

Current E-Prescribing Environment

While NYS recognizes that electronic prescribing may speed prescription processing, we are concerned about potential steering of recipients to specific pharmacies, as well as directing prescribers to specific drugs. This is especially a concern when pharmaceutical manufacturers 'donate' hand held prescribing devices, software or hardware to prescribers or institutions. In order to prevent steering and safeguard a patient's freedom of choice, CMS must develop patient safeguards.

Electronic Prescription Drug Program

Critical messaging for formulary and benefit information must include, at a minimum, standardized third party billing information and patient/physician options for coverage of non-formulary drugs.

In relation to Medicare Part D and any potential wrap-around coverage provided by Medicaid programs for their dual-eligible population, it is imperative that foundation standards provide standard specific messages to pharmacies emphasizing that Medicare is the primary payer, especially when a secondary payer is billed as primary (i.e., Other Insurance--Bill Medicare first). A patient's insurance coverage listing the primary and secondary payers should be available to prescribers through the electronic exchange of information between the sponsor and prescriber. This would aid a prescriber in selecting an appropriate covered drug under the primary payer's formulary.

In addition to aiding the prescriber in selection of covered drugs under Medicare Part D or any primary payer, if a necessary drug is non-formulary, the pharmacy/physician messaging must include a message that the plan sponsor's exception process may be accessed.

Submitter : Mrs. Elise Smith **Date:** 04/05/2005

Organization : American Health Care Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Issues

Background

Comments on Medicare Program; E-Prescribing and the Prescription Drug program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P

CMS-0011-P-33-Attach-1.PDF

202-898-2828
hdaub@ahca.org

April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-0011-P

Re: Comments On Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule *Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P.* AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical LTC. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L.108-173, signed into law on December 8, 2004, took a giant step forward in providing increased benefits to Medicare beneficiaries in the critical area of prescription drugs. The legislation established a new voluntary prescription drug benefit under a new Part D of the Medicare program which is to be effective January 1, 2006. The new Medicare Part D will provide many benefits and also many challenges.

AHCA was pleased to submit comments on the proposed Part D rule implementing the MMA,[1] particularly in areas directly affecting LTC residents and LTC facilities.[2] We were gratified at CMS' responsiveness to our concerns in the Part D final rule[3] and in the guidance that CMS issued on March 12 regarding performance and service criteria for network LTC pharmacies (NLTCPS) and requirements for Part D Plan sponsors for a process for coverage transitions. There is still work to be done and many issues to be addressed, but we believe that CMS has made great progress. We value being part of the mutual effort of the government and the private sector to help Part D achieve its full potential of achieving better lives for our citizens, and in particular the lives of residents in LTC, and in continuing to improve the quality of their care.

The MMA also required that prescriptions and certain other information for covered drugs that are transmitted electronically must comply with final uniform standards promulgated no later than 2008 by the Secretary. These standards must meet MMA's requirements, as well as be compatible with other standards, including standards adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In the final Part D rule published on January 28, 2005, CMS requires Medicare Part D Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006. On February 4, 2005, CMS published the proposed rule providing the first set of uniform final standards for electronic prescribing (e-prescribing) under Part D for which we are now providing comments.

The Importance of E-Prescribing in the LTC Environment

The use of the standards is mandatory solely for Part D sponsors and even then only to receive or reply to e-prescribing transactions initiated by other entities. Providers that prescribe or dispense Part D drugs are required to comply with the standards only when they electronically transmit prescription information or certain other related information.

CMS indicates that while 75 percent of the 57, 208 pharmacies in the United States already have e-prescribing capability, only between 5 and 18 percent of physicians and other clinicians are e-prescribing. Except for certain exceptional initiatives,

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[1] *Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule, 69* Federal Register *46632,* August 3, 2004.

[2] We use the term LTC facilities to refer to nursing facilities and intermediate care facilities for the mentally retarded (ICFs/MR). CMS expanded the definition of the term "long term care" facilities in 42 CFR 423.100 of the Part D final rule to encompass ICFs/MR.

[3] *Medicare Program; Medicare Prescription Drug Benefit, Final Rule*, 70 Federal Register 4193, January 28, 2005.

AHCA assumes that few if any physicians are e-prescribing with respect to residents of LTC facilities. This picture must change. The benefits of e-prescribing for patients are enormous. CMS articulates just some of the potential benefits as follows:

- E-prescribing can help prevent medication errors because, at the time of prescribing, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication.
- E-prescribing can also improve quality, efficiency, and reduce costs, by:
    - Improving patient safety and quality of care through immediate access to medication history information, and the prevention of adverse drug events;
    - Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
    - Speeding up the process of renewing medications; and
    - Providing instant connectivity between the health care provider, the LTC pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.
- E-prescribing also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, CMS also believes that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management (which is designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions) will be enhanced by e-prescribing.

CMS believes that these improvements, enabled by e-prescribing programs, will occur through, among other things, improved prescription drug-related quality and disease management efforts, and ongoing improvements in information systems 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. CMS also believes that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented.

It is clear that all these benefits and enhancements to quality of pharmacy care, deriving in great part from advancements such as e-prescribing, must be provided to LTC residents as well as Part D beneficiaries who do not reside in LTC facilities. They will constitute an advancement in -- and become a fundamental and integral

part of -- the quality of care in LTC facilities. Nationally, there are 1.6 million nursing home residents; this is a major group taking multiple medications and each medication requiring multiple nurse/physician communications (phone and fax) on a regular basis.

The benefits of e-prescribing that CMS articulates could assist LTC facility compliance with Medicare and Medicaid requirements of participation. For example, the survey guidance for requirements governing medication errors and unnecessary drugs is currently undergoing major revision under CMS contract to the American Institutes for Research (AIR). The AIR product is intended to provide specific information to assist surveyors in making appropriate determinations and severity assessment of noncompliance cited under the related regulations. It is inconsistent for CMS on the one hand to "beef up" the survey guidance in this area, while on the other hand ignoring e-prescribing as a tool that could assist nursing facilities to achieve and sustain compliance.

Yet, CMS' proposed rule is completely silent on the impact of the e-prescribing standards in the LTC setting and thus utterly devoid of any recognition of the importance of e-prescribing to the LTC environment. In fact, the proposed foundation standards would not accommodate the LTC pharmacy services model because the standards are based on direct communication between the prescriber and the retail pharmacy and do not recognize the third critical entity involved in providing drugs in the LTC setting -- the LTC provider. Likewise, CMS has also failed to provide any consideration of how e-prescribing standards might require modification and further development to meet the complex operational and regulatory environment of LTC facility pharmacy services and the role of the consultant pharmacist, or addressed how the development and adoption of LTC e-prescribing could be supported and incentivized. Thus, CMS has not raised the issue of protection for LTC providers under the Anti-kickback statue related to certain e-prescribing incentives -- protection which the Office of Inspector General (OIG) intends to afford other providers, such as physicians, in further regulation.

It is also clear that if CMS hopes to substantively increase the participation of physicians in e-prescribing for Medicare patients, it cannot ignore the LTC patient population. Failure to address the LTC environment in the development of e-prescribing can have serious adverse consequences: it could disincentivize and impede physicians who have LTC patients from adopting e-prescribing technology and or it could disincentivize physicians from caring for LTC patients, thus exacerbating a bias that exists today. Without concurrently including LTC in physician e-prescribing efforts, chemotherapeutic care for the chronically ill will continue to be delivered in a silo, devoid of all benefits from instant information exchange, leaving the physician to deal with e-prescribing for one set of patients and continued use of phone and fax for others. Having physicians using multiple medication systems is confusing, burdensome, costly and will lead to error. This

situation, alone, has the propensity to derail physician e-prescribing technology efforts.

In the final e-prescribing rule and in its future activities in this area, CMS must rectify the omission of consideration of LTC and LTC residents. To that end, we recommend below several steps that CMS should take.

Development of Standards for the LTC Facility Environment

First, we ask that CMS work with the National Council for Prescription Drug Programs (NCPDP) on standards that will make possible and promote e-prescribing in the LTC environment. CMS has adopted the prescription SCRIPT standard of the NCPDP and certain NCPDP standards for eligibility. These final standards are referred to as foundation standards by CMS because they would be the first final set of final standards adopted for an electronic prescribing program. According to CMS adequate industry experience exists with respect to these proposed standards thus allowing CMS to propose and adopt these foundation standards as final standards without pilot testing. However, these standards, based on direct communication between the prescriber and the retail pharmacy, do not accommodate the LTC pharmacy services model. NCPDP has developed a work group to address e-prescribing in the LTC environment. We ask that CMS work with the group developed by the NCPDP to provide design alternatives for standards used within the LTC setting. We understand that the design alternatives being examined by the work group are focused on accounting for and connecting all three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility.

In order to ensure that futher e-prescribing standards work within the context of the three-way prescriber, LTC provider, LTC pharmacy environment, AHCA recommends that additional standards, as well as updates and revisions to e-prescribing standards be subject to formal agency rulemaking. E-prescribing standards represent substantive responsibilities for LTC providers, prescribers, and LTC pharmacies, and a Notice of Proposed Rulemaking (NPRM) process is the only way LTC providers can be assured of notice and an opportunity to comment on e-prescribing standards that affect the services provided to nursing home residents.

As CMS knows, the LTC facility bears the primary responsibility for safe and effective drug distribution to its residents. For example, the requirements with respect to nursing facilities are manifold and strict, as they should be. The core mandate is that "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care." 42 CFR 483.25. Further, "A drug whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort

or endangers his or her health and safety, then this requirement is not met." 42 CFR 383.60 and 483.75(h). In addition, as a vital part of the quality of care requirements, the facility must ensure that it is free of medication error rates of 5 percent or greater; and residents are free of any significant medication errors. 42 CFR 483.25 (m).

As indicated above, these regulatory mandates place the ultimate responsibility for safe and effective drug distribution with the LTC facility. A critical aspect of this responsibility is the fact that the medical record of the patient is kept at the LTC facility. Thus, a key operative concept in designing an operative LTC e-prescribing system is to acknowledge the responsibilities of the LTC facility, the role of the LTC facility as the guardian of the resident's medical record, and the key role of LTC facility staff.

The act of prescribing in the LTC facility environment involves direct communication between LTC nursing staff and the physician and further communication between the LTC facility staff and the LTC pharmacy. No matter how streamlined the process may become, the LTC facility stands at the heart of the process. Again, this is a model that involves three entities: the physician, the pharmacy, and the LTC facility. Any e-prescribing system that provides the benefits of e-prescribing to LTC residents must involve all three entities.

Most importantly, the system must facilitate and support the ability of the LTC facility to provide the highest quality of care for its residents and meet all of the mandates of law and regulation pertaining to the provision of pharmacy services. Thus, to reiterate, we ask that CMS work with the NCPDP designated workgroup to provide design alternatives for standards used within the LTC profession which will address the vital roles of the three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility. As CMS moves toward full implementation of electronic prescribing for medications covered under Medicare Part D, it is essential that the proper framework be developed for prescribing medications for LTC residents.

Pilot Testing and Demonstrations

Secondly, the MMA requires pilot testing for initial standards for which adequate industry experience is lacking. Testing of such standards would, pursuant to the proposed rule, occur during the 2006 calendar year. The results of the pilot project would be evaluated and, based upon those results, final standards will be published not later than April 1, 2008. The proposed rule indicates that in order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary is mandated to conduct an evaluation of the pilot project,

and to submit a report to the Congress on the evaluation, not later than April 1, 2007. Again, there is no inclusion of LTC providers.

We reiterate our request that CMS work with the NCPDP to develop and pilot test standards that are appropriate for the LTC environment. We are concerned that any pilot study will not provide a true picture of standardization needs for electronic prescribing unless the pilots include the full spectrum of health care, including long-term care. AHCA also recommends that the evaluation of the pilot testing specifically address the experience of physicians, LTC providers, and LTC pharmacies in its report to Congress on the outcome of the pilot testing.

Lastly, we ask that CMS use its demonstration authority to develop and test various appropriate e-prescribing models in LTC facility environments.

Overcoming Barriers to E-Prescribing

Third, CMS must help LTC overcome barriers to the development and application of LTC e-prescribing. In the proposed rule, CMS clearly recognizes the barriers to increased usage of e-prescribing by physicians. One major barrier is the cost of buying and installing a system which includes the time involved in training staff and changing record systems from paper to electronic. CMS also cites lack of reimbursement for e-prescribing costs and resources. Since CMS does not address the LTC environment, the agency never discusses the fact that such costs also will be borne by both LTC facilities and LTC pharmacies in evolving toward e-prescribing.

