Submitter : Ms. Virginia Bartlett
Organization : IMS HEALTH
Category : Private Industry
Date: 04/05/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

Issues

Background

See Attachment.

Provisions of the Proposed Regulation

See Attachment.

CMS-0011-P-51-Attach-1.DOC

CMS-0011-P-51-Attach-2.DOC

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April 5, 2005

Dr. Mark McClellan
Centers for Medicare and Medicaid Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan,

IMS Health, the world's premier source of prescription intelligence, applauds the Centers for Medicare and Medicaid Services (and the advisory body, the National Committee on Vital and Health Statistics) for its work to advance the standard-setting process. As IMS Chief Privacy/Security Officer, I am pleased to offer comments on the Medicare Electronic Prescribing Proposed Rule (Fed Register Vol. 70, No. 23, Friday, February 4, 2005).

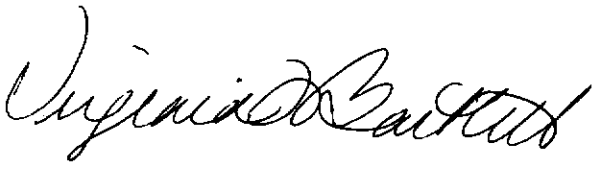
A demonstrated leader in precision statistical methodologies and accurate reporting for 50 years, IMS delivers a total picture of prescription activity across channels, locations, drug types and specialties. As a trusted partner to pharmaceutical and healthcare companies worldwide, we believe that patient information is among the most sensitive of all data and must be protected. More detailed information on IMS is attached.

In response to the CMS request for comments, IMS provides recommendations on four areas we believe will facilitate electronic prescribing. These specific suggestions are:

- Establish HIPAA Privacy as a foundation "standard";
- Develop a workable approach to preemption;
- Make inclusion of the National Provider Identifier optional until there is sufficient industry experience and a system for authentication and access; and
- Do no harm to statistical integrity during the uptake period.

IMS is available to provide assistance and further information on e-prescribing, health data privacy and standards development as needed. Thank you for your consideration of these comments.

Sincerely,



Virginia Bartlett
Chief Privacy/Security Office

Overview of Comments on the Proposed Medicare Electronic Prescribing Rule

Passage of the Medicare Modernization Act (MMA) codified many key changes in the health care system, including an ambitious agenda for uptake of electronic prescribing within the Medicare program. Understood within the larger context of a National Health Information Network, we view electronic prescribing as a valuable tool for improving patient safety and cutting costs. IMS HEALTH (IMS) has engaged in policymaking on HIPAA, electronic prescribing and electronic health care, and work on the National Health Information Network by monitoring the National Committee on Vital and Health Statistics (NCVHS), meeting with key policymakers on Capitol Hill and within the Department of Health and Human Services, participating in relevant coalitions in Washington, and submitting official filings on related topics (including a response to the Office of the National Coordinator for Health Information Technology's Request for Information on the NHIN and interoperability).

IMS identifies the following components of an effective implementation of electronic prescribing and realized success of the agency's electronic prescribing objectives for patient safety and cost savings. For electronic prescribing to succeed, we believe electronic prescribing must:

1. Encourage prescriber adoption and meet state requirements for prescription drug dispensing;
2. Be interoperable with existing marketplace analytics to assure broadest acceptance of the standards;
3. Facilitate the tracking of drug utilization, therapy adherence and quality systems in order to improve patient safety;
4. Maintain patient confidence about safety, security, and value of the system; and
5. Further the goals of the National Health Information Network.

Our comments analyze electronic prescribing success within this framework.

Patient Privacy: HIPAA Should Be A Foundation Standard

Our overarching view of both electronic prescribing and electronic health care is that attention must be paid to patient privacy, interoperability and the integrity of data systems and statistics that are key to advancing the President's goal of electronic health care, improvements in patient safety, and cost savings.

While IMS Health supports the standard setting underway as a means to motivate adoption of electronic health care, we believe acceptance may be more rapidly achieved by including as a foundation standard existing patient privacy and security protections. We believe HIPAA Privacy & Security Rules should be guiding principles for the implementation of electronic prescribing.

Recognizing and preserving the HIPAA Privacy Rule is essential to the success of e-prescribing. It is also an area that meets the adequate market experience baseline for a foundation standard as called out in the e-prescribing proposed rule. While the MMA does not require that physicians gain a patient's approval to electronically prescribe, we anticipate that as electronic prescribing, and electronic health generally, achieve market uptake, patient confidence – and willingness to participate – will be key to success. By adopting a known patient privacy standard at the outset of standard-setting, CMS may improve patient confidence in an electronic health system. A recent study found that Americans are divided on whether the benefits of electronic health care (patient safety, quality of care, etc) outweigh the risk (unauthorized disclosures of health information)[1]. Reinforcing the applicability of HIPAA as a foundation standard may help allay some of these concerns.

By applying HIPAA as a foundation standard to e-prescribing, the Department will also accomplish the baseline protections it will need to generate statistics and comparative value information from the dispensing activity that occurs inside an e-prescribing network. In particular, IMS highlights the section of the HIPAA Privacy Rule that contains the industry standard for the de-identification of patient data. Companies such as IMS already de-identify data successfully as standard practice. With HIPAA as a guide, the industry can create and release research statistics and link their own data to other types of health outcomes information. IMS believes this standard for de-identified data is an appropriate solution as CMS looks to analytics on dispensing activity, drug utilization, and therapeutic effectiveness as well as insight to therapy progression in treatment of specific diseases such as Parkinson's, analysis of concomitant medications and identification of those that might be contra-indicated in combination.

Acceptance of the HIPAA baseline is essential for anyone, including patient safety advocates, the FDA and medical researchers, who monitors prescribing activities and the drug pipeline for regulatory and other public good purposes. Prescriptions written in a new e-prescribing network may be for new patients or by physicians who have switched from paper prescriptions to electronic prescriptions. In either case, visibility is necessary to ensure valid public good results. By applying the HIPAA rules for access, CMS can capture this activity and assure statistical integrity during the uptake period.

The NCVHS aptly described the importance of privacy protections to the Secretary by stating, "the main privacy issue that needs to be resolved in an e-prescribing regulation is what rights consumers should have to limit access to their prescription records." While patient identifiable data is necessary for certain basic prescribing functions (ie: filling and claims processing), de-identifying patient data provides a means of using data for key research and patient safety and quality tracking while providing patients with the highest level of protection. We refer CMS to Dr. Alan Westin's

[1] Professor Alan Westin testifying at the National Committee of Vital and Health Statistics; February, 23, 2005.

(Professor of Public Law and Government at Columbia University) recommendation to the NCVHS that among other privacy considerations, a privacy working group should "identify and test anonymization techniques to enable both advanced medical research and data-analysis services."[2] Anonymization, or de-identification, promoted in HIPAA and the Privacy Rule for research and data analytics purposes, should be a model for data security in an electronic environment – especially at a time when security breaches and identity theft are at the forefront of public debate.

In summary, IMS urges that CMS establish the HIPAA Privacy and Security Rule as a baseline foundation standard for e-prescribing. Action taken now will facilitate confidence, establish certainty, and ensure patient acceptance of a known standard. It will also establish a means for CMS to maintain statistical integrity and evolve the value of e-prescribing.

Preemption

"CMS invites comments on the scope of preemption."

It is no surprise to see a continuation of debate on state preemption given either the intensity of negotiations during HIPAA deliberations or the much-debated use of "and" linking the two criteria for exemption of state law within the MMA.[3] If CMS chooses to stay with the current interpretation of preemption, we note the importance of investing in information solutions to help negotiate differences between federal and state law. The legal efforts involved with determining where state and federal laws intersect and diverge are extremely costly and time consuming and may well serve as yet another reason physicians cite for opting not to prescribe electronically. Thus, CMS should engage in discussions with industry on how best to bridge (using reference files) or "crosswalk" between information fields required to meet state and federal law. Doing so will diminish some of the legal and technological barriers to physician uptake.

Such crosswalks currently exist and are successful due to economies of scale (that is, large quantities of prescribing information that demand crosswalks between state and federal law enable a more cost-efficient means of creating and executing the crosswalks than if there were a fewer amount of prescriptions to consider). For example, IMS builds crosswalks between the federal and state Medicaid prescription drug rebate rules for pharmaceutical manufacturers. Without these information solutions, our clients would have enormous complexities involved with achieving a single rebate calculation in the

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[2] Dr. Westin's full testimony to the NCVHS is available at www.pandab.org and www.ncvhs.hhs.gov, see testimony from February 23, 2005. Dr. Westin expands on the recommendation: "From the start, EMR systems need to develop the identification filters and maskers that will enable researchers and data analysts to access anonymized health records sources. Surveys have shown the public to be very nervous about researcher access to their medical records, and this calls for powerful anonymizing processes to be installed, verified, and communicated to the public from the start, not retrofitted."

[3] Relevant section of the Medicare Modernization Act cited in the Proposed Rule on Electronic Prescribing: *Federal Register,* Vol. 70, No, 23: February 4, 2005. 6258.

context of state and federal laws. Our crosswalks are a cost-efficient way of achieving a single calculation. As a company that performs this service, we know that every change in regulations adds cost and confusion to meeting state and federal law. For example, under the new MMA, we will now need to account for the transition of dual eligibles from Medicaid to Medicare. That said, crosswalks that exist on a large scale (ie: broader than a single company or case) are a cost-efficient way of negotiating regulatory differences and changes.

To this end, IMS urges CMS to define crosswalks to state law and test such information solutions in pilot testing. We also encourage the Secretary to preempt state law for the purposes of pilot testing. Without doing so, pilot testing in certain states may be unable to occur or be ineffective.

National Provider Identifier

> *We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliances dates alternatives to the NPI, particularly in the short term and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process...NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispenser and the NCPDP HCIdea for identifying prescribers... 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..."*

IMS does not believe the NPI is an adequate prescriber identifier for electronic prescribing use at this point in time. We believe there are numerous unresolved short and long term problems with the identifier that need to be resolved before the industry can achieve the experience necessary for use.