CMS should first assist the LTC profession in trying to estimate and quantify these costs and then work with LTC providers and pharmacies to find ways to assist the funding of this new technology. For example, with regard to physicians, CMS acknowledges that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees. CMS states that the OIG will create an exception to the Stark law and an Antikickback safe harbor for such e-prescribing physician incentives. If health plans consider similarly incentivizing LTC pharmacies and facilities to join physicians in the three-way LTC e-prescribing environment, then CMS and the OIG should consider similar legal protection for LTC facilities and pharmacies.

Lastly, as we have indicated above, a concomitant barrier to overall adoption of e-prescribing is prolonging an environment in which physicians would face having to use multiple prescribing systems: with e-prescribing for one set of patients and continued use of phone and fax for others. Thus assisting the LTC profession to meet the costs of participating in e-prescribing will help to hasten the adoption of this critical system by all physicians.

CMS Support for LTC Profession Efforts in Information Technology, Adoption of Electronic Records and E-prescribing

Last but not least, e-prescribing is only one facet of the overall revolution that is occurring in the development and adoption of health information technology and the development of electronic health records (EHRs). AHCA is at the forefront of an intensive comprehensive effort to support the development of electronic records and their adoption by LTC providers and the development of appropriate and necessary health information technology (HIT) for introduction to, and adoption by, LTC providers. We are on record with many efforts in these areas.

CMS itself acknowledges that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive EHR system with decision support functionality and that it must be interoperable with other functions of an EHR. CMS indicates that the need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. CMS acknowledges that one option might have been to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time.

However, CMS rejected this approach since it would postpone the implementation of any e-prescribing functionality, including the attendant benefits and was beyond the scope of the MMA. Instead CMS is attempting to propose foundation standards that are appropriately accredited and have adequate industry experience. CMS believes that this will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. CMS solicits comment on this approach, as well as on other critical success factors for assuring interoperability.

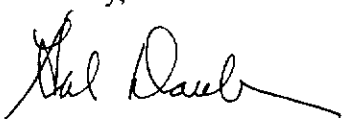
We agree with this approach since it is our belief that movement forward must be made on all these fronts -- but not without LTC -- and not without the support of CMS as AHCA proceeds with its many initiatives. For instance, we are identifying, reviewing, synthesizing and distributing existing steps/protocol for selecting software, systems and vendors; identifying the need for additional or enhanced criteria to improve the selection protocols; organizing an LTC summit bringing together LTC operators, vendors, and government officials; identifying products available and trying to resolve impediments to product development; collaborating on the Continuity of Care Record (CCR) as part of our EHR initiative; reviewing and commenting on HL7 EHR standards; and promoting LTC profession's efforts to align with Regional Health Information Organizations (RHIOs). This includes monitoring barriers preventing LTC from participating and helping AHCA affiliated state associations efforts to promote LTC partnerships with RHIOs.

Conclusion

In conclusion, LTC residents deserve the finest quality care possible. LTC providers have made enormous strides in improving and enhancing that care. They cannot be left behind as technological innovation is increasingly introduced into the health care environment. The LTC profession assisted by AHCA is taking giant steps in promoting the development of and access to quality enhancing technology.

In the final rule, CMS should address e-prescribing standards that would apply to the provision of pharmacy services in the LTC profession. Further it should articulate the ways and means that it would employ to promote and support e-prescribing in the LTC facility environment. This may include pilot testing, demonstrations and encouragement of health plan support for incentivizing LTC facilities and pharmacies to participate in e-prescribing. I would gladly work with you on these issues and welcome discussion with you on inclusion of the LTC in CMS' e-prescribing efforts.

Sincerely,



Hal Daub
President and CEO

April 5, 2005

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

RE: File code CMS-0011-P

Dear Dr. McClellan:

Express Scripts appreciates the opportunity to comment on the NPRM for the Medicare Program; E-Prescribing and the Prescription Drug Program (CMS-0011-P) that was published in the Federal Register on February 4, 2005 (the "NPRM").

Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, serving thousands of client groups including managed care organizations, insurance carriers, third-party administrators, employers, government and union-sponsored organizations. We currently provide pharmacy benefit services to six million seniors enrolled in a variety of funded retiree health plan arrangements.

Our company strongly supports the development of standards for electronic prescribing, and we have actively participated in the process of the National Committee for Vital Health Statistics leading up to the NPRM. We believe standards cannot be effective in encouraging adoption of electronic prescribing technologies or meaningfully impacting the deliver of quality, cost-effective health care, unless such standards are true *standards*, impacting *all* electronic prescriptions. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to passage of the Medicare prescription drug bill, and we believe the Congress intended to achieve true standardization of electronic prescribing for the benefit of the nation's health care. We address this and other concerns in our comments.

Attached please find our comments (Attachment 1) on the NPRM. We thank you for the opportunity to comment on these proposed rules and regulations.

Sincerely,

EXPRESS SCRIPTS, INC.
By: Thomas M. Boudreau
Senior Vice-President and General Counsel

ATTACHMENT 1

Comment: I. BACKGROUND, A. Statutory Basis and II. PROVISIONS of the Proposed Regulation, B. Proposed Definitions

According to the NPRM, "Electronic media" means:

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

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

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

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

Electronic faxes cannot comply with the proposed standards, as they do not utilize the NCPDP Script standard. In addition, electronic faxes present special authentication concerns and will require special consideration, perhaps even specific standards. While the proposed definitions adequately capture what is electronic media and what is included in "e-prescribing," it will be important in the final rule to make special consideration for electronic faxing. Electronic prescribing generally will benefit from the elimination of electronic faxing as a means of transmission. However, until the industry is ready to support broad use of electronic data interchange ("EDI") transmission of prescriptions, electronic faxing will continue and will need to be specifically dealt with in the standards. In any case, we want to ensure that dispensers are not required to distinguish between traditional (paper) faxes and electronic faxes. It is difficult or impossible to distinguish between them.

Comment: I. BACKGROUND, A. Statutory Basis and F. Evolution and Implementation of an Electronic Prescription Drug Program

Also relates to: II. PROVISIONS of the Proposed Regulation

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American National Standards Institute (ANSI) accredited. We are concerned that in some cases this may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

While we support the goal of leveraging the capabilities, experience, and broad industry participation of ANSI-accredited organizations in the quest for identifying standards, we are concerned about including ANSI accreditation as a threshold for a standard to be considered to have adequate industry experience, given that the process by which these organizations work to develop standards is but one way to assess industry consensus. The Secretary, in reliance on NCVHS and the testimony it heard, is also capable of determining whether a sufficient industry consensus exists, and whether a particular transaction standard has been accepted and implemented broadly enough for purposes of determining whether adequate industry experience exists with the use of the transaction and whether that transaction standard should be adopted as a "standard" for purposes of the directive in the MMA.

Relying on industry standard setting organization creates a risk that parties with particular agendas or ulterior motives can "hijack" the process, preventing any standard from getting passed, despite broad consensus and/or the lack of any alternative standard for a given transaction type. Deferring these decisions to ANSI-accredited organizations, at least in cases where significant adoption and use of a standard exists, is an unnecessary additional step in the process, and is inconsistent with the directive in the MMA for the Secretary to adopt standards.

Comment: I. BACKGROUND, A. Statutory Basis and H. Summary of Status of Standards for an Electronic Prescription Drug Program
(Also relates to I. BACKGROUND, C. Standards Design Criteria and IV. Regulatory IMPACT ANALYSIS)

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Moreover, it could undermine the momentum that electronic

prescribing enjoyed even before Congress sought to promote it as a means to manage costs associated with the Part D benefit under the MMA. Without adoption by physicians, the benefits of electronic prescribing cannot be realized. Clearly this was not Congress' intent.

Specifically, we believe the preemption provisions adopted by Congress in Section 1860D-4(e)(5)(B) must be reasonably interpreted to address any state law or regulation that in any way relates (i.e., "pertains") to the electronic transmission of medication history, eligibility, benefits or the actual prescription for any drug designated as a "covered Part D drug." As discussed in more detail below, rules of statutory construction support this interpretation. This would create a single, predictable, national methodology for the electronic transmission of this type of information, whether within a state or across state lines, while respecting the ability of states to continue to regulate paper prescriptions which, by definition, are not transmitted across state lines.

This outcome does not require resort to interpreting the statutory language of "and" to mean "or," nor does it render paragraph (B) meaningless, but it does give meaning and purpose to the standards which the Act anticipates. The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available.

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

- If a state requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that state require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payor?
- Does a Medicare prescription transmitted electronically need to meet state rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable state forbids such intermediaries?

- Can the physician or pharmacist be disciplined under state law where a prescription is sent electronically according to the federal rule but it is deficient for state law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payor) which can only be applied when the claim is adjudicated?

Uncertainty among physician and pharmacists about their professional obligations will diminish their willingness to adopt and use this technology. The likely result of all this confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. Consequently, we believe the statements (on page 6268 under Regulatory Impact Analysis) that suggest that the proposed standards will accelerate adoption of e-prescribing are misguided. The opposite, in fact, is true.

The Regulatory Impact Analysis, on page 6269, also states, in part:

> The primary method [to encourage adoption] chosen by the Congress was to increase the value of e-prescribing systems by mandating uniform standards for e-prescribing. Uniform standards reduce barriers to adoption by reducing uncertainty in the marketplace regarding which standards will be the industry standards of the future. These incentives are created without imposing substantial costs. For potential new e-prescribers, whose choice to adopt e-prescribing is voluntary, these standards provide the advantages of uniformity and reduced uncertainty, and, hence, reduce costs or increase benefits of adoption.

These statements are all in fact quite true to the extent that CMS is willing to create uniform "standards" as required by Congress under the MMA. However, the limited scope of what is proposed in the NPRM, coupled with the narrow view espoused regarding preemption, eliminate the possibility of achieving these benefits. Therefore, these statements are also misguided as applied to what is currently proposed.

By taking a partial approach and not creating a single, national standard that deals with all issues relating to electronic transmission of prescriptions, we believe the proposed rules do more to harm the progress of electronic prescribing than they do to advance adoption. The current 50-state scheme is difficult to navigate. Adding a 51st scheme that is to be interwoven into each of the other 50 does not solve the problem, but only creates an additional, and more burdensome problem. This certainly seems to conflict with the statutory requirement in Section 1860D-4(e)(3)(C)(i) which specifies that the design criteria for electronic prescription drug program standards require that the "standards be designed so that, to the extent practicable, they **do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists.**" (emphasis added)

We believe that, in including the electronic prescribing program under the Act, and providing for standards which were to preempt state law, Congress intended to achieve a single national methodology for all electronic prescriptions, recognizing that some would ultimately be covered by the Medicare program. Stopping short of this in the name of federalism, and creating a confusing overlay that must be interpreted on a state-by-state

basis, undermines Congress' intent and benefits neither the federal government nor the states. It also undermines the goal of better, more cost-effective health care. This is clearly a problem of national significance where a single national approach is vital, and there is statutory authority enabling CMS to act.

The NPRM takes language from Section 1860D-4(e)(1), which relates to when prescribers are **required** to send prescriptions according to the standards, and inappropriately applies that language as a limitation on when the standards are applicable vis-à-vis state law, thus ignoring a distinct difference in that Section as opposed to the language in the preemption Section (1860D-4(e)(5)). Section 1860D-4(e)(1) states, in relevant part:

> [As of the applicable effective date], prescriptions and other information described in paragraph (2)(A) [describing the electronic prescription drug program under the MMA] for covered Part D drugs prescribed for part D eligible individuals that are transmitted electronically **shall be transmitted only in accordance with such standards** under an electronic prescription drug program that meets the requirements of paragraph (2). (emphasis added)

While the MMA did not mandate the use of electronic prescribing technologies, this first paragraph sets forth the intent that *if* such technologies are used in the treatment of a Part D eligible individual, then the established standards must be followed. Conversely, Section 1860D-4(e)(5) seeks to prevent states from deterring adoption by the imposition of conflicting or competing requirements related to electronic prescribing. It states:

> The standards promulgated under this subsection shall **supersede any State law or regulation that -**
>
> (A) is **contrary to the standards** or restricts the ability to carry out this part; and
> (B) **pertains to the electronic transmission** of medication history and **of information** on eligibility, benefits, and prescriptions **with respect to covered part D drugs** under this part. (emphasis added)

Assuming, as rules of statutory construction require, that the differences in these two sections were intentional, and putting them in the context of Congress' desire to promote uniformity and encourage adoption, we believe the statement at page 6257 in the NPRM that "... the best reading of [1860-D-4(e)(1)], as well as the intent of Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans..." is unfounded. To the contrary, we believe the statutory language makes clear Congress' intent for the Secretary to create a regulatory scheme to govern all electronic prescription of any drugs included in the Part D program, so as to ensure a single, national electronic prescription drug program that would be adopted and used consistently by prescribers to the benefit of Medicare and the rest of the health care system.

We believe a single, national set of standards for electronic prescribing are in the interest of all parties, including the states. The principal concern of states would not likely be that the federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that state boards of pharmacy typically seek to address in their rules. We believe the issues fall into four primary categories:

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

Addressing all of these issues with a single, national, comprehensive set of standards applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a patchwork of varying and sometimes conflicting federal and state laws affecting all electronic prescriptions. The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant state law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as federal standards are adopted for electronic prescriptions, they preempt any contrary state standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all state rules on those topics with respect to all electronic prescriptions. However, it will be imperative for the Secretary to move quickly in order to avoid confusion which may be created by only dealing with part of the problem.

Comment: I. BACKGROUND, F. Evolution and Implementation of an Electronic Prescription Drug Program, and H. Summary of Status of Standards for an Electronic Prescription Drug Program

Express Scripts believes it is vitally important for HHS to adopt a process by which the standards for electronic prescribing can evolve in conjunction with the industry's evolution and in a manner that is more flexible and practical than what currently exists under HIPAA. We believe this process should leverage the expertise and industry participation of ANSI-accredited standards organizations, however, HHS should work with the standards organizations to ensure interoperability between standards and across versions of standards.

In this same vein, we encourage HHS to pursue a course to modify the existing HIPAA rules to provide for a more flexible and practical approach to evolving standards, consistent with what is adopted for electronic prescribing.

Comment: I. BACKGROUND, G. Electronic Prescription Drug Program and H. Summary of Status of Standards for an Electronic Prescription Drug Program. Also relates to: II. PROVISIONS of the Proposed Regulation

ASC X12N 270/271

We support the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers.

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

Provider and Dispenser Identifiers

We believe that the timeline currently in place for the implementation of the NPI should not be altered as any change will not likely result in a feasible solution and may create unintended difficulties for the industry. However, we do believe that having a single system for the identification of providers is in the industry's best interests, and the long-term goal should be to use the same identifier for all transactions which require one.

In the meantime, we believe CMS should make use of identifiers that are currently available and in use, rather than try to implement something new that will be replaced when the NPI becomes available. The NCPDP Provider Identifier Number is currently widely used by the industry and should be adopted for electronic prescribing until NPI is fully in place. For prescribers, the identifier most commonly used by the electronic prescribing industry is the DEA registration number. While we understand that DEA does not support use of the DEA number for this purpose, we believe it is most practical to adopt it for electronic prescribing in the short-term, with the recognition that it will be replaced in the near-term with the NPI. Any other approach will create significant inefficiencies by forcing the industry to change processes and adapt to something new, only to have to make additional changes in the next 12-18 months to adapt to the implementation of the NPI (scheduled for May, 2007).

Formulary and Medication History Standards

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

We value the contribution NCPDP and other ANSI-accredited organizations have made and continue to make in developing consensus among various industry participants. However, given that these standards were developed through an industry consensus process, that they have been implemented and used extensively by the industry, and that no alternative standards exist, the Secretary should adopt these as standards under the authority granted in the MMA. There is no value to be gained in delaying the adoption of these standards. Furthermore, given that there is not an ANSI-accredited standards development organization comprised solely of the entities who will use these transaction sets (i.e., payors and electronic prescribing solution vendors), there is a risk that industry participants without a direct stake in the outcome, who may prefer to slow down the adoption of electronic prescribing or otherwise influence it for their own gain, could derail accreditation of these standards without ensuring that an alternative that addresses the problem is approved, particularly since there are no other viable alternatives in existence.

Comment: IV. Regulatory Impact Analysis, B. Impact on Health Plans/PBMs and C. Impact on Prescribers

We agree with many of the statements in the NPRM regarding the potential benefits of electronic prescribing, both in terms of quality of care and of cost savings to many of the participants in the chain. However, we believe the NPRM fails to recognize the true costs of implementing the technologies necessary to provide formulary and benefit information at the point of prescribing and is incorrect in it's assessment that there will not be any material impact to any participant in the chain. Cost or, perhaps more accurately, a lack of documented cost/benefit analysis, has been one of the primary barriers to adoption thus far. Furthermore, there are costs involved in supporting electronic prescribing that the industry may not be prepared to absorb, transaction fees in particular.

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

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

Contact Information

If you have any questions relating to our comments, please contact:

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Vice President, Business Development
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Maryland Heights, MO 63043
(314) 702-7109
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prothermich@express-scripts.com

Submitter : Ms. Kristin Lewis **Date: 04/05/2005**

Organization : Tufts Associated Health Maintenance Organization

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Because of the need to ensure data security and privacy, we feel that health plans should be allowed to use their discretion in selecting E-Prescribing Point of Care Vendors. It takes considerable time and effort to validate appropriate security and privacy practices on the Point of Care Vendor side. While we agree that at least one Point of Care Vendor should be required, additional vendors should be at the health plan?s discretion and not required.

Issues

Regulatory Impact Analysis

Health Plans? Costs and Financial Benefits. CMS states that it believes that costs incurred by health plans will be minimal, even in those few cases where plans do not currently support e-prescribing directly or through PBM contracts. However, CMS further states that it is possible that some plans will experience consequential costs that CMS has not foreseen. CMS requests comments on possible costs to plans, and on steps CMS could take to ameliorate any unnecessary costs. CMS also requests comment on the Agency?s expectation that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans.

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

Organization : **Express Scripts, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

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See Attachment

CMS-0011-P-35-Attach-1.DOC

April 5, 2005

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

RE: File code CMS-0011-P

Dear Dr. McClellan:

Express Scripts appreciates the opportunity to comment on the NPRM for the Medicare Program; E-Prescribing and the Prescription Drug Program (CMS-0011-P) that was published in the Federal Register on February 4, 2005 (the "NPRM").

Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, serving thousands of client groups including managed care organizations, insurance carriers, third-party administrators, employers, government and union-sponsored organizations. We currently provide pharmacy benefit services to six million seniors enrolled in a variety of funded retiree health plan arrangements.

Our company strongly supports the development of standards for electronic prescribing, and we have actively participated in the process of the National Committee for Vital Health Statistics leading up to the NPRM. We believe standards cannot be effective in encouraging adoption of electronic prescribing technologies or meaningfully impacting the deliver of quality, cost-effective health care, unless such standards are true *standards*, impacting *all* electronic prescriptions. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to passage of the Medicare prescription drug bill, and we believe the Congress intended to achieve true standardization of electronic prescribing for the benefit of the nation's health care. We address this and other concerns in our comments.

Attached please find our comments (Attachment 1) on the NPRM. We thank you for the opportunity to comment on these proposed rules and regulations.

Sincerely,

EXPRESS SCRIPTS, INC.
By: Thomas M. Boudreau
Senior Vice-President and General Counsel

ATTACHMENT 1

Comment: I. BACKGROUND, A. Statutory Basis and II. PROVISIONS of the Proposed Regulation, B. Proposed Definitions

According to the NPRM, "Electronic media" means:

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

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

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

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

Electronic faxes cannot comply with the proposed standards, as they do not utilize the NCPDP Script standard. In addition, electronic faxes present special authentication concerns and will require special consideration, perhaps even specific standards. While the proposed definitions adequately capture what is electronic media and what is included in "e-prescribing," it will be important in the final rule to make special consideration for electronic faxing. Electronic prescribing generally will benefit from the elimination of electronic faxing as a means of transmission. However, until the industry is ready to support broad use of electronic data interchange ("EDI") transmission of prescriptions, electronic faxing will continue and will need to be specifically dealt with in the standards. In any case, we want to ensure that dispensers are not required to distinguish between traditional (paper) faxes and electronic faxes. It is difficult or impossible to distinguish between them.

Comment: I. BACKGROUND, A. Statutory Basis and F. Evolution and Implementation of an Electronic Prescription Drug Program

Also relates to: II. PROVISIONS of the Proposed Regulation

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American National Standards Institute (ANSI) accredited. We are concerned that in some cases this may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

While we support the goal of leveraging the capabilities, experience, and broad industry participation of ANSI-accredited organizations in the quest for identifying standards, we are concerned about including ANSI accreditation as a threshold for a standard to be considered to have adequate industry experience, given that the process by which these organizations work to develop standards is but one way to assess industry consensus. The Secretary, in reliance on NCVHS and the testimony it heard, is also capable of determining whether a sufficient industry consensus exists, and whether a particular transaction standard has been accepted and implemented broadly enough for purposes of determining whether adequate industry experience exists with the use of the transaction and whether that transaction standard should be adopted as a "standard" for purposes of the directive in the MMA.

Relying on industry standard setting organization creates a risk that parties with particular agendas or ulterior motives can "hijack" the process, preventing any standard from getting passed, despite broad consensus and/or the lack of any alternative standard for a given transaction type. Deferring these decisions to ANSI-accredited organizations, at least in cases where significant adoption and use of a standard exists, is an unnecessary additional step in the process, and is inconsistent with the directive in the MMA for the Secretary to adopt standards.

Comment: I. BACKGROUND, A. Statutory Basis and H. Summary of Status of Standards for an Electronic Prescription Drug Program
(Also relates to I. BACKGROUND, C. Standards Design Criteria and IV. Regulatory IMPACT ANALYSIS)

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Moreover, it could undermine the momentum that electronic

prescribing enjoyed even before Congress sought to promote it as a means to manage costs associated with the Part D benefit under the MMA. Without adoption by physicians, the benefits of electronic prescribing cannot be realized. Clearly this was not Congress' intent.

Specifically, we believe the preemption provisions adopted by Congress in Section 1860D-4(e)(5)(B) must be reasonably interpreted to address any state law or regulation that in any way relates (i.e., "pertains") to the electronic transmission of medication history, eligibility, benefits or the actual prescription for any drug designated as a "covered Part D drug." As discussed in more detail below, rules of statutory construction support this interpretation. This would create a single, predictable, national methodology for the electronic transmission of this type of information, whether within a state or across state lines, while respecting the ability of states to continue to regulate paper prescriptions which, by definition, are not transmitted across state lines.

This outcome does not require resort to interpreting the statutory language of "and" to mean "or," nor does it render paragraph (B) meaningless, but it does give meaning and purpose to the standards which the Act anticipates. The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available.

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

- If a state requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that state require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payor?
- Does a Medicare prescription transmitted electronically need to meet state rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable state forbids such intermediaries?

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

Provider and Dispenser Identifiers

We believe that the timeline currently in place for the implementation of the NPI should not be altered as any change will not likely result in a feasible solution and may create unintended difficulties for the industry. However, we do believe that having a single system for the identification of providers is in the industry's best interests, and the long-term goal should be to use the same identifier for all transactions which require one.

In the meantime, we believe CMS should make use of identifiers that are currently available and in use, rather than try to implement something new that will be replaced when the NPI becomes available. The NCPDP Provider Identifier Number is currently widely used by the industry and should be adopted for electronic prescribing until NPI is fully in place. For prescribers, the identifier most commonly used by the electronic prescribing industry is the DEA registration number. While we understand that DEA does not support use of the DEA number for this purpose, we believe it is most practical to adopt it for electronic prescribing in the short-term, with the recognition that it will be replaced in the near-term with the NPI. Any other approach will create significant inefficiencies by forcing the industry to change processes and adapt to something new, only to have to make additional changes in the next 12-18 months to adapt to the implementation of the NPI (scheduled for May, 2007).

Formulary and Medication History Standards

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

We value the contribution NCPDP and other ANSI-accredited organizations have made and continue to make in developing consensus among various industry participants. However, given that these standards were developed through an industry consensus process, that they have been implemented and used extensively by the industry, and that no alternative standards exist, the Secretary should adopt these as standards under the authority granted in the MMA. There is no value to be gained in delaying the adoption of these standards. Furthermore, given that there is not an ANSI-accredited standards development organization comprised solely of the entities who will use these transaction sets (i.e., payors and electronic prescribing solution vendors), there is a risk that industry participants without a direct stake in the outcome, who may prefer to slow down the adoption of electronic prescribing or otherwise influence it for their own gain, could derail accreditation of these standards without ensuring that an alternative that addresses the problem is approved, particularly since there are no other viable alternatives in existence.