In the short-term, the NPI will not be available widely in 2006, it has never been tested in industry in any capacity, and it fails to meet CMS' definition for a foundation standard for e-prescribing. Concerns that require further experience include: use of key information fields, crosswalks between the NPI and other industry identifiers, and failure to link the identifier to physical location or mandate that there be a single identifier per prescriber. Resolution of these issues is critical to the success of the NPI as an identifier and also to e-prescribing should CMS determine the NPI appropriate for use in the future.

The limited use of key information fields is inadequate. With only one location field[4] and a lack of validation during the enumeration process[5], there is very little means for users of the NPI to authenticate the NPI against other records and thus adequately protect against fraud and abuse – already a prescribing concern. While we understand that the Final Rule on the National Provider Identifier does give the Secretary of HHS the

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[4] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3450

[5] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3446

authority to use the NPI for various purposes[6], we note for CMS that the decision not to validate physician-submitted information (in order to keep enumeration costs down) renders the NPI less valuable than other commonly used physician-identifiers. As another example, we would bring to CMS' attention that an NPI is not mandatory for all individual prescribers. If an individual does not require a unique NPI for billing, or is not a covered entity under HIPAA, then they need not apply for one.[7] This leaves a potentially disruptive gap for the processing of e-prescribing transactions and normal prescription claims processing, where an identifier is needed for all prescribers.

We urge CMS to thoughtfully consider the characteristics of the NPI that, while sufficient for claims processing, are not adequate for prescribing purposes. Such a consideration would look at the NPI's inability to ensure accuracy, credibility, and usability in a prescribing environment.

Therefore, it is our recommendation that in the short-term, CMS permit use of existing, currently used identifiers for electronic prescribing purposes. Other identifiers, including the SureScripts Prescriber ID (SPI), the DEA number, medical license numbers, and other proprietary identifiers are currently used widely in the industry for prescribing purposes and we recommend continued use until an identifier can be deemed sufficiently tested and workable for all industry partners. For example, after a period of use and when CMS resolves problems (such as validation and mandatory use for all individual prescribers) the NPI potentially could be an appropriate identifier.

In the event that the NPI is used in electronic prescribing, we urge CMS to ensure that the data dissemination strategy recognizes the importance of crosswalking between the NPI and legacy identifiers. Failure to do so will compromise the quality of health care data tracking, including the prescription drug monitoring that IMS does on behalf of both the government and the private sector. More importantly to CMS, if there are not accurate crosswalks available for all stakeholders in prescription claims processing, the new identifier will not be wholly adopted in that arena, and all the existing identifiers will continue to be used along with the NPI. Administration simplification therefore depends on creation and widespread availability of crosswalks. To this end, CMS should make the NPS reference files available so that data analysis may continue unhampered. This access must be permitted beyond HIPAA covered-entities. We recommend an approach that allows for file use to those who certify their compliance with relevant HIPAA regulations, including the Security Rule, in order to ensure appropriate use of the information.

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[6] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3449

[7] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3438

Based on these concerns, IMS opposes adoption of the NPI as part of the e-prescribing rules until there the aforementioned concerns are appropriately addressed. In short, IMS urges the Secretary to in the final rule to:

1. Validate the continued use of authentication crosswalks such as the SureSpripts, DEA and Medical Education (issued by state license board) number at least until 2010;
2. Assert that within the e-prescribing network identifiers must be assigned for all individual prescribers; and
3. Mandate that physical location be tied to that prescriber.

Additionally, we do not view HCIdea as an adequate interim solution to the NPI. HCIdea is not currently widely used in the industry, does not meet CMS criteria for "adequate industry experience,"[8] and does not meet the criteria outline above.

Other Comments: Interoperability Testing Is Needed for Metrics

IMS believes the most efficient way to achieve the dual goals of e-prescribing and the NHIN is to facilitate, not replace, industry ability to generate metrics about prescription activity. Today, data that analyzes prescribing practices is key to many public health efforts, including tracking prescribing patterns, drug safety recalls, understanding drug utilization, treatment patterns and therapy progress, resource utilization, market trends and usage. In order to continue these essential functions, and, indeed, to facilitate the patient safety and quality tracking promise of electronic prescribing, CMS must ensure continued access to data. Continued access will prevent any inconsistencies or holds on the data flow to currently useful and thriving data tracking and analysis.

Two examples in which access to and use of de-identified data facilitate key public health functions while protecting patient privacy are:

1. In the marketplace today, the FDA requires that pharmaceutical manufacturers self-monitor and report new product market introductions to ensure appropriate prescribing and use. This is most frequently accomplished through use of statistics on dispensed prescriptions. Visibility to the data dispensed within an e-prescribing network is therefore essential to manufacturers compliance and patient safety.
2. Uses of prescription drug data by indication – where the patient is de-identified – can help to identify under-treated conditions, managed care management techniques and proper use of drugs for specific age groups, (e.g. antidepressants in children)

[8] Proposed Rule on Electronic Prescribing: *Federal Register,* Vol 70, No, 23: February 4, 2005. 6261.

These examples, each representing permissible activities under HIPAA, are also necessary for a successful e-prescribing network, EMR and NHIN. Given the critical importance of this issue, IMS strongly recommends that statistical interoperability be tested in the pilot projects and that there be two goals: 1) to assure integrity; 2) to develop a comparative base about in-network dispensing for the marketplace. Specific issues such as the impact of additional and conflicting points of collection can also be included in test requirements.

Conclusion

IMS appreciates the opportunity to offer these comments on this important initiative and hopes CMS will:

- Protect patient privacy and research by recognizing the HIPAA Privacy and Security Rules as a foundation standard.
- Allow for continued access to and use of de-identified patient data as set forth in the Privacy Rule;
- Explore the role information solutions can play in helping stakeholders meet requirements of state and federal laws, should the narrow interpretation of preemption remain;
- Consider the characteristics of the NPI that make it an insufficient identifier for prescribing purposes and recommend continued use of multiple identifiers for prescribing use; and
- Include statistical interoperability as a component of pilot testing to ensure ongoing data integrity.

We look forward to the next phase of electronic prescribing rulemaking and engaging in forthcoming pilot projects.

Attachment:
Background on IMS Health

IMS HEALTH is the world's leading provider of information, research, and analysis to the pharmaceutical and health care industry with data collection activities in over 100 countries. In the United States alone, the company collects information from pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes over 375 million de-identified records each month.

IMS HEALTH's business includes tracking patterns of diseases, treatments, outcomes, prescriptions, and sales of pharmaceutical products. The company receives and analyzes de-identified data. Using this data, we are able to assist the medical, scientific, and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. The company's databases of de-identified prescription drug transactions are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, and assessment of drug utilization patterns (i.e., on- and off-label uses and regional variations in prescribing behavior).

IMS HEALTH recognizes the sensitivity of health information and has operated with long-standing comprehensive practices to protect the privacy of individuals and preserve the confidentiality of the information we collect. These practices include: requiring that transaction data be de-identified prior to being sent to IMS HEALTH; screening records before acceptance to ensure that they are de-identified; tightly controlling access to data; requiring informed patient consent before collecting any individually identifiable information; restricting use of information; routinely auditing information practices; and entering into confidentiality agreements with data sources, employees, and clients.

CMS-0011-P-53

Submitter : Ms. Kathleen Jaegar

Date: 04/05/2005

Organization : Generic Pharmaceutical Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-0011-P-53-Attach-1.DOC

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

March 5, 2005

TRANSMITTED ELECTRONICALLY

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

Dear Sir or Madam:

The Generic Pharmaceutical Association (GPhA) is pleased to transmit its comments on the proposed rule for electronic prescribing in accordance with Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

We support CMS's decision to utilize the National Council for Prescription Drug Programs SCRIPT Program standard. SCRIPT has been widely adopted and should serve as an appropriate basis for electronic prescribing in accordance with the MMA.

GPhA urges CMS to use this opportunity to promote maximum substitution of generic drugs for brand name drugs in the interests of assuring economic efficiency for taxpayers and affordability of prescription drugs to Medicare beneficiaries. The MMA clearly mandates transmission of information on the availability of lower cost alternatives for the drug prescribed to both the prescribing clinician and the dispensing pharmacist under any electronic prescription program. Such information may be of particular helpful to Medicare beneficiaries.

We commend CMS for its leadership in this electronic prescribing initiative and appreciate this opportunity to comment.

Sincerely,

Kathleen D. Jaeger
President and CEO

neric Pharmaceutical Association (GPhA)
0 Clarendon Boulevard, Suite 400 • Arlington, VA 22201 • ph: 703-647-2480 • f: 703-647-2481 • www.gphaonline.org

Submitter :

Date: 04/05/2005

Organization : **WellPoint, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see two (2) attachments

CMS-0011-P-54-Attach-1.DOC

CMS-0011-P-54-Attach-2.DOC

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Thousand Oaks, California 91362
Tel (805) 557-6761
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Email: dana.mcmurtry@wellpoint.com

Dana E. McMurtry
Vice President
Public Policy

April 5, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

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

Dear Dr. McClellan:

On behalf of WellPoint, Inc., thank you for the opportunity to comment on the E-Prescribing and the Prescription Drug Program proposed rule (proposed rule or NPRM) published February 4, 2005 in the Federal Register (CMS-0011-P). These rules represent an important component of the Medicare Modernization Act (MMA) and are critical to the continued development and implementation of electronic prescribing (e-prescribing) technology. We greatly appreciate your agency's solicitation of comments on this rule.

WellPoint, Inc. (WellPoint) is the leading health plan in the U.S. with approximately 28 million medical members. WellPoint is a Blue Cross or Blue Cross Blue Shield licensee in 13 states: California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, Ohio, Virginia, excluding the immediate suburbs of Washington, D.C., and Wisconsin. One in ten Americans receives coverage for their medical care through WellPoint's health plans. We offer a broad range of medical and specialty products. WellPoint filed applications to offer Medicare Prescription Drug Plans to beneficiaries nationwide.