Comment: IV. Regulatory Impact Analysis, B. Impact on Health Plans/PBMs and C. Impact on Prescribers

We agree with many of the statements in the NPRM regarding the potential benefits of electronic prescribing, both in terms of quality of care and of cost savings to many of the participants in the chain. However, we believe the NPRM fails to recognize the true costs of implementing the technologies necessary to provide formulary and benefit information at the point of prescribing and is incorrect in it's assessment that there will not be any material impact to any participant in the chain. Cost or, perhaps more accurately, a lack of documented cost/benefit analysis, has been one of the primary barriers to adoption thus far. Furthermore, there are costs involved in supporting electronic prescribing that the industry may not be prepared to absorb, transaction fees in particular.

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

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

Contact Information

If you have any questions relating to our comments, please contact:

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Submitter : Ms. Laura Blum

Date: 04/05/2005

Organization : JCAHO

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-0011-P-36-Attach-1.DOC

Joint Commission
on Accreditation of Healthcare Organizations

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-1850
http://www.cms.hhs.gov/regulations/ecomments

RE: Comments on Medicare Program: E-Prescribing and the Prescription Drug Program

File Code: CMS-0011-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Joint Commission is the nation's oldest and largest standard-setting and accrediting body in health care.

The Joint Commission evaluates and accredits more than 15,000 health care organizations and programs in the United States. Our accreditation programs evaluate the performance of home care agencies; ambulatory care settings whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care plans. Further, the Joint Commission is active internationally and has provided consultation and accreditation services in over 60 countries.

This rule proposes to adopt uniform standards for electronic prescribing that promote patient safety, quality of care, as well as cost savings for the new Prescription Drug Program (PDP)—known as Medicare Part D. This proposed rule describes the NCVHS process and recommendations as well as the process to implement the standards using an incremental approach. Ultimately, the goal is to achieve an electronic health record system and this proposed rule on electronic prescribing is a step in the right direction. Until health care reaches its goal of interoperability, studies estimate that broad implementation of electronic prescribing will prevent adverse events, improve care (e.g. greater continuity of care) and reduce costs.

It is evident that in the course of drafting the proposed rule, CMS and NCVHS staff had to address a myriad of issues associated with electronic prescribing in a complex environment. We recognize the tremendous amount of work that has gone into the preparation of this proposed rule and commend CMS and NCVHS on a job well done. JCAHO staff attended several NCVHS hearing on electronic prescribing and witnessed the extensive information gathering process that was undertaken prior to drafting this proposed rule. Along with general comments, this letter addresses the following:

- Initial standards versus final standards
- Criteria to assess adequate industry experience
- State preemption
- Regulatory impact to improve patient safety and quality
- Incremental approach for adoption and implementation

General Comments

To promote patient safety and quality care, the Joint Commission is a strong supporter of the development of a health care information technology infrastructure. The Joint Commission recognizes that electronic prescribing is an important stepping-stone for achieving interoperability. The Joint Commission can provide invaluable assistance in developing and promoting electronic prescribing standards. Our experience in developing standards and performance measurement metrics, and issuing National Patient

Safety Goals provides valuable insights that can facilitate the development and adoption of electronic prescribing.

JCAHO National Patient Safety Goals

The Joint Commission's National Patient Safety Goals are closely aligned with the goals that support the establishment of an electronic prescription program. For example, in an effort to reduce communication errors, the Joint Commission issued a Patient Safety Goal that requires a person receiving a verbal or telephone orders to verify the accuracy of the information by "reading back" the complete order or test results. A 2005 National Patient Safety Goal requires health care providers to accurately and completely reconcile medication use across the continuum of care. To achieve this goal, providers must develop a process for obtaining and documenting a complete list of patients' current medications upon admission. The process must include a comparison of the medications the organization provides with those on the patient's list. A complete list of the patient's medications must also be communicated to the next provider of service when a patient transfers to another setting, service, practitioner or level of care within or outside the organization.

Initial standards versus final standards

Section 1860D-4 (e) outlines the distinct provisions for initial and final standards. Given the obstacles of electronic prescribing related to the lack of interoperability and inadequate industry experience with many electronic prescription standards, it is prudent for HHS to pilot test disparate standards before issuing final standards by April 1, 2008. Additionally, it will take time to process applications from physicians, physician groups, hospitals, prescription drug plan sponsors, Medicare Advantage organizations and pharmacies who want to pilot new or emerging standards.

An issue for consideration is that the foundational standards will not be tested against each other. Hence, a better delineation of "testing" may be required for certain standards proposed in this regulation. While the Joint Commission supports CMS's accelerated timetable to roll out the foundational standards, we also recommend that CMS maintain the more conservative 2008 projection to accommodate unexpected debates.

Criteria to assess adequate industry experience

The proposed rule outlines criteria to assess adequate industry experience with those standards that already exist (i.e. standards that do not need to be pilot tested). The Joint Commission supports these criteria to assess adequate industry experience.

State Preemption

The proposed federal rule indicates that a state law cannot be contrary to the rule if the law pertains to electronic prescribing under Part D. State preemption is a critical and complex issue because many prescribers transmit across state lines. The language regarding state preemption in the proposed rule serves as a framework to states as they contemplate legislation regarding electronic transmission of prescriptions. This rule serves as a guideline because it allows a state to draft a law that suits its needs and budgetary capabilities as long as it is consistent with the federal rule.

Regulatory Impact to Improve Patient Safety

As noted in the proposed rule, electronic prescribing can improve quality, efficiency and reduce costs by providing real-time access to drug information and instant connectivity between health care providers. A primary objective of this proposed rule is to enhance patient safety. The proposed electronic prescribing standards cover: transmission of data about the patient's drug utilization history, possible interactions, and information on the drug plan (e.g., formulary and cost sharing, lower-cost, and therapeutically-appropriate alternatives). These are important pieces of information that should be accessible from any patient safety information system.

Incremental Approach

The MMA (Section 1860D-4(e)) requires the implementation of a pilot project unless there is adequate industry experience with whatever standards the Secretary is planning to adopt. This proposed rule puts forth a basic set of foundational standards- or building blocks- that are ready for implementation and recommends pilot testing more advanced standards that are less mature.

The Joint Commission supports phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, Medicare Advantage organizations, and PDPS to comply with the foundational standards. These standards could facilitate the transmission of medical history, alerts to adverse drug interactions, and suggestions for lower-cost, therapeutically equivalent alternative medications. The incremental approach is preferable over a "big-bang approach" in which the federal government mandates overnight compliance.

As part of the incremental approach, CMS proposes both mandatory and voluntary elements to encourage adoption of the standards. The Joint Commission agrees that the mandatory elements to encourage adoption are enabling and affirming for providers (e.g., positive financial incentives, increasing the value of e-prescribing systems, mandating uniform standards).

Once again, we commend CMS's hard work to adopt standards for electronic prescribing. The Joint Commission stands ready to work with CMS to share Joint Commission's expertise. If you have any question or require additional information regarding the issues presented in this letter, please contact Laura Blum, Associate Director of Federal Relations, at lblum@jcaho.org or 202.783.6655.

Submitter : Ms. Lorraine Tarnove **Date: 04/05/2005**

Organization : American Medcial Directors Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-37-Attach-1.DOC

CMS-0011-P-37-Attach-2.DOC

amda

American Medical Directors Association

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American Medical Directors Association

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April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Re: E-Prescribing and the Prescription Drug Program; 70 Fed. Reg. 6256 (Feb. 4, 2005); File Code CMS-0011-P

Dear Administrator McClellan:

The American Medical Directors Association (AMDA) appreciates the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) on this important proposed regulation. AMDA represents more than 7,000 medical directors, attending physicians, and others who practice in nursing homes. AMDA physicians see an average of 100 nursing facility patients per month per member (approximately 8.5 million visits in 2000 or 42 percent of the total number of nursing facility visits that year). AMDA physicians also care for patients in other venues in the long term care continuum, which includes home health care, assisted living settings, hospice and other sites of care for the frail elderly. Our comments on this proposed regulation reflect that experience, as well as the commitment to provide the best quality of care to our patients.

Generally AMDA supports the use of electronic prescribing and electronic health records, although we are cautions regarding the level of impact the proposed regulation will have on long term care settings.

Electronic Prescription Drug Program

The prescribing environment in long term care settings raises additional issues regarding implementation of e-prescribing, because the nursing facility represents an additional "loop" in the prescription

process. In the vast majority of cased, physician orders are given directly to the nursing facility, which, in turn, sends them on to a long term care pharmacy. Leaving the nursing facility out of this loop will frustrate efforts to achieve e-prescribing for the 1.6 million residents of nursing facilities.

Anti-kickback Statute Safe Harbor and Stark Exception

The MMA (Section 1860-D-4(e)(6)) requires HHS to promulgate regulations that provide for a safe harbor under the anti-kickback statute and an exception under the physician self-referral statute for nonmonetary remuneration in the form of hardware, software or information technology and training cervices that are necessary for electronic prescribing. The statute specifies as subjects for safe harbors and exceptions:

- By hospitals, for members of their medical staffs;
- By group practices, for prescribing health care professionals who are members of the practice; and
- For MMA Part D drug plans, by drug plan sponsors for pharmacists and prescribing health care professionals.

The intent of this provision, to promote conversion to e-prescribing, addresses the ability of some large providers or groups of providers to assist the health care professionals with which they work. Unless specifically excluded by legislative language, we believe that CMS has the flexibility under this provision to allow safe harbors and exceptions for drug plans to also provide such nonmonetary remuneration to nursing facilities, as well as prescribing health care professionals who care for nursing facility residents.

Incentives for Implementing E-Prescribing

AMDA reiterates our concerns regarding the need for incentives for physicians and nursing facilities to adopt e-prescribing technology. The cost of hardware and software for e-prescribing is likely to be at least equaled by the attendant costs of training staff and reorganizing office and facility operations. As one of our physicians put it, "At this point, it seems cost-prohibitive to implement e-prescribing on the scale necessary to see the outcomes for which we strive." Physicians and nursing facilities will arguably absorb much of the cost of adopting e-prescribing, not only in terms of hardware and software, but also in modifications that will be needed to train staff and reorganize operations. Yet many of the benefits touted for e-prescribing will occur "downstream" in the health care system.

For nursing facility patients, physician prescriptions are generated at the facility level, so that incentives to nursing facilities must be created in order to support the shift to e-prescribing in long term care.

We support incentive payments for physicians for e-prescribing under both managed care and independent drug plans. Few long term care patients are likely to be enrolled in MA-PDPs (managed care drug plans), so that restricting the ability for physician incentives to only MA-PDPs will not reach the vast majority of physicians who prescribe medications for long term care patients. Physician overhead is high, and current

reimbursement levels are not likely to encourage individual practitioners to invest in e-prescribing technologies.

CMA anticipated future pilot tests for e-prescribing, and AMDA suggests one that would focus on incentives for and impact of e-prescribing in long term care settings.

AMDA appreciates the opportunity to comment on these proposed regulations. Please feel free to call me if you have questions or wish additional information.

Sincerely,

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Executive Director

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April 5, 2005

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Lorraine Tarnove

Lorraine Tarnove
Executive Director

Submitter :

Date: 04/05/2005

Organization : **Council for Affordable Quality Healthcare (CAQH)**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-38-Attach-1.DOC

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

Dear Centers for Medicare and Medicaid Services:

The Council for Affordable Quality Healthcare (CAQH) is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit Notice of Proposed Rule Making (NPRM) (42 CFR Part 423).

CAQH is a not-for-profit alliance of the nation's leading health plans and networks that develops, implements and promotes collaborative initiatives to help make healthcare more affordable, share knowledge to improve the quality of care, and make administration easier for physicians and their patients. Among the initiatives currently underway, CAQH has been at the forefront of efforts to promote e-prescribing and integrated access to a standardized, single source of formulary information from all payers.

In March 2004, CAQH partnered with RxHub to create a comprehensive, centralized source of formulary data. Formulary information from participating CAQH member health plans is being combined with that from RxHub's participating PBMs to create a centralized formulary file available to technology vendors. As a result, physicians have access to more accurate and complete information from a larger number of plans when reviewing treatment options with patients at the point of care. The combined database covers a majority of commercially insured Americans.

Because of our work with electronic formularies, our comments here focus mainly on that particular portion of the NPRM as well as our market experience with e-prescribing.