WellPoint understands the enormous potential of e-prescribing to improve patient safety and streamline prescription writing and filling processes. WellPoint has been a strong and early supporter of e-prescribing technology, recently implementing a $40 million pilot program to provide network physicians with hand-held e-prescribing devices. In order to realize the benefits of e-prescribing, health plans, pharmacy benefit managers

(PBMs), patients and providers need strong, uniform e-prescribing standards that have been appropriately tested and provide maximum functionality.

Our comments address a range of concerns with the proposed rule, but focus on the following principles that we believe are critical to both the successful implementation of the rule and to build a stable platform for the growth of e-prescribing:

- **Standards should be implemented within a reasonable timeframe that allows for pilot testing and adequate industry preparation.**
- **The proposed foundation standards should be pilot tested to ensure robustness and effectiveness in the new MMA environment.**
- **E-prescribing standards should be uniform nationwide, pre-empting existing state standards if necessary to achieve this goal.**
- **E-prescribing regulations must protect the ability of plan sponsors to manage the Part D benefit in a cost-effective way.**

Unless otherwise specified in the enclosed comments, WellPoint agrees with the comments submitted by our national trade associations: America's Health Insurance Plans and the Blue Cross Blue Shield Association. I respectfully refer you to their comment letters for additional recommendations regarding the proposed rule.

We look forward to continuing to work with you and your staff on the finalization and implementation of this rule. If you have any questions, please do not hesitate to contact me at (805) 557-6761 or dana.mcmurtry@wellpoint.com.

Sincerely,

Dana E. McMurtry
Vice President
Public Policy

WellPoint Comments on Medicare E-Prescribing and Prescription Drug Program Proposed Rule
April 5, 2005

I. Background

STATE PREEMPTION

Issue: The proposed rule interprets the e-prescribing section of MMA as preempting State law provisions that conflict with Federal e-prescribing program requirements adopted under Part D. HHS views its authority as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards or that restrict the ability to carry out the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. This limited interpretation of preemption authority is inconsistent with congressional intent and will make e-prescribing less efficient and less likely to be utilized by payors, physicians and pharmacists.

WellPoint Recommendation: ***State preemption should be broadly interpreted and applied to ensure a clear, predictable national scheme for all electronic prescriptions regardless of the ultimate payer.*** With the increased attention on the value information technology (IT) can provide the health care system, policy makers are becoming more familiar with the barriers that exist to broad health IT adoption. An often noted barrier to adoption is the possibility of numerous, disjointed standards that directly impact how these systems will work in the practice setting. In fact, the Department of Health and Human Services (HHS) press release announcing the release of this proposed rule stated: "The current lack of common standards is a barrier to the use of health information technology, including e-prescribing."[1] The HHS Goals for a Strategic Framework for Health IT adoption further state that "the government has made a commitment to using common standards and architecture…The result will be a more cost-effective and efficient healthcare system."[2]

In addition, the Government Accounting Office identified in its 2004 report "HHS Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption" specific financial, technical, and cultural barriers to adopting Health IT. Technical barriers include a "lack of uniform standards for data submission and reporting." In developing health IT policy it is critical for the federal government to reduce or eliminate as many barriers to adoption as possible.

In the absence of broad federal preemption, many plans will have to meet multiple standards in the states where they operate resulting in significant costs and inefficiencies. We believe broad preemption of State law is consistent with the congressional intent of

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[1] "E-prescribing proposed rule," Department of Health and Human Services-Press Release.

[2] "Goals of Strategic Framework." Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONCHIT);

MMA, as limited preemption in this area is contrary to the core purpose of establishing uniform national standards to facilitate the development of e-prescribing.

ANTI-KICKBACK STATUTE SAFE HARBOR AND STARK EXCEPTIONS

Issue: Statute requires HHS to issue regulations creating a "safe harbor" under the anti-kickback statute and an "exception" under the physician self-referral statute for certain non-monetary remuneration related to e-prescribing IT items and services. These regulations are scheduled for publication in the near future. In the interim, any arrangements meeting this description must comply with an existing Stark exception or the new community-wide health IT exception (42 CFR 411.357(u)) and must not violate the anti-kickback statute.

WellPoint Recommendation: ***Accelerate publication of these new regulations and issue interim guidance on protected activities.*** Early experience has shown that certain types of incentive programs, including programs that provide free or reduced-cost hardware and software to prescribers, are critical to changing practice patterns and facilitating the implementation of new technology. The publication of these new e-prescribing standards necessitates clear guidance on what constitutes an allowable program. The absence of clear guidance could have a chilling effect on private sector programs to disseminate and encourage the use of e-prescribing technology. Therefore, until regulations are issued, HHS should publish interim guidance on the types of activities that will be protected.

DETERMINATION OF "ADEQUATE INDUSTRY EXPERIENCE"

Issue: The regulation proposes to adopt "foundation standards," which are standards that do not need to be pilot tested because adequate industry experience with these standards is believed to exist. Adequate industry experience is based on three criteria: 1) The standard is ANSI accredited; 2) The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner; and 3) The standard is recognized by key industry stakeholders as the industry standard.

WellPoint Recommendation: ***The three proposed "foundation standards" should be pilot tested prior to final adoption and implementation.*** Adequate industry experience criteria must be applied in the context of how the new Part D benefit will operate under MMA. For example, there may be adequate industry experience in the current environment for the proposed ASC X12N 270/271 eligibility standard, but there is little experience with this standard among PBMs. In the new Part D environment, where direct eligibility transactions with PBMs are contemplated, adequate industry experience does not exist. The proposed "foundation standards" fail to meet the strict application of the adequate industry experience criteria and should undergo pilot testing as required by MMA. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations,

varying transaction volumes and system capabilities) and ensure we are getting the best standard with the broadest functionality. WellPoint respectfully disagrees with the recommendation of the Pharmaceutical Care Management Association, that the proposed foundation standards should be adopted absent any pilot testing.

NATIONAL PROVIDER IDENTIFIER

Issue: HHS is considering, and solicits comments on, the use of the national provider identifier (NPI) before the HIPAA-required compliance date. The proposed rule also solicits comments on viable alternative provider identifiers, as the NPI will not be implemented by January 1, 2006. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007.

WellPoint Recommendation: ***Until the NPI compliance date is in effect, e-prescribing standards should allow the NPI as well as other identifiers to be used.*** Health insurance plans, health care providers, and PBMs are already accustomed to using a variety of identifiers such as proprietary numbers, the Medicare provider number, and the Drug Enforcement Agency (DEA) provider numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

FORMULARY AND MEDICATION HISTORY

Issue: The proposed rule notes that standards are needed to permit communication of formulary information and medication history. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA-approved Standards Development Organization (SDO).

WellPoint Recommendation: ***Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested before adoption and implementation.*** NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history.

II. Provisions of the Proposed Regulation

PROPOSED REQUIREMENTS FOR PART D PLANS

Issue: HHS has tentatively concluded that the proposed foundation standards are not subject to pilot testing because adequate industry experience with the proposed standards already exists. Entities with electronic prescription drug programs would be required to

comply with the proposed applicable standards no later than January 1, 2006. Part D sponsors are required to have an electronic prescription drug program in place by January 1, 2006.

WellPoint Recommendation: ***The proposed foundation standards should undergo pilot testing. Assuming successful completion of the pilots, the compliance date for the foundation standards should be no sooner than January 1, 2007.*** As discussed above, there is not adequate industry experience with these standards in the new Part D environment to justify foregoing pilot testing. We recommend thorough pilot testing of all three proposed foundation standards and a corresponding adjustment to the implementation timeline. Assuming successful completion of the pilots, a compliance date of January 1, 2007 is reasonable and achievable.

It is also important to note that compliance with these standards will require significant resources on the part of many plans and PBMs. The accelerated timeline in the proposed rule does not provide adequate time for organizations to build these costs into their budget and operations plans for the coming year.

PROCESS FOR UPDATING STANDARDS AND ISSUING NEWER VERSIONS

Issue: The proposed rule notes that "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." If the updates to the standards include substantive changes, HHS will provide a formal notice and comment period. If the updates simply correct technical errors or eliminate technical inconsistencies, HHS will consider waiving notice and comment and will likely adopt the version that was previously adopted as well as the newer version. When determining whether to waive notice and comment, HHS will consider the significance of any corrections or revisions to the standard as well as whether the new version is "backward compatible" with the previously adopted version.

WellPoint Recommendation: ***The Centers for Medicare & Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed upon process for the annual adoption of modifications to the e-prescribing standards through an interim final rulemaking process.*** This will provide maximum opportunity for stakeholder input without creating an unnecessarily lengthy process for minor modifications and updates. The SDO that initially developed an e-prescribing standard, such as NCPDP, should annually review and recommend modifications to the standard. These modifications should be submitted directly to the CMS, which should release them as an interim final rule with a 60-day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted to allow any necessary

changes to technology and business systems, as well as any necessary testing and certification between trading partners. We refer you to the discussion of potential version management processes for advancing new and retiring old versions of standards in the NCPDP comment letter (March 30, 2005; Section 1.F). The overall concepts constitute a helpful starting point for ensuring a smooth transition to new versions of standards.

IV. Regulatory Impact Analysis

IMPACT ON HEALTH PLANS/PBMs

Issue: The regulatory impact analysis finds that "plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans." The analysis also notes that the only costs incurred by health plans or PBMs would be those that are voluntarily incurred by providing "financial incentives and technical assistance to participating physicians to conduct e-prescribing." These costs are estimated at approximately $1,500 per prescriber (to implement e-prescribing hardware and software on the prescriber's behalf).

WellPoint Recommendation: ***While e-prescribing has the potential to make a significant contribution toward transforming the health care system, further study is needed to determine the magnitude and timing of savings that may accrue to health plans due to e-prescribing technology. Further study is also needed to determine the total cost of effective incentive programs.*** There is little doubt that e-prescribing, if properly implemented, can offer tremendous benefit to the health care system and can make an important contribution toward meaningful reform of the system. For example, e-prescribing can:[3]

- Improve patient safety with an "informed" prescription;
- Provide access to more patient information at the point of care, reducing administrative costs for presribers and pharmacists;
- Free resources to provide new, consultative, and value-added services;
- Decrease wait times and confusion due to clarification calls between pharmacy, payer, and prescriber; and
- Reduce errors due to incomplete levels of information and transcription.

[3] See, for example, Walker J et al., "The Value Of Health Care Information Exchange And Interoperability." *Health Affairs*, January 19, 2005, which found that interoperability between outpatient providers and pharmacists would reduce the number of phone calls for both clinicians and pharmacists, saving upwards of $2 billion annually. Note that this study looked at the potential impact of complete electronic health records, of which e-prescribing is a vital part. See also, Institute of Medicine (IOM). *To Err is Human: Building a Safer Health System*. National Academy Press.

These contributions may result in significant savings for the health care system, as well as improved outcomes for patients. For example:

- The Center for Information Technology Leadership (CITL) estimates savings from avoidance of adverse drug events (ADEs) greater than $2 billion nationally.
- CITL also estimates that e-prescribing could prevent 1.3 million provider visits, 190,000 hospitalizations, and 136,000 life threatening ADEs per year.

Health plans can expect to realize some of the savings generated through the implementation of e-prescribing technology, but there is little evidence to show that these savings will accrue disproportionately to health plans, or that there will be significant near-term savings. WellPoint's own research (although not generalizable) has shown that e-prescribing can significantly improve utilization of generics and reduce overall costs. By making e-prescribing an element of pay-for-performance programs, however, the value of implementation of e-prescribing for providers increases as well.

With respect to the cost estimates provided in the impact analysis, these figures may have been derived from early estimates of e-prescribing pilot programs, which involved the dissemination of hand-held e-prescribing devices to network physicians. Actual experience has shown that these early estimates were unrealistically low, as, in many cases, they did not include service costs on the hand-held devices. The early estimates also assumed that participating physicians' offices already had a base level of technology in place, which was found in practice not to necessarily be the case.

Other Issues

MESSAGING IN E-PRESCRIBING TRANSACTIONS

Issue: The proposed rule does not include any guidance on permitted or prohibited messaging, such as pop-ups, which could be part of e-prescribing transactions. While some messaging, such as reminders of generic equivalents, are consistent with the goals of the Part D program, other types of messaging are for marketing purposes and do not further the goals of the Part D program.

WellPoint Recommendation: ***Marketing-oriented messaging that does not lower costs or enhance safety for patients should be prohibited.*** The cost estimates for the Part D drug benefit are highly dependent on the ability of plans to manage the Part D benefit cost effectively while ensuring access to medically necessary drugs. Marketing-oriented messaging would severely undermine the ability of plan sponsors to manage the pharmacy benefit as required by MMA.

Submitter : **Mr. Paul Baldwin**

Organization : **Long Term Care Pharmacy Alliance**

Category : **Other Association**

Date: **04/05/2005**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-55-Attach-1.PDF

Long Term Care Pharmacy Alliance

April 5, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Dr. McClellan:

The Long Term Care Pharmacy Alliance (LTCPA) is pleased to submit its comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on E-Prescribing and the Prescription Drug Program. 42 Fed. Reg. 6256 (February 4, 2005). The LTCPA is an alliance representing the four major national long-term care (LTC) pharmacies, estimated to serve three out of every five nursing home residents and numerous other beneficiaries in institutional settings, through over 500 LTC pharmacies nationwide. In the course of that service, LTCPA and its members have developed a preeminent expertise in providing prescription drugs and related services to this particularly frail and elderly population, virtually all of whom will be affected by proposed regulations on e-prescribing.

CMS proposes to implement a set of "foundation" e-prescribing standards ahead of the statutory timeframe. However, the proposed foundation standards include the National Council on Prescription Drug Programs' (NCPDP) SCRIPT Version 5.0 which do not work in the LTC pharmacy setting. The SCRIPT standards do not accommodate the type of three-way communication that is essential to the services we provide.

Given those concerns, we have numerous comments addressing both foundation standards and the overall proposed regulation in the long-term care context, which, in turn, directly affects the health and well-being of beneficiaries who are residents of LTC facilities. We also suggest a series of proposed solutions to improve the proposed regulations to ensure that medically necessary and appropriate prescription drugs are timely and properly delivered and administered to LTC residents and related populations served by the LTC pharmacy community. We urge CMS to seriously consider the issues we raise in our comments and the solutions we propose.

Our comments are divided into three sections. In the first section, we describe LTC pharmacy and its responsibility for the needs of the residents we serve. We also explain the critical role that LTC pharmacy has come to serve in today's health care system, and the specialized services

that LTC pharmacy alone can provide. Understanding these services is important, in that the functionality and structure of any e-prescribing system must accommodate these services and ensure they are integrated into any comprehensive e-prescribing regime. Section II contains LTCPA's response to the Proposed Rule in light of these specialized services and the three-way proscribing process that occurs in the long-term care setting. Section III summarizes LTCPA's recommendations and expresses our interest in continuing to work with CMS to develop e-prescribing standards that meet the needs of Medicare beneficiaries residing in long-term care facilities and other settings.

I. LONG-TERM CARE PHARMACY AND THE SPECIAL NEEDS OF THE RESIDENTS WE SERVE

Nursing Home and other LTC Residents Today have Specialized Drug Therapy Needs Far Different Than the Ambulatory Medicare Beneficiary. To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. CMS, in its Part D rulemaking, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into LTCPA's comments to the proposed regulation, we expand upon them below.

LTC Residents Typically Need Greater Drug Therapy. Unlike the typical ambulatory senior, residents in LTC facilities usually are older, in poorer health, and in need of greater care. A 1999 study by Bernabei *et al.* described the typical LTC resident, as follows:

- mean age of residents is 83.1 years;
- 62% of residents were admitted to the LTC facility from an acute care hospital;
- over half of LTC residents had abnormal cognitive function, and only 17% were characterized as independent or required limited assistance in performing the activities of daily living;
- residents typically had three medical conditions, with 45% having four or more and 10% having more than six medical conditions. Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents had dementia, and 20% were stroke victims; and
- LTC residents were taking an average of 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% were on some type of cardiac medication, and approximately 40% were on an analgesic.[1]

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more

[1] *See* Bernabei, *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*, J. 54 Gerontol. A. Biol Sci. Med. Sci. M25 (1999). At the time it was published, the Bernabie *et al.* study and the SAGE database were the only published statistics specific to long-term care structured to capture specific processes of care provided in LTC facilities. *Id.* at M29.

routine medications per day.[2] The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%).[3] The frequency of drug usage does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

LTC Residents Typically Need Different Drug Therapies Than Their Ambulatory Counterparts. Not only are elderly LTC residents on more medications, but they require different medications and different types of mediations. More specifically, as a person ages their body processes drugs differently due to their changing metabolism and typical decreases in kidney function.[4] There has been extensive treatment in the literature describing the need for a different formulary for the elderly,[5] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in these frail elderly people.[6] While these specialized formularies are often not widely known outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

In addition to differing drug needs, LTC patients often require specialized drug intake systems. One LTCPA member has estimated from their Minimum Data Set records of over 400,000 LTC residents that 9.3% of LTC patients cannot swallow and must be tube fed, and an additional 20.5% of residents have difficulty swallowing and must take their medications through capsules, liquids, injectables, or through pills that can be crushed. Oftentimes, doctors are not familiar with the specialized dosage forms that a nursing resident may need, and the pharmacy has to interact with the doctor to modify a prescription (this is but one example of why long-term care pharmacy must be integrated into the e-prescribing regime). While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail or other pharmacy or pharmacy benefit manager is not equipped to address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

LTC Residents Receive Enhanced Drug Services. In light of the significant patient needs noted above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy. These services include:

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[2] *See* D.E. Tobias and M. Sey, *General and Psychotherapeutic medication Use in 328 Nursing Facilities: A Year 200 National Survey*, 16 Consult. Pharm. 54 (2001).

[3] *Id.*

[4] *See* M. Fouts, J. Hanlon., C. Pieper., E. Perfetto, and J. Feinberg,, *Identification of Elderly Nursing Facility Residents at High Risk for Drug-Related Problems*, 12 The Consultant Pharmacists 1103 (1997).

[5] *Id.; see also* M. Beers, *Inappropriate Medication Prescribing in Skilled Nursing Facilities*, 117 Annals of Internal Med. 684 (1992); A. Stuck, M. Beers, *et al., Inappropriate Medication Use in Community-Residing Older Persons*, 154 Arch. Intern. Med. 2195 (1994); M. Beers, *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly*, 157 Arch Intern. Med. 1531 (1997).

[6] *See, e.g.*, Omnicare, Inc., *Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary* (2001). Omnicare is a member of the LTCPA.

1. Unit Dose and Other Specialized Drug Packaging. This packaging serves two important functions. First, the packaging allows for greater quality control of the drugs and dosages to ensure that medications are taken appropriately and without error. Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. The critical nature of this uniform distribution system throughout the facility cannot be overemphasized. LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day.[7] The specialized drug packaging provided by LTC pharmacy today is a critical system in helping to reduce patient risks of receiving the wrong drugs, or the inappropriate dosages, from a nurse making delivery rounds.

2. Around the Clock "24/7" Delivery. LTC pharmacy also provides round the clock availability, either through delivery services, med-carts and emergency carts,[8] all of which assist in getting patients necessary medications in a timely manner. This service is particularly important in having intravenous medications available for LTC residents, so that they do not have to be transported to a hospital for treatment. It is critical for CMS to recognize the enormous cost savings to the health care system just from this single service.

3. Consultant Pharmacist Services. In addition to providing the drugs, LTC pharmacy also provides a set of services through Consultant Pharmacists, who are able to review and assist in patient drug care. These services include retrospective drug regimen reviews, as required by law,[9] and prospective drug regimen reviews to screen for medical appropriateness of the prescribed drugs and for inappropriate drug interactions.[10] LTC pharmacists also counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services -- all in addition to providing medication. LTC pharmacists also provide a wide range of other primary care services to seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment assessments and support. In this way, LTC pharmacy is the principal defense against medical errors and ensures the highest quality of patient care.