BACKGROUND

"Section 1860D-4(e)(4)C)(ii) of the Act also permits an exception to the pilot testing for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users." (F.R. page 6257)

CAQH supports adoption of the RxHub protocol for formulary by CMS and can confirm that there is reasonable industry experience with the standard. However, based on the experiences of our member plans with HIPAA implementation, CAQH recommends that the RxHub formulary standard be included in the 2006 pilot tests.

Formulary and Medication History Standards. (F.R. page 6263)
"We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards."

Our experience has shown that to gain provider adoption of formulary, e-prescribing tools need to include formulary data for at least 70% of a provider's payer base. Thus, HHS's consideration of the RxHub formulary protocol is supported by CAQH since, if adopted, it would increase the number of payers using the same data standard, which should increase provider interest in adopting e-prescribing.

In terms of the characteristics of the RxHub formulary standard, the data content of the standard that is currently under NCPDP consideration includes all of the information identified as critical. In addition, the RxHub standard allows for important flexibility in linking the correct formulary to the patient; in that, the standard allows for formularies at both the product (plan) level and at a patient-specific level.

Because the rate of e-prescribing varies widely by region, flexible methods to link patients to formularies will be needed for some time. Plans will then be able to make their own cost-benefit decisions on which method is most effective for their respective markets. While there is a need to eventually link all formularies to the individual patient, moving to such a system will be costly to some plans in the short-term and should be viewed as a longer-term, but desirable goal.

IMPACT ANALYSIS

B. Impact on Health Plans/PBMs (F.R. page 6269)
"We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. The only expenses attributable to health plans by this impact analysis are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing."

From April 2003 to March 2004, CAQH conducted an e-prescribing pilot program in partnership with MedStar Health, Dr. First, and Safeway in the Washington D.C. area. 120 area physicians participated in the 12-month pilot and generated approximately 127,000 electronic prescriptions. Physicians were given the option of whether to enable the formulary check function and approximately 90 (75%) decided to do so. However, only 22% of enabled users actually referenced formulary. The key reasons for the low usage rate were:

- Time needed for manual entry (i.e., locating the patient's correct formulary and entering the drug name)
- Gaps in payer coverage (e.g., a large local plan did not participate)
- Time constraints/other priorities
- Lack of know-how
- Lack of interest

Although the number of enabled formulary participants was relatively small, the pilot program successfully demonstrated that prescribers will act on formulary warnings, and those actions can result in varying levels of savings for health plans and members (patients). Between the 1st and 4th quarters of the pilot, there was a 20% increase in providers changing a drug vs. ignoring or canceling it after receiving a non-formulary warning. One health plan that participated in the pilot noted a 35% net savings in health plan drug costs *when* a formulary warning was given, with an average savings of $29.21 per prescription for the initial prescription.[1] Other health plans, however, experienced minimal savings due to the low number of "hits" against the plan formulary. Members experienced savings in the form of reduced copays for on-formulary prescriptions.

In addition to these savings, health plans also incur direct costs internally. These costs are related to initial technology programming to meet the RxHub formulary standard (or other e-prescribing standards that may not be widely used) as well as staff costs for maintaining updated electronic formulary data and performing regular quality assurance checks on data files. As the e-prescribing market continues to evolve, health plans may also incur external charges for e-prescribing related transactions.

C. Impact on Prescribers (F.R. page 6270)

The Washington D.C. e-prescribing pilot program did result in reduced call volume between provider offices and pharmacies to resolve issues, and in time savings due to improved access to medication lists for provider office staff. Because of the small size of the pilot, however, providers were reluctant to quantify the savings amounts.

Clearly savings are possible for all stakeholders, but additional analysis is warranted.

CAQH appreciates the opportunity to provide these comments and is supportive of HHS's efforts to accelerate the adoption of e-prescribing. If you would like additional information on the results of our Washington D.C. pilot program, please do not hesitate to contact me.

Sincerely,

Robin J. Thomashauer

Robin J. Thomashauer
Executive Director

[1] Due to the small number of participants, these results cannot be extrapolated to all health plans.

Submitter : Mr. Bruce Rodman

Date: 04/05/2005

Organization : National Home Infusion Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-39-Attach-1.PDF

National Home Infusion Association
Providing solutions for the infusion therapy community

April 5, 2005

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

Re: Comments on CMS-0011-P
The Proposed Rule for the Medicare Program: E-Prescribing and Prescription Drug Program

Dear Dr. McClellan:

The National Home Infusion Association ("NHIA") is pleased to submit these comments on the proposed rule for the *Medicare Program: E-Prescribing and Prescription Drug Program* as issued in the Federal Register on February 4, 2005.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Currently, NHIA has over 2,000 members.

Throughout these comments, our references to "home infusion therapy" pertain to parenteral drugs, which are prescription drugs and biologics administered through catheters and/or needles, provided in a patient's home or other outpatient setting. Parenteral routes of administration include intravenous, intraspinal, intrathecal, intra-arterial, subcutaneous, and intramuscular.

100 Daingerfield Road • Alexandria, VA 22314 • Phone: 703-549-3740 • Fax: 703-683-1484 • www.nhianet.org

Before commenting on proposed E-Prescribing regulations that may apply to provision of home infusion therapy, we would first like to begin with more general comments on the proposed rule and CMS's admirable efforts to accelerate E-Prescribing in the Medicare Prescription Drug Program:

1. **We understand that E-Prescribing technologies as provided for in the MMA have the potential to improve the quality of care associated with provision of medications in the retail community and mail order pharmacy settings.**

2. **We also believe such technology and standards should be developed carefully to ensure achievement of intended benefits at acceptable cost. We support the statute provisions providing for a deliberative process by directing the NCVHS to study, select and recommend electronic prescribing standards.**

3. **We also support Congress' statutory provision for a one-year pilot of proposed E-Prescribing standards as necessary to achieve intended benefits.**

4. **We understand that, so far, all technology and standards development for E-Prescribing is designed for the model for prescribing and dispensing of retail pharmacy drugs. From NCVHS deliberations to-date, it appears that most proposed standards for selection by CMS are NCPDP E-Prescribing standards. NCPDP standards are developed primarily by the retail pharmacy payer and vendor software/systems industry. We will thoroughly present the distinct differences of home infusion therapy from retail pharmacy later in this letter.**

5. **NHIA appreciates the efforts that CMS is undertaking to consider comments from NCVHS and the pharmacy industry for promulgation of federal E-Prescribing regulations for the Medicare Part D prescription drug program. We are supportive of CMS view that significant benefits would be expected in improved patient safety and better outcomes as described in the Regulatory Impact Analysis, Item E (CMS-0011-P, page 6271)—for prescribing and dispensing of *retail pharmacy drugs* which are primarily oral medications that are taken by patients without the need for <u>substantial</u> ongoing care requirements associated directly with their medication therapies by caregivers such as home infusion therapy pharmacy providers.**

Provision of Home Infusion Therapy is Very Different from Provision of Retail Pharmacy Drugs

CMS has quite properly recognized on numerous occasions over the past two years the very significant differences in the clinical and administrative model for provision of home infusion therapy as compared to dispensing of retail pharmacy drugs, as well as the effectiveness of home infusion therapy. We cite some of these occasions (italics are quotes from CMS materials):

Letter to NHIA from Ms. Jared Adair on April 8, 2003 (signed by Ms. Karen Trudel)

> ***We have determined that home drug infusion therapy services are different from services provided by retail pharmacies, and that the business model for home drug infusion therapy providers is fundamentally different from a retail pharmacy for dispensing drugs.***
>
> ***We also acknowledge that a requirement to bill home infusion drugs using the NCPDP format would fail to meet the administrative, clinical, coordination of care, and medical necessity requirements for home drug infusion therapy claims.***

CMS HIPAA FAQ (Updated October 10, 2003; first released March 2003)

> ***Home Infusion Therapy typically has components of professional services and products that include ongoing clinical monitoring, care coordination, supplies and equipment, and the drugs and biologics administered – all supplied by the Home Infusion Therapy provider.***
>
> ***The ASC X12N 837 is the required standard format for claims for the provision of Home Infusion Therapy. Claims for Home Infusion Therapy care include the drugs, biologics, and nutrition components of the total Home Infusion Therapy encounter.***

Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule (Federal Register, August 3, 2004). Preamble (page 46648)

> ***Home infusion is covered under the medical benefits of most commercial insurers and MA plans as a cost-effective alternative to inpatient care for administering drugs.***

Health and Human Services Secretary Tommy G. Thompson Letters of January 14, 2005 to the National Medicaid EDI HIPAA Workgroup and National Council for Prescription Drug Programs:

> ***The Department of Health and Human Services maintains that a single standard, the X12N 837, should be used for the billing of home infusion therapy drugs and services.***

Medicare Program; Medicare Prescription Drug Benefit; Final Rule (Federal Register, January 28, 2005)

> *CMS has again recognized that home infusion pharmacies are not retail pharmacies. We cite the distinction in PDP pharmacy access regulations for retail vs. non-retail pharmacies in §423.120 (page 4537) and the*

discussion of inclusion/exclusion of home delivery costs in the dispensing fee (preamble page 4235) as two occurrences of such recognition.

This is in accordance with CMS' Part D definition of retail pharmacy in §423.100 (page 4535):

> ***Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.***
>
> *Home infusion pharmacies are excluded from this definition due to the* **ongoing clinical monitoring, care coordination and home infusion nursing that is provided by staff of or affiliated with the home infusion therapy provider—all activities essential to safe and effective administration of home infusion therapy.**

Technical Summary of What's Changed Since NPRM: Title I NPRM to Final Rule Matrix. Posted by CMS with Prescription Drug Benefit – Title I (CMS 4068-F) Regulation of January 28, 2005

> ***We believe that safe and effective access to such*** **[home infusion]** ***drugs in the home environment is only possible through the use of specialized home infusion pharmacies.***

Further factors distinguishing home infusion therapy from retail pharmacy include:

- **For infusion therapy, physician prescriptions are for drugs and biologics that are often compounded into solutions for parenteral administration, and nearly always require additional physician orders for the provision of supplies (such as IV tubing, dressings, syringes, etc.) and often require physician orders for DME (pumps and poles) and infusion nursing. Commonly, the medication prescription(s) and other physician orders are referred to as the complete home infusion prescription, or physician "order set".**

  By necessity, the home infusion prescription/physician-ordering process is far more complex than receipt and filling of physician prescriptions for most retail pharmacy drugs. Receipt of an initial physician prescription for infusion therapy typically results in identification and physician authorization for multiple medications and prescriptions* as well as multiple orders—i.e., the order set. In most cases, the process requires dialogue between the infusion pharmacist and the physician to completely specify and obtain authorization for the order set (including prescriptions). All orders and prescriptions are entered into computer

systems for tracking; and for producing documents needed to pick materials, for compounding, for packaging infusion supplies and equipment, for the infusion pharmacist's quality control checks, and for scheduling deliveries to patients among other activities.

*For example, provision of the anti-fungal therapy: amphotericin B. A typical therapy protocol would consist of pre-medications such as acetaminophen and diphenhydramine prior to administration of the amphotericin B which has been reconstituted with sterile water and compounded into D5W (dextrose 5% in water). This is followed by infusion of an electrolyte-containing hydration solution. In addition, prescribed are catheter flush solutions along with necessary supplies.

- For Medicare patients, when home infusion therapies are covered per national/local coverage determinations, it is the Part B medical benefit that covers the therapies. Private insurance coverage is almost always placed in the medical benefit. The prior authorizations used to manage health care costs are normally obtained for the expected duration of therapy, where a single authorization covers the provided drugs, supplies, equipment and services. Such authorizations are granted via coding using the standard HCPCS per diem S-codes for home infusion therapy. When home infusion claims are submitted, this is typically done through the X12N 837 professional electronic or CMS 1500 paper claim. Submission of such claims to payers is the established predominant model for home infusion therapy claiming, specifically including to private insurance, Medicare Advantage plans, and Medicare DMERC payers.

Quality Assurance for Home Infusion Patient Care, Including Prescriptions, Is Considerably More Comprehensive as Compared to Provision of Retail Pharmacy Drugs – As It Must Be

Of the most important benefits expected from E-Prescribing ("detecting various kinds of prescribing errors, including duplicate prescriptions, drug-drug, drug-allergy and drug-disease interactions; incorrect dosage strengths prescribed; and problems relating to coordination between health care providers and pharmacies" – CMS-0011-P, page 6271), some of these were first codified in OBRA 1990 and implemented through the NCPDP claim transaction.