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[7] *See also* R. Tamblyn, *Medication Use in Seniors: Challenges and Solutions*, 51 Therapie 296 (1996). Tamblyn aptly notes that [h]ealth care system policy and practice can have a substantial impact on the drug utilization among seniors." *Id.* at 275. "Although regulatory changes are made in [governmental] drug plan policies to control costs, there is virtually no information on the impact of drug policy interventions on drug utilization patterns and patient outcomes." *Id.* at 276.

[8] Med-carts and emergency carts are pre-positioned medicines provided to the LTC facility for emergency uses. Typically, several thousand dollars of drugs are stored in such carts, which are only used when a patient emergency arises.

[9] 42 C.F.R. 468.60(c).

[10] M. Dashner, S. Brownstein, K. Cameron J., Feinberg, *Fleetwood Phase II Tests A New Model of Long-term Care Pharmacy*, 15 The Consultant Pharmacist 989 (Oct. 2000). The Fleetwood Phase II project also documented the benefits of early pharmacist intervention on identification of high risk patients, interaction with the prescribing doctor, and development of care plans.

Critical for the provision of these important services is the need for the dispensing pharmacy and its consultant pharmacists to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization.[11] Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than retrospective) basis is for there to be a single dispensing pharmacy for any given patient.[12] Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate utilization of prescriptions. The value of these screening services is significant. Bootman *et al.* estimated that Consultant Pharmacist intervention saves $3.6 billion (in 1997 dollars) in avoided drug related problems.[13]

Bootman *et al.* explained their finding that drug-related problems in the LTC context ($4.6 billion with consultant pharmacists, as opposed to $8.2 billion without their services) were a third higher than those he had previously found in the ambulatory setting:

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the physiological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.[14]

The Vast Majority of LTC Residents Currently Receive Prescription Drug Benefits under Medicaid, and, As Dual Eligibles, Will Comprise a Significant Percentage of Enrolled and Active Part-D Beneficiaries In The Coming Years. A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare pharmacy benefits, for example, within their "first 100 days") and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with

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[11] Tamblyn, *supra* at note 6 at 275 (noting that risk of inappropriate drug prescriptions could be reduced 20 to 30 percent by ensuring that primary physicians and pharmacists have "better access to information about all drugs prescribed to patients") (emphasis added).

[12] While current law only requires retrospective drug regimen reviews, the advantages of prospective drug screening are documented in the literature. *See, e.g.*, Dashner, *supra* at note 10.

[13] *See* J.L. Bootman, D.L. Harrison, E. Cox, *the Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 Arch. Intern. Med. 2089 (1997). Bootman *et al.*'s analysis did not even account for prospective drug regime reviews which are conducted by many LTC staff pharmacists today. *Id.* at 2096.

[14] *Id.* at 2095.

both the National Health Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for Healthcare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%. Data provided by LTC operators from approximately 3,000 facilities suggest that within six months of entering a LTC facility, approximately 80% of private pay patients become Medicaid eligible and that by the end of a year, 99% of those residents entering as "private pay" patients become Medicaid eligible.

Thus, it is important for CMS to recognize that the vast majority of LTC residents receive Medicaid prescription drug benefits which include access to "medically necessary" prescription drugs. Virtually all of these so-called "dual eligibles" will be auto-enrolled into the Part D program, and will, likely be the most significant cohort of prescription consumers within the first few years of the Part D program. Thus, it is particularly important in this rulemaking that CMS focus upon this class of beneficiaries, and the pharmacies and doctors that provide prescription drugs to them, to ensure that a functional system is implemented.

LTC Pharmacy is Different from Retail Pharmacy. CMS must also recognize that LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network.[15] In the retail pharmacy setting, a prescriber transmits a prescription directly to the pharmacy on behalf of the Medicare beneficiary. The prescription is filled by the retail pharmacy, (after checking on the enrollment and benefit status of beneficiary, and charging appropriate co-pays,) and delivered to the beneficiary.

By contrast, the long-term care pharmacy must interact not only with the prescriber, but also with the nursing home in which the beneficiary resides. For example, in most cases, the prescription is transmitted to the long-term care pharmacy by nursing home staff. The prescription is then delivered to the nursing home facility, not to the individual beneficiary. The long-term care pharmacist relies on medication records and medical records at the nursing home to check on drug interactions and other contraindications. The nursing home relies on the long-term care pharmacy for specialized packaging, prompt delivery, and the specialized services of its consultant pharmacist.

In addition to dispensing medications, the long-term care pharmacy represents the beneficiary in coverage issues and appeals. Currently, under Medicaid, long-term care pharmacists engage in adjudication with fiscal intermediaries for prior authorization and appeals processes for dual-eligible beneficiaries. As of January 1, 2006, Medicare beneficiaries or their physicians must request coverage determinations from PDPs or appeal those coverage determinations. If a Medicare beneficiary appoints the long-term care pharmacist as his or her representative for grievance, coverage determination, or appeals processes, the long-term care pharmacist also will need to communicate with the PDP to request coverage determinations and, possibly, appeal negative coverage determinations. These responsibilities require access to beneficiaries' medication history and medical history and interaction with staff at the nursing home and the prescribing physician in order to document the need for a particular medication.

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[15] CMS has previously recognized this distinction in its 2002 rulemaking on the ten-proposed discount drug card program . *Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative*, 67 Fed. Reg. 56,617, 56,640 (Final Rule, Sept. 4, 2004).

In summary, long-term care pharmacies have responsibilities for the prescription drug needs of residents of long-term care facilities that are qualitatively different from those of retail pharmacies. These special responsibilities are reflected in the contracts that long-term care facilities enter into with nursing homes, and illustrate the three-way relationship between the prescriber, the nursing home, and the long-term care pharmacy that must, in turn, be reflected in the e-prescribing process.

II. Comments on the Proposed Regulation

A. The Proposed Regulation Does Not Account for The "Three-Way Transaction" Which Is A Part of Every Long-Term Care Pharmacy Prescription Cycle

Before addressing the specifics of the proposed regulation, LTCPA would like to preface its comments by noting that the Proposed Rule does not address the specific locations in which e-prescribing occurs. As long-term care pharmacy providers, our comments are based on our experience as one component of a prescribing process that also includes physicians and nursing home administrators and staff. At each point in the prescribing process, these three entities will interact. Particularly given the anticipated predominance of dual eligibles in the Part D program, and the prevalence of those beneficiaries in long-term care facilities, we believe CMS should expressly recognize and accommodate the needs of these beneficiaries in e-prescribing regulations.

Under the new Medicare prescription drug benefit, physicians will transmit prescriptions to the long-term care pharmacy through the nursing home staff, and the long-term care pharmacy will interact with the nursing home staff to check medication history and medical history records that are kept in the nursing home. Physicians will initiate prior authorization and other coverage determination requests and also can file appeals on behalf of their patients, and these determinations will be communicated to the long-term care pharmacy by the nursing home staff. If the long-term care pharmacist is designated to represent the beneficiary, these requests can be initiated by the long-term care pharmacist on behalf of the Medicare beneficiary, and the long-term care pharmacist will relay the outcome of these requests to both the nursing home and the prescribing physician so that beneficiaries' records can be updated.

The nature of this three-way transaction makes the setting in which e-prescribing takes place an important consideration in CMS' design of e-prescribing standards. In evaluating its proposed regulation, therefore, we strongly urge CMS to depart from a "one size fits all" approach, and to recognize explicitly in its proposed regulation that there needs to be unique and different e-prescribing standards for the long-term care community that function within the three-way transaction construct. We hope that our comments below provide insight for the agency into the unique e-prescribing issues that we face as one party to these three-way e-prescribing transactions, and offer our assistance as CMS develops e-prescribing standards that reflect the needs of prescribers, nursing homes, and long-term care pharmacies.

B. CMS' Proposed SCRIPT "Foundation" Standard Does Not Work for LTC Pharmacy Because LTC Pharmacy Needs an E-Prescribing Standard That Accommodates Three-Way Communication Between the Physician, Nursing Home, and LTC Pharmacy

CMS requests comment on whether a set of "foundation" standards are ready to be implemented ahead of the statutory timeframe, and whether these standards should only apply to Part D eligible individuals enrolled in Part D plans. Section 1860D-4(e)(4)(C)(i) of the Act permits an exception to the pilot testing of standards when the Secretary determines that there is "adequate industry experience" with the standards. After receiving input from various industry entities, CMS proposes to forego pilot testing of the NCPDP's SCRIPT, Version 5.0 (except for the Prescription Fill Status Notification Transaction and its three business cases) and Telecommunication Standard Guide, Version 5.1 and implement them as "foundation" standards ahead of the statutory timeframe.

Although some retail pharmacies may have adequate industry experience with these foundation standards, LTCPA does not believe that the real-world functionality of SCRIPT has been well tested. SCRIPT communicates only between two healthcare entities, the prescriber and the pharmacy. This rudimentary communication capability does not work for LTC pharmacies because the nature of our prescribing process necessitates a three-way communication between prescribers, nursing homes, and LTC pharmacies.

SCRIPT reflects a prescribing physician-to-pharmacy communication, not the three-way communication path that occurs in a long-term care setting. For example, SCRIPT does not support a refill request from a nursing home to a LTC pharmacy, nor does it support an order discontinuation request from the nursing home to the LTC pharmacy. In the long-term care setting, the nursing home and the LTC pharmacy work in tandem and information systems for prescription drugs must include the nursing home in the e-prescribing process.

In addition, nursing homes receive the majority of their admissions from hospitals., and SCRIPT does not capture the robust information transfer that currently occurs between the hospital, physician, nursing home, and LTC pharmacy. A newly admitted LTC resident coming from a hospital stay is likely to have greater co-morbidities, more complex drug regimens, and a need for more complex medications, including infusion therapy. In order to provide proper pharmaceutical care, a prescriber and an LTC pharmacist must communication with other healthcare providers serving the resident. Hospitals and other health care environments use Health Level 7 (HL-7) which allows this type of communication, and SCRIPT is not compatible with HL-7.

Therefore, LTCPA opposes the use of SCRIPT as a foundation standard. Instead, we propose that CMS revise its approach to e-prescribing standards development, including foundation standards, to incorporate the type of three-way communication that is essential in the long-term care setting.