We note that the OBRA 1990 standards were written for retail pharmacies. The drafters of these standards did not attempt to address the standard of care for home infusion pharmacies. Infusion pharmacies that are in compliance with the infusion-specific standards established by accrediting organizations (such as JCAHO) meet the OBRA 1990 standards, but the OBRA 1990 standards do not reflect contemporary pharmacy practice for infusion pharmacies.

While infusion pharmacies certainly must meet the OBRA 1990 standards, the true community standard of care for infusion pharmacies is found in the accreditation standards that are required by virtually every private health plan, as well as

numerous Medicare Advantage (MA) plans, to participate in their provider networks.

The quality assurance standards used for home infusion by accreditation organizations far exceed the OBRA 1990 standards. The level of patient data collection, assessment and intervention in the infusion clinical model goes far beyond the quality standards currently used by Medicaid under the OBRA 1990 standards.

As compared to the retail pharmacy patient, we note that infusion patients need a significantly higher level of assessment and services because:

- **The patients, by virtue of their need for parenteral therapy, are generally medically complex patients;**
- **The patients require vascular access and drug delivery devices which must be determined to be compatible with the infusion drug regimen;**
- **The patients are (typically) post-hospitalization or post-surgical (or both), which often leads to a change in their medications or medication dosage;**
- **The patients frequently have multiple providers of care (medical equipment provider, infusion pharmacy, home care agency, clinic or physician office staff), each with clinical records that may contain overlapping information but which frequently reflect only their particular data set and not that of the other providers.**

Therefore, in accordance with the well-established quality standards used for infusion therapy, the collection of data occurs through "hands on", direct personal interview and assessment of a patient during several different steps of the home infusion patient admission process: 1-clinical pharmacy assessment after collecting data from other involved health providers, 2-consultation with physician, 3-nurse assessment in the home. This is quite different and is far more complex and intensive than the OBRA 1990 prospective drug review standards. There is also ongoing pharmacy reassessment once a course of the infusion therapy is initiated, again a step well beyond OBRA 1990. All of these home infusion quality standards are the accepted practice and have resulted in cost-effective patient outcomes as recognized by most health care plans today.

RECOMMENDATIONS

- **NHIA concludes and strongly supports that it is most appropriate to develop the standards and prove the effectiveness of E-Prescribing for the overwhelming majority of prescriptions which are for retail pharmacy drugs.**

- **Given the extensive quality assurance standards (above) that are the established practice in provision of home infusion therapy that go well beyond OBRA 1990 and substantial differences from retail pharmacy (next point), it is reasonable to conclude that current CMS and industry efforts to**

set standards and implement E-Prescribing should not be diluted through focus at this time on E-Prescribing standards for home infusion therapy.

- **The differences in home infusion therapy compared to retail pharmacy will necessitate a thorough analysis of the requirement essentials and development of workable standards. In home infusion, eligibility is determined and prior authorization is obtained as a whole for all the drugs, services, supplies and equipment necessary to provide the medical service. Further, with home infusion therapy the pharmacies provide everything pursuant to a physician "order set" (described earlier)—orders for multiple prescription drugs needed for these therapies as well as necessary supplies, equipment and services, and which usually requires dialog between the physician and pharmacist to formulate an optimal and complete home infusion order set for the patient. The drug components of these physician orders are entered (as authorized by the physician) and tracked in accordance with state pharmacy laws that may differ by state. E-Prescribing for home infusion therapy will be quite different from retail pharmacy because of the complexities of multiple prescriptions combined with the other essentials of the physician's order set.**

- **There may be certain benefits to be obtained from E-Prescribing for home infusion therapies such as more efficient communication for physician orders from doctors to infusion pharmacies. Perhaps it will at some future time be demonstrated that there could also be some improved results in patient outcomes. Therefore, regulations CMS may establish now for E-Prescribing that also encompass home infusion therapy should be consistent with the standard of practice for home infusion therapy clinical and claiming models. If contrary to the standard of practice, there will never be a realistic opportunity for E-Prescribing for home infusion therapies.**

- **This would include consistency with CMS's HIPAA decision that home infusion therapy claims are routed through the X12N 837—as most recently communicated by HHS Secretary Thompson on January 14, 2005.**

In accordance with HIPAA regulation, it is probable that there are other non-retail pharmacy drug claims that are to be claimed through the X12N 837 transaction. Examples may include drugs dispensed by clinics, by American Indian/Alaskan Native pharmacies, infusion drugs by long term care pharmacies and more.

RECOMMENDATIONS

- **X12N 837 claims containing drugs from pharmacies are obviously a very small minority of total claims, as CMS has recognized by writing that just 5 percent of pharmacies do not conduct NCPDP eligibility transactions (CMS-0011-P, page 6267). Any E-Prescribing standards that CMS may establish now or in the future for non-retail pharmacy drugs should be consistent for**

the occurrences in which claims are routed through the X12N 837 under HIPAA regulation.

- **E-Prescribing for retail pharmacy drug claims should have standards fully determined and should be proven to achieve the expected benefits, before focus is placed by NCVHS or CMS on non-retail pharmacy dispensing of drugs. Expending resources on the exception cases of non-retail pharmacy will dilute progress on achieving E-Prescribing end results for retail pharmacy drug claims.**

- **After most, if not all, standards are developed and selected for E-Prescribing of retail pharmacy drugs, then NCVHS and CMS should perform an analysis of the data content within NCPDP (and potentially Rx-Hub) E-Prescribing standards (including the prior authorization component) vs. the X12N 837 claim for home infusion therapy and other types of non-retail pharmacy drug treatment. The analysis scope must also include differences in the process for obtaining physician orders and prescriptions, as compared to retail pharmacy*. They should assess if it makes sense to build upon the NCPDP (and potentially Rx-Hub) standards to be well integrated with the X12N 837 claim and the different ordering/prescription processes for various non-retail pharmacy categories. And, assess if alternative approaches for standards for E-Prescribing for home infusion therapy and other non-retail pharmacy drug therapies are better options. Plus, assess the economic feasibility of both options as compared to expected benefits. NHIA will be ready to contribute to this analysis.**

  ***See earlier discussion of the differences for home infusion therapy.**

While CMS writes that the industry has indicated that 75 percent of US pharmacies already have E-Prescribing capability (CMS-0011-P, page 6271), we are unaware of any home infusion therapy pharmacies with this capability. Clearly, this is due to home infusion quality assurance processes in place (see earlier) and distinct differences in how a prescription is ordered for a retail pharmacy drug as compared to development of an order set that includes multiple prescriptions (see earlier).

RECOMMENDATIONS

- **There should be no assumption that NCPDP and (potentially) Rx-Hub "foundation standards" identified for retail pharmacy drug prescriptions—not requiring a pilot period—are also in use for home infusion therapy prescriptions.**

- **It is too early to select NCPDP or Rx-Hub E-Prescribing standards that would apply to home infusion therapy prescriptions.**

To ensure the initial E-Prescribing regulations for provision of non-retail pharmacy drugs (such as in home infusion therapy) are (i) consistent with the use of X12N 837 claim submission and other X12N HIPAA transactions by dispensers that aren't

retail pharmacies and (ii) are not selecting NCPDP and Rx-Hub standards prematurely (prior to the NCVHS and CMS analysis described above), NHIA urges CMS to modify the proposed regulations with changes as underlined next.

RECOMMENDATIONS

- **§423.160 (b) (1) on Standards for Prescription (CMS-0011-P, page 6273)**

  The NCPDP SCRIPT standard listed should be for communication of a prescription or prescription-related information between prescribers and dispensers <u>including mail order pharmacy prescriptions with the exception of prescriptions for other non-retail pharmacy drug prescriptions</u>.

  NHIA Explanatory Note: This change does not necessarily preclude future possibility of using the NCPDP SCRIPT standard for non-retail pharmacy drug prescriptions. Rather, it will ensure that the NCPDP SCRIPT standard isn't selected prematurely for non-retail pharmacy drug prescriptions, including prescriptions for home infusion therapy.

- **§423.160 (b) (2) (i) on Standards for Eligibility (CMS-0011-P, page 6273)**

  In addition to specifying use of the X12N 270/271 Health Care Eligibility Benefit Inquiry and Response for transmitting eligibility inquiries and responses between prescribers and Part D sponsors, <u>this regulation should also specify use of X12N 270/271 for non-retail pharmacy drug prescription eligibility inquiries and responses between dispensers and Part D sponsors excepting when drugs are dispensed by mail order pharmacies.</u>

  NHIA Explanatory Note: This change acknowledges that non-retail pharmacy drug eligibility inquires, such as those for home infusion therapy eligibility, are routed through the X12N 270/271 which is consistent with use of the X12N standards for claims and all other HIPAA standard X12N EDI transactions by non-retail pharmacy drug providers.

- **§423.160 (b) (2) (ii) on Standards for Eligibility (CMS-0011-P, pages 6273 and 6274)**

  The NCPDP standards listed should be for transmitting eligibility inquires and responses between dispensers and Part D sponsors <u>including mail order pharmacy eligibility inquires and responses with the exception that the standard for other non-retail pharmacy drug eligibility inquires and responses is as specified in §423.160 (b) (2) (i)</u>.

  NHIA Explanatory Note: See previous note.

- **Potential Selection of Rx-Hub standards as foundation standards for (1) medication history and (2) formulary and benefit coverage information**

  CMS may select the Rx-Hub standards as foundation standards in its final rule that promulgates from the CMS-0011-P proposed rule. So as to not prematurely define the standards for non-retail pharmacy drugs, the regulations should be written to include mail order pharmacy prescriptions but have an exception for other non-retail pharmacy drug prescriptions.

  NHIA Explanatory Note: This would not necessarily preclude future possibility of using the Rx-Hub standards for non-retail pharmacy drug prescriptions. Rather, it would ensure that the Rx-Hub standards aren't set prematurely for non-retail pharmacy drug prescriptions, including prescriptions for home infusion therapy.

If E-Prescribing is to work for the home infusion therapy model of care, it will be essential for CMS, NCVHS, the Standards Development Organizations, and the technology vendors to understand and build E-Prescribing to support the described physician order set for infusion therapy, and to be compatible with the X12N 837P claiming process. It will also be essential that the technology vendor marketplace determines that it will be economically feasible to build to the necessary standards and technology to support home infusion therapy E-Prescribing. E-Prescribing for home infusion therapies cannot work effectively without these prerequisite events. As the national association of home infusion therapy providers, NHIA stands ready to work with all involved principal parties.

Sincerely,

Bruce Rodman

Bruce E. Rodman
Director, Health Information Policy
Chair, Home Infusion EDI Coalition

Submitter : Mr. Thomas Leary

Date: 04/05/2005

Organization : HIMSS

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-40-Attach-1.DOC

CMS-0011-P-40-Attach-2.DOC

Walgreens
The Pharmacy America Trusts

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

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

Centers for Medicare and Medicaid Services:

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

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

I. Background (F. R. page 6257)

A. Statutory Basis

Although there is no requirement that providers write prescriptions electronically, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.

Section 1860D–4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is "adequate industry experience." Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.

WALGREEN RESPONSE:

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

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American

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

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

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

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

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

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

WALGREENS RESPONSE:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Regarding Long Term Care Settings:

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

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

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

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

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

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

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

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

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

Walgreens Response:

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

We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.

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

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

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

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

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

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

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

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

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

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

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

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

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

(F.R. page 6263)
We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.

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

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

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

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

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

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

(F.R. page 6263)
NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.

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

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

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

Formulary and Medication History Standards (F.R. page 6263)
We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:

WALGREENS RESPONSE:

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

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

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

WALGREENS RESPONSE:

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

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

We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:

- *The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*
- *The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*
- *The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

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

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

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

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

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

(F.R. Page 6264)

While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.

WALGREENS RESPONSE:

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

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

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

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

- *Dispenser means a person, or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.*
- *Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.*
- *E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.*
- *Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.*
- *Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.*
- *Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information or a Part D eligible individual enrolled in a Part D plan.*

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

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

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

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

Walgreens supports the definition of electronic media.

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

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

(F.R. Page 6265)

We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.

WALGREENS RESPONSE:

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

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

We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.

WALGREENS RESPONSE:

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

(F.R. Page 6265)

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

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

+Get message transaction
+Status response transaction
+Error response transaction
+Verification transaction
+Password change transaction

WALGREENS RESPONSE:

Walgreens supports these transactions being adopted.

(F.R. Page 6266)

We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.