With respect to CMS' request for comments on its interpretation of Congressional intent for the scope of e-prescribing standards, LTCPA supports CMS' view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans. While some may argue that this view is unnecessarily narrow and that e-

prescribing standards should be required for a broader set of transactions, LTCPA believes the narrow interpretation is the correct understanding of Congress's intent. Developing and implementing e-prescribing standards within the Part D prescription drug benefit is an enormous challenge for the agency, plans, prescribers, and pharmacies, including LTC pharmacies, and is best accomplished by confining these efforts to the Part D Medicare program. LTCPA's member companies want to be prepared to engage in e-prescribing for Part D eligible individuals in a range of settings, including long-term care facilities, assisted living facilities, and intermediate care facilities for the mentally retarded (ICF/MRs). Rather than over-extending the application of these standards, LTCPA believes that CMS should devote its resources to provide technical assistance and monitoring of the implementation of e-prescribing standards within the Part D program.

C. Pilot Testing of Initial Standards Should Include Long-Term Care Pharmacies Participating in PDP Networks

In order to conduct pilot testing of initial standards for an electronic prescription drug program prior to promulgation of the final uniform standards, the Secretary is required to enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards. (Section 1860D-4(C)(iii)). Prescriptions for long-term care residents are written by the physician and sent to the nursing home and then transmitted to the long-term care pharmacy, which, in turn, communicates with the nursing home and prescribing physician. Pilot testing of these initial standards must, therefore, occur in settings where this three-way transaction is integral to e-prescribing processes.

LTCPA believes that the timeframe for the implementation of pilot testing is too short, and must be extended. If CMS intends to implement pilot testing on January 1, 2006, the agency should implement a staggered implementation in which initial standards can be pilot tested as they are developed with input from all parts of the industry. LTC pharmacies would be logical sites for early pilot testing. Moreover, pilot testing in LTC pharmacies will provide the agency with information on the application of these initial standards to entities involved in complex prescribing procedures involving multiple entities as well as information on how e-prescribing standards are working with an institutionalized population of dual-eligible beneficiaries.

LTCPA recommends that CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies, and that these standards are working in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside. CMS's evaluation of the pilot testing must also specifically address the experience of physicians, nursing homes, and long-term care pharmacies in its report to Congress on the outcome of the pilot testing.

D. Preemption is Not Appropriate Until CMS Resolves Issues Related to Existing DEA and Other State Pharmacy Regulations

CMS proposes that the e-prescribing standards it develops will preempt State laws when the state law or regulation: (1) is contrary to the standards or restricts the ability of CMS to carry out e-prescribing in the Part D program; and (2) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs. The State law or regulation would have to meet both of these requirements before it is preempted by Federal electronic prescription program drug requirements adopted through rulemaking.

LTCPA believes that it is important to maintain state pharmacy regulations that impact e-prescribing standards until CMS has worked through the issues it identifies in the proposed regulation. For example, CMS acknowledged during the Special Open Door Forum on the Proposed Rule that it is still attempting to negotiate with the DEA on conforming Medicare's Part D e-prescribing standards with DEA regulations for prescriptions for controlled substances. LTCPA recommends that CMS and the DEA resolve this issue prior to CMS promulgating final e-prescribing standards involving controlled substances. LTCPA also recommends that CMS work with states and other insurers that require non-electronic signatures, so that Federal e-prescribing standards do not put long-term care and other pharmacy providers in the position of needing to comply with two sets of standards for prescriptions for controlled substances.

CMS also should not subject to preemption state pharmacy regulations that require the prescription to be first transmitted to the pharmacy. In the long-term care setting, physicians and nursing home staff do not necessarily know a resident's pharmacy benefits and eligibility coverage, which may change based on level-of-care. The long-term care pharmacy industry standard is for the long-term care pharmacies to keep this information. Under Part D, it will be important for long-term care pharmacies to have this information in real time so that they can meet the coordination of benefits requirements for Medicare Part A, B, and D.

Therefore, LTCPA believes it is essential that Federal e-prescribing standards not preempt state regulations that require a prescription to be submitted to the pharmacy by the prescriber (or by the prescriber via the nursing home), rather than first submitted to a pharmacy benefit manager and then to the pharmacy. Long-term care pharmacies operate under this system in states with this pharmacy regulation, and believe that this procedure will help to ensure timely dispensing of prescription drugs for beneficiaries residing in long-term care facilities. LTCPA recommends that state regulations that require a prescription to be submitted to the pharmacy first not be preempted by CMS' Medicare E-Prescribing Standards.

E. Anti-kickback Statute Safe Harbor is Needed as Guidance for LTC Pharmacies

As CMS notes in the Preamble to the Proposed Rule, Section 1860D-4(e)(6) of the MMA requires the Secretary to promulgate regulations that provide for a safe-harbor under the Anti-kickback statute and an exception under the physician self-referral (Stark) statute for certain non-monetary remuneration (in the form of hardware, software, or information technology and training services) related to e-prescribing information technology items and services. LTCPA recommends

that CMS and the Secretary request the Office of the Inspector General to promulgate these regulations for PDP sponsors for pharmacists and pharmacies participating in their networks as quickly as possible (but surely no later than December 1, 2005, so that they can be used when the Part D program begins on January 1, 2006) so that long-term care pharmacies will have guidance on the types of non-monetary remuneration that are not subject to sanctions under the Anti-kickback statute.

LTCPA anticipates that there will be circumstances in which PDP plans or the pharmacies themselves may be interested in providing non-monetary remuneration in the form of hardware and software (e.g. pre-programmed PDAs for prescribing physicians) and training for prescribers and nursing home staff related to e-prescribing. A safe-harbor under the Anti-kickback statute will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration that are acceptable under the statute.

F. CMS' Proposed Incremental Approach to Standards Development Is Flawed And Contrary to Law; All Standards Should be Subject to Notice of Proposed Rulemaking

CMS requests comments 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. LTCPA has serious reservations about CMS' proposed "incremental approach" to adopting final uniform standards for e-prescribing, and is particularly disturbed that CMS would consider requiring any additional standards without a Notice of Proposed Rule Making (NPRM) process. Any standard, including the foundation standards proposed in this rule, represents a substantive requirement for Part D plans and, as standards for electronic e-prescribing, will impact the work of prescribers and providers, including long-term care pharmacies. Only formal rule-making processes will ensure that these entities will have an opportunity for notice and comment. The federal Adminstrative Procedures Act, 5 U.S.C. § 501, *et seq.*, requires no less.

Long-term care pharmacies now serve the vast majority of Medicare beneficiaries in long-term care facilities and our input regarding adequate industry experience must be factored into CMS' assessment of industry experience with any proposed e-prescribing standards. LTCPA supports the standards design criteria outlined in the MMA, particularly the requirement that standards not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists. We believe that the e-prescribing practices in place throughout our member companies help to prevent adverse drug events (ADEs) for the residents of long-term care facilities we serve. Because we serve nursing homes on a 24/7 and emergency delivery basis, instant connectivity between the health care provider, the nursing home facility, the pharmacy and the PDP plan is a goal we support. However, e-prescribing standards must not unduly burden prescribers, nursing homes, or long-term care pharmacies. Therefore, LTCPA recommends that the third proposed criteria for the development of e-prescribing standards be amended as follows: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard." We believe this recommendation conforms with CMS' interest in proposing standards that are "vendor neutral" and will ensure that final e-prescribing standards will work for LTCPA members and other long-term care pharmacies.

Any future standards should be subject to formal agency rulemaking, even if CMS decides to forego pilot testing because of adequate industry experience. The National Committee on Vital and Health Statistics (NCVHS) and standards setting organizations may make recommendations to CMS on e-prescribing standards, but only CMS can promulgate standards through formal rulemaking. Section 1860D-4(e)(4)(B) requires the NCVHS to make recommendations for standards, in consultation with standard setting organizations and other entities, to CMS after consultation with organizations and entities. Section 1860D-4(e)(4)(A) requires the Secretary to *take these recommendations into consideration when developing, adopting, recognizing, or modifying* initial uniform standards, which then are to be pilot tested prior to the agency issuing final standards. The only exception to this process, is that the Secretary, after consultation with standard setting organizations and industry users, may decide not to pilot test standards for which there already is adequate industry experience. The exception provided by Congress applies to the pilot testing requirement, not the rule-making requirement. Clearly, Congress intended for CMS to promulgate rules for the adoption of e-prescribing and for other bodies, including NCVHS, to serve in an advisory capacity, not a rule-making capacity.

G. Issues Related to the Electronic Prescription Drug Program

1. Provider and Dispenser Identifiers

LTCPA will cooperate with efforts by CMS to properly identify dispensers. With regard to unique identifiers for prescribers and dispensers in e-prescribing transactions, LTCPA would support either a National Provider Identifier (NPI), should it become available by January 2006, or the continued use of the NCPDP Provider Identifier Number. At present, NCPDP's Provider Identifier Number can identify long-term care pharmacies with the suffix it uses in the Dispenser Identifier. Adoption of NPI for e-prescribing in all likelihood will be a longer process, however LTCPA will work with CMS to implement the NPI should the agency adopt it. In order to facilitate CMS' task of accelerating the enumeration of all providers, LTCPA member companies are willing to provide a listing of long-term care pharmacy providers serving Medicare beneficiaries to the agency.

2. Formulary and Medication History Standards

Although the NCVHS has recommended that CMS use the RxHub protocol as a basis for rapidly developing an NCPDP standard for formulary and medication history, LTCPA opposes any approach that precludes timely three-way interactions between prescribers, nursing homes, and long-term care pharmacists in the e-prescribing process. We believe certain features of RxHub, e.g. automatically sending a non-formulary prescription back to the prescriber, precludes the involvement of the long-term care pharmacy or nursing home in this process. If, for example, a Medicare beneficiary designates a nursing home administrator or long-term care pharmacist to represent him in coverage determinations requests, these entities must know about the drug that the physician is attempting to prescribe so that they can request a prior authorization on behalf of the beneficiary.