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

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

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

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

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

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

2. Eligibility (F.R. Page 6266)

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

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

We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.

WALGREENS RESPONSE:

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

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

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

(F.R. Page 6267)
If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the ***Federal Register*** *of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

WALGREENS RESPONSE:

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

(F.R. Page 6267)
We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

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

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

We invite public comment on our expectations for prescriber participation.

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

D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)
Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.

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

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

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

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

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

WALGREENS RESPONSE:

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

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

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

WALGREENS RESPONSE:

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

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

WALGREENS RESPONSE:

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

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

We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.

WALGREENS RESPONSE:

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

(F.R. Page 6273)

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

WALGREENS RESPONSE:

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

PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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

Conclusion:

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

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

Thank-you

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Healthcare Information and Management Systems Society
Comment on CMS-0011-P: on CMS Proposed Rule: Medicare Program;
E-Prescribing and the Prescription Drug Program
Submitted April 5, 2005

Background

The Centers for Medicare and Medicaid Services (CMS) rule proposes to adopt standards for an electronic prescription drug program (hereafter referred to as 'E-Prescribing') under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the Foundation Standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in an incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

Section 1860D—4(e) of the Act specifies that initial standards, which are used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. Pilot testing is not required for those standards for which the Secretary of the Department of Health & Human Services (HHS), after consultation with affected standard setting organizations and industry users, determines there is "adequate industry experience." The Secretary is required to provide a report to the Congress by April 1, 2007.

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

Overview of HIMSS' Response

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM (Notice for Proposed Rule-Making). Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule.

Overall, HIMSS applauds CMS for promulgating the proposed rule. E-Prescribing is one of the integral steps to achieving broad deployment of electronic health records (EHRs). However, we have several concerns that require comment. Most significantly, HIMSS is concerned that the Foundation Standards identified in the proposed rule may not be adequately tested, and therefore recommends a pilot program to determine understanding and use of the Foundation Standards in real settings.

Additionally, we have concerns that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to go with a legal entity versus a physical location or healthcare location enumeration. We would also like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that Integrating the Healthcare Enterprise (IHE) will continue to help drive the healthcare industry toward interoperability.

Finally, HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for healthcare information technology (HIT) efforts between various entities. To reiterate our comments from the January 2005 Collaborative Response to the Office of the National Coordinator of Healthcare Information Technology (ONCHIT) Request for Information (RFI), complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing

a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information-sharing networks are created, especially in meeting the needs of rural and underserved communities. We encourage CMS to work closely with ONCHIT to continue to move the process for the Standards and Policy Entity into an implementation phase of development.

Standards-Section 1860D-4(e)

Summary of Proposed Rule

Under the MMA, the HHS Secretary is given the authority to adopt proposed standards as final standards prior to the dates specified in the statute. Pilot testing is required only for standards that do not have prior adequate industry experience. Final standards are required by April 1, 2008.

HIMSS' Response

I. A.1: Initial Standards Versus Final Standards

As the largest information systems organization representing healthcare providers and systems vendors, HIMSS respectively submits that there is not adequate industry experience with the standards proposed as "Foundations Standards." Additionally, the proposed Foundation Standards may not fully meet the criteria set out in Sections 1.F and 1.G. We strongly encourage CMS to utilize the pilot process for all E-Prescribing standards.

This recommendation is based on sound information systems principles, the lack of experience with the proposed Foundation Standards in the healthcare provider community, and concern that the proposed Foundation Standards have too many implementation options to achieve the desired E-Prescribing capabilities.

System Testing of Standards

Successful deployment of information systems requires testing of individual components or units, and testing of collections of units through full system testing. If one unit changes, regression testing is required to ensure that the total system still performs as designed. A thorough design, analysis and testing process should be conducted for the full set of standards through pilot testing.

E-Prescribing, as envisioned in the mandates of MMA, is a very complex system unlike any current implementation. The full collection of pertinent standards should be tested both as individual components and collectively as a complete system. Pilot testing is needed on the as-yet-undeveloped or unfinished standards (e.g., Formulary, Medication History, RxNorm or similar prescriber-level drug dictionary and the Sig standard).

Lack of Healthcare Provider Experience with Proposed Standards

While widely used in retail pharmacy and pharmacy benefits management, NCPDP standards have had very limited use in provider environments. Providers are, of course, a significant constituency that will be essential for the success of E-Prescribing. In the HIMSS/Phoenix Systems Winter 2005 survey of HIPAA compliance, we found that even two years after the mandated implementation date, only 73% of providers and 70% of payors are capable of handling HIPAA transactions including the 270/271. Compliance with the 270/271 was a mere 31% for providers and 33% for payors. We know that the percentage actually using the transactions routinely is substantially less than the percentage claiming capability. (See http://www.himss.org/Content/files/WinterSurvey2005.pdf for the full survey report.)

HIMSS considers this low level of utilization as evidence of a failure to meet the requirement for "adequate industry experience" for acceptance of any standard as a foundation standard.

Proposed Standards Necessary But Not Sufficient

The standards proposed by CMS as Foundation Standards can be used to meet E-Prescribing objectives. However, the standards allow so many options that a system may be perfectly compliant in the standard but not capable of supporting Part D E-Prescribing, let alone a "uniform means" of conducting E-Prescribing. The 270/271 illustrates this problem. This transaction pair has a number of levels. While a Level 1 implementation is HIPAA compliant, it is useless for E-Prescribing because the 271 response is a basic Yes/No. Part D E-Prescribing standards need a minimum of Level 3 of the 271 response, which will include benefit information (the "EB" record segment 2110) such as co-payment. Substantial study through pilot testing is needed to determine if the 270/271 can accommodate the total possible benefit/formulary structure a PDP or MA-PD may want to implement. While the 270/271 transaction may be capable of meeting the objectives of an E-Prescription, there are too many optional segments and fields in this standard for simply specifying ASC X12N 270/271. An MMA E-Prescribing Companion Guide, if not a separate standard, is necessary. Because E-Prescribing must support-tiered and other benefit structures related to formulary, the 270/271 Companion Guide must be prepared in the context of formulary communication standards and all other E-Prescribing standards. Please see our response in the Interoperability section (starting on line 370) regarding other best practices that could be used to ensure the proper profiling, testing and implementation of E-Prescribing standards.

The details that make the 270/271 inadequate reflect one of the major reasons HIPAA has failed to meet the promise of efficiency and savings. Realization of the benefits of Part D E-Prescribing as envisioned by the Legislature requires well planned and executed testing and piloting of the full set of standards. HIMSS stands ready to assist CMS in accomplishing this important task.

State Preemption-Section 1860D-4(e) (5)

Summary of Proposed Rule

The standards promulgated under this subsection shall supersede any state law or regulation that is (A) contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

HIMSS' Response

Clarification is needed regarding whether the state law preemption also applies to the prescription of controlled drugs. HIMSS believes that state law preemption should be very inclusive and incorporate controlled drugs, as well as any other state rules or laws that discourage or prevent electronic prescribing.

Testimony was previously given to the National Committee on Vital and Health Statistics (NCVHS) indicating that state variations would impede the development and implementation of E-Prescription systems by adding complexity to the HIT industry.

It has been HIMSS' position that E-Prescribing regulations, to every extent possible, should also be preemptive of state regulations regarding transaction standards and pertinent vocabularies. If preemption is not possible, CMS should prepare, distribute and support model state legislation and regulations to promote interstate consistency.

In addition, HIMSS recommends that these preemptions cover all electronic prescriptions including those covered by all other health plans, and not only Medicare Part D drug coverage as it is unreasonable to expect providers to use different rules for different patients.

Anti-kickback Statute Safe Harbor and Stark Exception – Section 1860D-4(e) (6)

Summary of Proposed Rule

HHS' Office of the Inspector General will provide regulations for a "safe harbor" from sanctions and prohibition with respect to the provision of non-monetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. This applies in the case of hospitals to their members of medical staff; group practices, by the practice to prescribing healthcare professionals who are members of such practice; or a prescription drug plan (PDP) sponsor or MA organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing healthcare professionals.

HIMSS' Response

Legal and policy changes (e.g., Stark Safe Harbor and Anti-kickback Safe Harbor) and financial incentives that increase the healthcare IT market should be structured to align the economic incentives of all stakeholders with the achievement of effective, practical interoperability. A significant barrier to achieving interoperability is the current challenge of building consensus among stakeholders, including healthcare providers, who have competing economic interests with respect to interoperability standards and policies, whether it pertains to E-Prescribing or other types of healthcare information exchange.

Significant legal and policy changes and financial incentives that encourage market expansion should be used to foster the deployment of true, practical interoperability standards once they have been established.

The present Stark law exemptions must be clarified. HIMSS recommends that safe harbor status for health information exchange be provided under a Standards and Policy Entity (SPE), as proposed in the Collaborative Response to the ONCHIT RFI, January 18, 2005. The SPE is a public-private collaborative entity that identifies and specifies the detailed implementation rules, including business rules, for the standards and policies that make up the common framework – which consists of the essential technical and policy standards necessary to ensure interoperability, serve the patients whose data it shares, and connect systems of varying technical sophistication. The SPE identifies and recommends the technical standards and information policies essential for establishing privacy, security and interoperability. The SPE is responsible for the identification, specification, interpretation, and dissemination of these standards and policies. E-Prescribing and related health information exchange standards should be governed by the SPE, who can determine if full interoperability is provided and recommend what safe harbors, if any, should be allowed. (See the Collaborative Response to RFI for the National Health Information Network (NHIN), lines 189-192 and 1048-1054, http://www.himss.org/ASP/ContentRedirector.asp?ContentID=64748.)

It is critical that such anti-kickback exemptions and safe harbors also be pre-emptive of any state regulations or rules that are more restrictive in order to promote E-Prescribing use.

Electronic Prescription Drug Program

Summary of Proposed Rule

The Act specifies that an electronic prescription drug program for covered Part D drugs for part D enrolled individuals shall provide for the electronic transmittal to the prescribing healthcare professional and the dispensing pharmacy and pharmacist of the following:

- Prescription;
- Information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization);
- Information on the drug being prescribed or dispensed and other drugs listed on the medication history;
- Information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments; and
- Information that related 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.

HIMSS' Response

Formulary

HIMSS believes that a controlled vocabulary for drugs correlated to National Drug Code (NDC) code will be essential to the success of the program. In the "Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule," as well as in the Proposed Rule, the Food & Drug Administration (FDA) committed to a separate rulemaking initiative to address the inadequacies and deficiencies of the NDC system (II.C.1) and to maintaining a database of all unique NDC numbers identifying dosage, strength, nature, and form of administration (VII.D and VII.E.6.). We are unaware of any movement on these critical issues. While the NDC system has apparently been acceptable for the pharmacy supply chain, E-Prescribing and point-of-care systems would require a much improved system for identifying medications at the time of prescribing. As our industry moves forward with not only bar code-enabled medication administration, but also initiatives such as computerized provider order entry (CPOE) or E-Prescribing, the deficiencies and limitations of the current NDC system become all too evident. From the provider perspective, there is a need for development of a standard "doctor-level" dictionary of medications. The NDC code standard addresses pharmacy packages. Even if there were no problems with the NDC code, it does not meet provider needs where different systems will use different vocabularies.

The government project, the National Library of Medicine RxNorm project, is making headway in resolving this, but it has not been established as a recognized standard. We encourage the FDA to coordinate with the CMS as they revise their drug establishment registration and listing regulations to make the NDC number unique and more useful to informational databases. We believe that RxNorm and NDC should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be accepted as the drug identification standards for all federal initiatives. We are eager to see publication of a Preliminary Rule for the NDC system and establishment of the NDC database.

HIMSS recommends the development of a standard clinician dictionary of medications. While there is a standard for pharmacy packages (the NDC code), clinicians use different systems with different vocabularies. It is also recommended that the RxNorm project be accelerated and adopted as the standard medication vocabulary for E-Prescribing. We believe NDC and RxNorm should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be the drug identification standards accepted for E-Prescribing.

While RxNorm shows promise in providing semantic interoperability between systems using different proprietary drug databases, the use of RxNorm in real world E-Prescribing situations has not yet been established and needs to be tested for comprehensiveness. In particular, E-Prescribing transactions using RxNorm as a common orderable drug identifier need to be tested to ensure that the prescriber's intent can

be fully captured – especially when characteristics of a medication other than dose form, strength and chemical composition can impact the prescribing decision. Such characteristics include the presence of animal products in a medication or allergens such as egg products or preservatives situations where the patient is unable to consume such products for medical, personal or religious reasons.