CMS proposes a set of characteristics it considers critical for formulary, benefit, and medication history messaging and requests comments on whether these characteristics should be considered for adoption as foundation standards. LTCPA recommends that the critical characteristics for formulary and benefit data standards be amended to reflect the three-way

transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

Moreover, within the long-term care setting, dual-eligible beneficiaries are not subject to premium and co-pay provisions, and it will be important to distinguish these individuals in the e-prescribing process. LTCPA proposes that the standards for formulary and benefit data be amended to include reference to "long-term care dual eligible resident" and "long-term care non-dual eligible resident" categories so that long-term care pharmacies will be able to quickly identify dual eligible residents who are not subject to premiums and co-payments and other residents of long-term care facilities.

3. Drug Information

Residents of long-term care facilities have complicated drug regimens often consisting of 8 or more drugs per day. Electronic prescription drug information that includes information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments is crucial in the long-term care pharmacy setting. Long-term care pharmacies dispense medications on a 24/7 and emergency basis to nursing homes. Having access to this information in electronic format will assist physicians in appropriately prescribing medications, as well as assist long-term care pharmacies to efficiently and safely dispense prescriptions to Medicare beneficiaries in compliance with the Nursing Home Reform Act of 1987 and other industry standards of care.

4. Medical History

CMS notes in the Preamble to the Proposed Rule that NCVHS has not yet provided recommendations on standards for medical history. LTCPA stands ready to work with NCVHS to provide recommendations to CMS on e-prescribing standards for medical history. In the long-term care setting, medical records for Medicare beneficiaries, like all other residents, are located at the nursing facility, not in the physician's office. Accurate, timely, medical histories are essential for long-term care pharmacies to dispense medications to residents of long-term care facilities. Ideally, medical history e-prescribing standards will be interoperable with electronic medical records (EHRs). LTCPA believes that these e-prescribing standards should be subject to rulemaking in order to assure that they, too, will be interoperable with future EHR standards.

H. Internal E-Prescribing Transactions Should Not Be Subject to Standards for Prescription Communications Within Their Enterprise

CMS has asked whether any standards it adopts for prescription communications should be required for internal as well as external transactions. LTCPA agrees with NCVHS' recommendation to CMS that organizations, including long-term care pharmacies, that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise. As we noted, LTC pharmacies engage in specialized dispensing services (e.g. emergency deliveries) not required of retail pharmacies. CMS has recognized these specialized services in the guidance it has developed for long-term care under the Part D benefit. Because our services are specialized, our internal communications reflect the provision of those specialized services. LTCPA is concerned that if standards for prescription communications are applied within an entity that our communication needs will not "fit" a standard

prescription communications template. Therefore, LTCPA recommends that e-prescribing standards only apply to external communications.

I. New Versions of E-Prescribing Standards Should Be Subject to Formal Rulemaking

As noted above, LTCPA is concerned about the process by which standards will be updated, once adopted, and new versions developed and urges CMS to make new or updated standards subject to formal rulemaking. CMS is proposing to use an incorporate by reference update approval process in which CMS will publish an amendment to a standard in the Code of Federal Regulations in the Federal Register. If the updates are technical in nature (e.g. correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction), CMS proposes that the Secretary consider waiving notice and comment. In this case, compliance with an earlier version or the new version would constitute compliance with the standard. If the updates are substantive (e.g. a new function is considered necessary for an e-prescribing transaction), CMS proposes to modify the required standards through notice and comment rulemaking. CMS proposes to base its determination on whether to waive notice and comment on the significance of any corrections or revision and whether the newer version is "backward compatible" with the previously adopted version. According to CMS, "backward compatible" means that the newer version retains the full functionality of the previously adopted version that had been adopted through rulemaking.

LTCPA disagrees with NCPDP's position that the decision to change a standard is dependent on the standards setting organization and should not be constrained by the federal standard version naming process. The NCPCP vetting process is a consensus process, but individual members of the NCPDP may have specific business practices which will be negatively affected by allowing NCPDP to determine the timing and release of new versions of Federal e-prescribing standards. Apparently, NCPDP is interested in avoiding the formal rulemaking process when introducing new versions of a standard. This is not acceptable to LTCPA members.

LTCPA urges CMS to subject all updated and newer versions of e-prescribing standards to the NPRM process. Only by having an opportunity to formally comment on updated and newer versions of Medicare e-prescribing standards will LTCPA be assured that the needs of prescribers, nursing homes, and long-term care pharmacies will be met.

III. Conclusion

In summary, LTCPA recommends that:

- CMS not use SCRIPT as part of its "foundation" standards for e-prescribing within the Medicare prescription drug program because SCRIPT does not accommodate LTC pharmacies' need for a set of foundation standards that reflect the three-way communication that is essential in a LTC setting.

- CMS adopt the view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans,

and, accordingly, implement these standards only for Part D eligible individuals enrolled in Part D plans.

- CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and that these standards work in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside.

- CMS include in its report to Congress, an evaluation of the pilot testing that specifically addresses the experience of physicians, nursing homes, and long-term care pharmacies.

- CMS resolve its issue with the DEA regarding DEA regulations for non-electronic signatures for prescriptions for controlled substances prior to promulgating final e-prescribing standards.

- CMS not subject to preemption state regulations that require a prescription to be submitted to the pharmacy by the prescriber first rather than to a pharmacy benefit manager.

- CMS urge the Secretary to quickly promulgate a safe-harbor to the Anti-kickback statute that will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration related to e-prescribing information technology items or services that are acceptable under the statute.

- CMS amend its e-prescribing standards to include: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard"

- CMS subject any e-prescribing standards to formal agency rulemaking.

- CMS amend its critical characteristics for formulary and benefit data standards to reflect the three-way transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

- CMS add categories to distinguish long-term care dual eligible and non-dual eligible beneficiaries to its e-prescribing formulary standards.

- CMS apply e-prescribing communication standards to external transactions only and not communications within an entity.

- CMS subject all updated and newer versions of e-prescribing standards to formal agency rulemaking.

LTCPA looks forward to working with CMS in developing Part D e-prescribing standards that work for prescribers, nursing homes, and long-term care pharmacies in meeting the prescription drug needs of Medicare beneficiaries. We would be pleased to meet with CMS staff involved in the development of these standards to further articulate our comments, and also look forward to participating in CMS' plans for piloting the initial e-prescribing standards.

Sincerely,

Paul Baldwin, Executive Director

Date: 04/05/2005

Submitter : Mr. Roy Bussewitz

Organization : National Association of Chain Drug Stores

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-56-Attach-1.DOC

NACDS' Comments on the MMA Electronic Prescribing NPRM
5 April 05

Submitted electronically: http://www.cms.hhs.gov/regulations/ecomments

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)

File Code: CMS–0011–P

Dear Dr. McClellan:

The National Association of Chain Drug Stores (NACDS) appreciates this opportunity to comment on CMS' proposed e–prescribing "foundation" standards, which are the first set of final standards in your incremental approach to adopting final standards for an electronic prescription drug program under the MMA. NACDS' comments are organized, as CMS requested in this proposed rule, by the section of the proposed rule to which they apply, including the specific "issue identifier" that precedes that section. We have also included the *Federal Register* page numbers for convenient reference.

NACDS' chain members, Albertsons, Kerr Drug, Walgreens, and Wal–Mart, have testified on three separate occasions since July 04 at the e–prescribing standards hearings held by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security. NACDS and its chain members look forward to working with CMS to implement these foundation standards and to become actively involved in the MMA mandated 2006 pilots that will test candidate standards that may find their way into the Final Rule, which will be issued no later than April 1, 2008.

Founded in 1933 and based in Alexandria, Virginia, NACDS membership consists of more than 210 chain community retail pharmacy companies. Collectively, chain community retail pharmacy comprises the largest component of pharmacy practice, with 120,000 pharmacist positions and 110,000 FTE pharmacists. Chain community retail pharmacy operates over 35,000 community retail pharmacies with annual sales over $193 billion. Chain operated community retail pharmacies fill approximately 71% of the more than 3.2 billion prescriptions dispensed annually in the United States. For more information about NACDS visit www.nacds.org.

If you have any questions concerning NACDS' comments, please contact either:

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NACDS' Comments

I. Background

A. Statutory Basis [F.R. at page 6256]

NACDS' Comments: "BACKGROUND"—We agree that the HIPAA definition of "electronic media", defined at 45 CFR 160.103, should be applied to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e–prescribing standards.

"Electronic media" is defined at 45 CFR 160.103 to include both electronic storage media and transmission media, including the "internet (wide–open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media."

A. 2. State Preemption [F.R. at page 6258]

NACDS' Comments: "BACKGROUND"—The great variations in state laws and regulations, which negatively impact e–prescribing, have definitely slowed the expansion of e–prescribing. For this reason, NACDS supports an expansion of federal preemption of those state laws and regulations.

The reasons that most variations in state laws and regulations have negatively impacted e–prescribing were *not* by intent, but as a result of unintended consequences. Virtually all of these state laws and regulations were *not* intended to be barriers to e–prescribing, but many were not well enough crafted to withstand the passing of time and new technology and consequently have had that effect.

For example, some state laws and regulations use the term electronic and digital signature interchangeably. Today, many of the individuals who wrote those state laws and regulations would likely recognize the huge differences in the meaning of those terms and their very different impact on e–prescribing.

Realizing that a state educational effort was necessary to correct either the language of the laws and regulations or their interpretation, many entities, including chain pharmacies, initiated independent efforts to educate the states. This educational process was not only directed at trying to eliminate the negative impact of those laws and regulations, but also to offer specific suggestions on how to change those laws and regulations to retain the intent while eliminating the negative impact on e–prescribing.

Needless to say, this state educational process was a very slow process because of the number of states and the wide variations in the wording of their respective laws and regulations. It must be realized that this educational process will need to be continued as long as new state laws and regulations that *could* possibly negatively impact e–prescribing are enacted or promulgated and/or new technology is developed, which would require revisiting the *possible* negative impact of current state laws and regulations.

However, after all of this is said about the negative impact of the variations of state laws and regulations on e–prescribing, it is essential to emphasize that e–prescribing has increased dramatically in that environment. It is very likely though, that e–prescribing would have increased even more dramatically if there was a "total" federal preemption of the state laws and regulations that had *any* adverse impact on e–prescribing.