HIMSS recommends that CMS conduct pilots to adequately test the ability of RxNorm to provide a bridge between prescribing systems using different databases, while fully communicating the prescriber's intent.

HIPAA

Summary of Proposed Rule

Transactions subject to regulation under HIPAA standards, including those for privacy and security, must continue to comply with HIPAA standards. Providers are HIPAA-covered entities if they engage in electronic transactions for which there are HIPAA standards. If a provider was not otherwise a covered entity under HIPAA, the provider would become a covered entity if it conducts an E-Prescribing transaction that is also a HIPAA transaction, such as the 270/271 eligibility and response.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. The AOA should consider public announcements to ease the concerns of our patients in this regard.

HIMSS' Response

HIMSS supports present federal HIPAA standards, including those for privacy and security. HIMSS interprets the present HIPAA rules as stating that any provider that is not otherwise a covered entity under HIPAA would become a covered entity if they conduct E-Prescribing transactions.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. HIMSS, therefore, recommends more aggressive educational programs for the public.

HIMSS also urges HHS to write federal HIPAA regulations to preempt more restrictive state privacy regulations whenever these state regulations would impede the implementation of E-Prescribing.

NPRM

Use of Standards In "Closed Enterprises"

Summary of Proposed Rule

CMS recognizes that many closed networks currently conduct E-Prescribing within the confines of their enterprise. Recommendations have been offered by NCVHS that closed enterprises should not be subject to the proposed E-Prescription Standards unless the prescription is sent outside the organization. The NCVHS recommendation is different from HIPAA transaction requirements; therefore, CMS is soliciting comment on whether they should adhere to the NCVHS recommendations or require closed enterprises to be compliant with the HIPAA transaction requirements.

HIMSS' Response

HIMSS supports the principles espoused in section II. C of the NPRM with regard to continuing to allow "closed" enterprises to use whatever means they have in place for electronic transactions covered under the NPRM. We support the interpretation that Part D plans should not be required to use the standards defined in the regulation within the confines of an enterprise. Specifically, we recommend that the proposed language for Section 423.160 (a) (2) be amended not to apply to transactions within closed enterprises.

We specifically note that HL7 and NCPDP have worked together to ensure that the information content of HL7 and NCPDP SCRIPT transactions can be translated between the two standards for outpatient prescriptions. It is critical that entities be required to provide for interoperability for E-Prescribing with outside entities – even though they may choose to use proprietary methods within their enterprise. This interoperability is critical for the promotion of the NHIN, as well as the safe transfer of patient care from inpatient to outpatient settings. Many of the most serious and costly adverse drug reactions occur due to lack of accurate medication lists during patient transfers between hospitals and outpatient setting, resulting in duplicate or omitted medications.

The language in the NPRM regarding the exclusive use of NCPDP SCRIPT for the purposes of electronically transmitting a Medicare Part D prescription could be interpreted to mean that a provider entity (e.g., a hospital) using some other internal method for generating prescriptions electronically (e.g., a CPOE system using HL7) would be required to generate an NCPDP SCRIPT message for outpatient prescriptions without the use of an intermediary. While some larger provider organizations may be able to create their own means for translating these messages internally, many provider entities do not have these resources and would be dependent upon an intermediary to provide these services. As long as the receiving entity (e.g., the community pharmacy) receives a NCPDP SCRIPT message, there should be no restriction on the use of intermediaries for performing this translation. HIMSS requests that this appropriate use of intermediaries be clearly permitted in the final rule.

HIMSS also recommends that specific rules are included to prevent restrictions of choice of E-Prescribing software as well as patient choice for provider, pharmacy and medication so that optimum patient care is protected.

National Provider Identifier

Summary of Proposed Rule

NCVHS found that it was important to address the issue of provider identifiers for various E-Prescribing standards it reviewed and, more generally, for an E-Prescribing drug program. They further recommend the use of National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available. The NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers can be used in the event that the National Provider System is not available in time for Medicare Part D E-Prescribing.

HIMSS' Response

HIMSS shares CMS and NCVHS anticipation of broad-ranging benefits the industry will receive once the NPI becomes ubiquitous. Efforts urging for faster implementation of the NPI are supported by HIMSS. However, we have two concerns with the proposal to use NPI for E-Prescribing:

- NPIs will enumerate legal entities but it may be more useful to identify physical locations in E-Prescribing systems and processing; and

- NCPDP's Provider Identifier Number enumerates the dispenser's physical location, but a broader consideration of healthcare location enumeration may be warranted.

Both of these issues should be subject of careful study and pilot testing before CMS designates interim or final enumeration of dispensers and prescribers.

NPI will enumerate legal entities. This information is useful for many purposes, but identification of the dispenser's legal entity may not be the most useful identification for E-Prescribing. In fact, enumeration of physical location may be essential for the envisioned E-Prescribing. For providers, NPI may be ideal, but there must also be a mechanism for patients and dispensers to identify an authorized person for questions or other follow-up related to a prescription. Until they are implemented, we cannot know whether NPI enumeration will meet all functional requirements of E-Prescribing. HIMSS recommends that as part of the comprehensive assessment and pilots, the primary identifier for dispensers and prescribers be more carefully evaluated.

HIMSS further recommends that similar careful study and pilot testing be done of any interim enumeration of dispensers and prescribers. The NCPDP Provider Identifier Number, which enumerates dispensers, is widely used and seems effective for the current retail e-commerce. Its effectiveness for broader use in the envisioned MMA E-Prescribing environment should be evaluated and tested.

HIMSS is also concerned by the number of healthcare enumerators. A confusing collection of competing enumeration systems actually inhibits technology adoption. Fees increase healthcare costs without benefits to patient care. The Coalition for eHealth Standards (CHeS) has addressed this situation and recommends the EAN.UCC Global Location Identification Number (GLIN) for enumeration of locations of healthcare entities. In the pilot testing, HIMSS recommends consideration of GLIN for enumeration of dispensers and prescribers.

Whether NCPDP, GLIN, or another enumerator is selected, HIMSS requests that fees and maintenance costs of the identifier be added to the Regulatory Impact Analysis

Interoperability

Summary of Proposed Rule

CMS acknowledges that E-Prescribing must be interoperable with other parts of an electronic health record (EHR) and that there is much support for postponing the adoption of standards for E-Prescribing until interoperability standards are developed for EHRs. CMS has chosen to proceed with E-Prescribing standards to take advantage of the obvious patient safety and healthcare quality benefits associated with E-Prescribing. CMS proposes foundation ANSI-accredited standards to begin the E-Prescribing process. CMS is convinced that E-Prescribing standards will spur interoperability standards for EHRs and other HIT hardware and software solutions.

HIMSS' Response

While there is extensive industry experience in transmitting prescriptions electronically in general, the proposed foundational standards and the additional E-Prescribing requirements under MMA not addressed by the Foundation Standards have not been adequately tested together in a wide range of settings that represent healthcare delivery today. HIMSS requests that CMS conduct one or more pilots that incorporate all the Foundation Standards and the proposed additional standards in order to assess the overall impact of E-Prescribing on Medicare and the impact to E-Prescribing performed outside of Medicare.

Additionally, with respect to achieving interoperability between E-Prescribing tools, EHRs, and the entire HIT continuum, HIMSS offers to work with CMS to leverage the successes and findings from IHE. IHE is a multi-year, global initiative that creates the framework for passing vital health information seamlessly—from application to application, system to system, and setting to setting—across multiple healthcare enterprises. IHE brings together HIT stakeholders to implement standards for communicating patient information efficiently throughout and among healthcare enterprises by developing a framework for interoperability that is made available in the public domain. In its seven-year history, IHE has succeeded in engaging vendors and establishing implementation momentum. Hundreds of HIT, radiology, laboratory, and cardiology products have already successfully demonstrated support for IHE. Because of its proven process of collaboration, demonstration and real world implementation of interoperable solutions, IHE is in a unique position to significantly accelerate the process for defining, testing, and implementing the standards-based interoperability that is necessary for E-Prescribing and ultimately the President's goal of achieving widespread adoption of HIT solutions and ultimately the NHIN.

IHE has developed a unique process for producing its framework for interoperability by: (1) combining the collaboration of the primary stakeholders in an efficient and focused manner; (2) operating on a yearly cycle to ensure rapid and immediately applicable advances in HIT innovation; (3) providing practical tools and information resources in the public domain that facilitate adoption of standards-based integration solutions, and (4) enabling both healthcare entities and vendors to improve access to information incrementally.

HIMSS and its partner organizations, including the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC) recommend the IHE process to the federal government for consideration in developing a role for the IHE process in its efforts to advance E-Prescribing and other pertinent HIT initiatives.

Finally, the HIMSS' Integration & Interoperability Steering Committee has been working on a proposed interoperability definition that may be useful to CMS. HIMSS is coordinating an industry-wide interoperability definition for later this summer and looks forward to the opportunity to showcase the completed product to CMS and our industry partners.

Impact Analysis

Summary of Proposed Rule

Included as a requirement of the Regulatory Flexibility Act of 1980, the CMS impact analysis reviews the likely impact of the E-Prescribing regulation on the delivery of healthcare in the U.S., as well as on a number of healthcare constituencies, including health plans and pharmacy benefit managers (PBMs), clinician prescribers, pharmacies and dispensers, individual patients, and small businesses. CMS concludes that the E-Prescribing regulation will positively impact healthcare delivery, particularly in measurable clinical outcomes, cost reductions, and improvements in business processes. Impact analyses are based largely on testimony before NCVHS and documents in the public domain.

HIMSS' Response

HIMSS concurs with the CMS assessment that E-Prescribing will have a positive impact on healthcare delivery in the U.S. Overall, we anticipate an increased interest in E-Prescribing as the inclusion of E-Prescribing provisions in MMA has already heightened awareness of the benefits the variety of devices and connectivity solutions available offers prescribers, along with the fact that many of the standards under consideration are already in use. Given the experiences of many of our members, we anticipate a reduction in adverse health events associated with anticipated improvements in prescription drug compliance as identified in previous sections of our response.

HIMSS' subject matter experts stress that E-Prescribing will be successful if all constituencies are empowered to participate in the process. To that end, HIMSS encourages CMS to continue interacting with the community-at-large as CMS develops the E-Prescribing program to ensure that the necessary tools and metrics are in place to provide appropriate and timely information to the provider. At every step along the chain of custody of an E-Prescription, measurements need to be in place to provide adequate incentives for implementation and long-term use by participants. Additionally, CMS must demonstrate that E-Prescribing will streamline clinician workflow and ensure the availability of necessary interoperability tools within and between systems to gain clinician buy-in.

HIMSS expects that, if the necessary business and clinical tools are in place, as many as 15-25% of physicians would elect to participate in the early stages of an MMA E-Prescribing Program with another 50% joining after a year or two. The last 25-35% may be very slow to participate and may eventually require other measures to encourage their participation.

Finally, HIMSS encourages CMS to address the issue of incentives to participate in the E-Prescribing program. A number of organizations within the healthcare continuum will participate based on community empowerment and federal regulation. However, HIMSS anticipates that a significant number of organizations will not participate until they receive adequate reimbursement through implementation funding, deferential reimbursement, or pay-for-performance.

Conclusion

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM. Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule. We are pleased to have worked closely with the HIMSS Board of Directors and various entities within the HIMSS community to develop a response that is consistent with the views of our membership.

In summary, HIMSS is concerned that the Foundation Standards may not be adequately tested, and therefore recommend a pilot program to determine understanding and use of the Foundation Standards in real settings. Our membership would be pleased to discuss this issue further with CMS to ensure adequate metrics are collected during scheduled pilot programs.

We are also concerned that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to use a legal entity versus a physical location or healthcare location enumeration.

HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for HIT efforts between various entities. As we stated in the Collaborative Response to the ONCHIT RFI, complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information sharing networks are created, especially in meeting the needs of rural and underserved communities.

In closing, HIMSS would like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that IHE will continue to help drive the healthcare industry toward interoperability. We look forward to continuing our excellent working

relationship with CMS, and to offering the collective voice of our membership as the proposed rule is finalized and the collaboration is underway.

HIMSS and our members look forward to continuing the necessary dialogue with CMS as we strive to achieve a successful rollout of the E-Prescribing program, from the pilot program through full implementation. If you need any additional information, please feel free to contact Thomas M. Leary, HIMSS Director of Federal Affairs, at tleary@himss.org or 703.299.9712.