NACDS believes that it is important to realize that there is an *assumption* by some that designing a federal preemption law, which would *only* preempt those state laws that adversely impact e–prescribing, would be an easy task. However, this task would require an educational effort directed at the federal government, which may be no easier or less time consuming than the state educational efforts.

In addition, the federal educational effort will also have to continue just as long as the state educational efforts… as long as new federal laws are enacted or promulgated that *could* possibly negatively impact e–prescribing and/or new technology is developed, which would require revisiting the *possible* negative impact of current federal laws.

NACDS suggests that CMS request NCVHS to hold a reasonable number of days of hearings… perhaps 5–10 days of hearings… concerning whether or not federal preemption should be expanded and if so, how best to expand that preemption. However, *before* CMS/NCVHS even announces its intent to hold such hearings, they must very carefully frame the issues(s) of that *possible* expanded federal preemption so that elected officials and their constituents are not unduly alarmed.

In addition, CMS/NCVHS must acknowledge that virtually all of the state laws and regulations negatively impacting e–prescribing were certainly well intentioned, but in many cases not crafted precisely enough to withstand the passage of time and the development of new technology, which lead to unintended negative impacts on e–prescribing.

One of the reasons some of the state laws and regulations are now perceived as not written well, is that the authors were writing these laws in the very early days of e–prescribing when no one could predict the future directions of e–prescribing. Many states did as good of a job drafting their laws as they could be reasonably expected to do at that time.

In addition, CMS/NCVHS must make it clear that any *possible* expansion of federal preemption is *not* aimed at politically sensitive issues (e.g., sharing HIV or mental health information). The narrow focus of any possible expansion of federal preemption must be e–prescribing between prescribers and dispensers.

Now, to answer the specific questions posed by this NPRM section. While NACDS agrees with the proposed rule to preempt state law and regulation provisions that conflict with federal electronic prescription program drug requirements that are adopted under Part D, we urge CMS to request that NCVHS hold hearings that would determine whether or not federal preemption should be expanded and if so, to determine specifically how that would be done.

NACDS agrees that the "Relation to State Laws" section of the Act mandates federal preemption of state laws and regulations that are either contrary to the federal e–prescribing standards, or that restricts the ability to carry out or stand as an obstacle to the Medicare Part D electronic prescription drug program requirements. Again, NACDS urges CMS to request that NCVHS

hold hearing that would determine whether or not that federal preemption should be expanded, and if so how.

NACDS also believes that this preemption provision, addressed in the paragraph immediately above, applies only to electronic prescription transactions.

NACDS believes that NCVHS federal preemption expansion hearings could be beneficial even if CMS does *not* now currently have the Congressional authority to expand federal preemption. Those same hearings could provide the essential information necessary for Congress to revisit the issue of expanding federal preemption of state laws and regulations that negatively impact e–prescribing. It will certainly be necessary for Congress to act to increase federal preemption to e–prescribing that exists beyond the MMA Part D program. The continued growth of e–prescribing is dependent upon the creation of *one* national set of e–prescribing standards for *all* e–prescribing.

D. Current Prescribing Environment [F.R. at page 6260]

NACDS' Comments: "BACKGROUND"—The *Current Prescribing Environment* should also reflect that community pharmacies have significant patient clinical medication information. This awareness is essential to local, regional, and national health information networks so that they understand the value of including community pharmacies in their electronic information sharing networks.

Specifically, Congress recognized that community pharmacies have a vital role in reducing medication errors and adverse drug interactions as well as improving medication use when it enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) Public Law 101–508. OBRA '90 applies only to Medicaid recipients, but it was not long before all the states passed laws that assured that this higher standard of pharmacy care for Medicaid patients would be available for all of their citizens.

OBRA '90, and the state laws that expanded OBRA '90's coverage to all state citizens, requires a set of prospective Drug Use Review (DUR) requirements that are more expansive than those required by the MMA. In addition, and more to the point of this comment, OBRA '90 also required that:

> "A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:
> "(aa) Name, address, telephone number, date of birth (or age) and gender.
> "(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
> "(cc) Pharmacist comments relevant to the individual's drug therapy."

The OBRA '90 required maintenance of information concerning patients' diseases, allergies, drug reactions, list of medications and relevant devices, certainly has value to be included within patients' electronic health records (EHRs) in addition to other e–prescribing information required by the MMA.

F. Evolution and Implementation of an Electronic Prescription Drug Program [F.R. at page 6261]

NACDS' Comments: "BACKGROUND"—We agree with CMS' proposed criteria to assess "adequate industry experience" as the rational for supporting CMS' proposed foundation standards without the need to be first pilot tested:

1. The standard is American National Standards Institute (ANSI) accredited;
2. The standard has been implemented by entities to which the final standard will be applied in multiple e–prescribing programs with more than one external health care partner; and
3. The standard is recognized by key industry stakeholders as the industry standard.

NACDS believes that the first of these CMS proposed criterion to assess "adequate industry experience" is an essential safeguard of broad industry input into the development of the candidate standard. The ANSI accreditation process of the standard runs largely parallel to the ANSI accredited standards development organizations (SDO) development of that standard. There is only about a 6–8 week lag in ANSI accreditation of the standard as an *American National Standard* to the SDO's adoption of that standard. Thus, while the ANSI accreditation process of the standard provides an independent verification of broad industry input into the development of that standard, it does not unduly slow the adoption and implementation of that standard.

In addition to these three CMS proposed criterion to assess "adequate industry experience", NACDS strongly suggests that the standard must also be developed and adopted by an ANSI accredited SDO such as NCPDP, HL7, and X12.

NACDS' Comments: "BACKGROUND"—CMS must adopt/acknowledge a standard development organization's (SDO) standards version control/management process that would be used to evolve currently adopted standards and to determine an appropriate implementation time sequence, consistent with the Administrative Procedures Act and other applicable legal requirements.

NACDS continues to believe that the ANSI accredited SDOs play the critical role of bringing together industry stakeholders and providing the forum to develop industry consensus standards, including standards for version control/management. NCVHS' role should continue to be one of holding hearings to assuring greater public input and debate on the SDO adopted standards and then to recommend those standards, supported by the information derived from its hearings, to the Secretary of HHS.

Specifically, CMS must adopt/acknowledge a SDO's process to support a range of standards that are backwards compatible. Backwards compatibility allows for "interoperability" over a range of standard versions. The range must be advanced as industry use dictates, which is best determined by the respective SDO. The result is a "moving range" of standard versions.

The SDO version control/management process, which NACDS described in the paragraph immediately above, would advance the industry as a whole, but does not force everyone to stay in lock–step in order to maintain interoperability. Naming only one version of a standard as the only acceptable version would impede progress and innovation. On the other hand, requiring the simultaneous adoption of a newer version could create disruptive and inefficient transitions. The solution is for SDOs to approve a moving range of standards, which would allow the use of a newer version while still supporting older versions.

Market forces, which are more perceptible to the SDO, will dictate the moving range of standard versions. Competition supports the moving range of standard versions, which allows entities to leapfrog from an older to a newer version when they perceive the time is right to maximize efficiencies. For leapfrogging to occur there must be a minimum of two newer versions. A moving range of standard versions also supports flexibility of decision making in a competitive market.

The many positives of CMS adopting or acknowledging the above described SDO version controlled/managed process for MMA standards, strongly suggests that CMS consider that same process for the HIPAA named standards. It is NACDS' understanding that the community pharmacy SDO, NCPDP, is willing to sit down with CMS and work out the particulars of developing and coordinating such an SDO controlled/managed version process for both the MMA and HIPAA named standards.

G. Electronic Prescription Drug Program [F.R. at page 6261]

NACDS' Comments: "BACKGROUND"—We agree with NCVHS and CMS that it is very important to adopt national unique pharmacy and prescriber *identifiers* for e–prescribing program transactions *as well as the HIPAA transactions*. NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D

However, CMS must understand that e–prescribing not only requires a unique provider identifier, but also requires a unique routing number that can be used to route an e–prescription to one of a prescribers' multiple practice sites. The NPI, being a *unique* identifier, can only be used to route to one practice site.

It would be much more efficient, and far less costly, to be able to use the unique provider identifier as also the number for routing to one of a prescribers' multiple practice sites. To this end, NACDS strongly suggests that CMS ask NCVHS to hold hearings to determine whether or not the NPI 's functionality could be increased to include routing to multiple prescriber sites.

If these hearings determine that such multiple routing functionality is *not* possible, CMS must do everything it can to make it as easy and as cost effective as possible to facilitate that multiple routing, including allowing the continued use of the different methods being used today.

Again, NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D, and for that matter, also for all the HIPAA transactions.

Congress thought that these unique identifiers were critical when it enacted HIPAA in 1996 and at that time required the Secretary of HHS to adopt them. The NPI Final Rule states that the effective date that providers may apply for a NPI is 23 May 05 and that the compliance date for the NPI is "no later than" 23 May 07.

The implementation date for the Medicare Part D drug benefit (i.e., 1 January 06) falls between the date that providers may become enumerated with the NPI and the "no later than" compliance deadline. Therefore, NACDS strongly recommends that CMS immediately begin enumerating all

prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans. This NACDS recommendation is consistent with NCVHS' urging that HHS accelerate the enumeration of all providers to support transition to the NPI for e–prescribing. CMS should require the use of the NPI in the Medicare Part D drug benefit e–prescribing programs beginning 1 January 06.

NACDS strongly recommends that CMS *not* consider an alternative unique identifier to the NPI, including in the short term, because such implementation would create additional and unnecessary expenses for our chain pharmacy members with *no* benefit. Specifically, the "short term" would have to represent the time frame of the less than two months that remain before the NPI effective date of 23 May 05 when prescribers may begin requesting NPI enumeration by CMS. We strongly recommend that CMS focus its NPI enumeration on Medicare Part D prescribers.

NACDS' Comments: "BACKGROUND"—CMS' question, with an invitation for the public to comment, concerns the possible use of the HCIdea number as an alternative for identifying prescribers, which was based on the NPI *not* being available. As NACDS recommended in our comment immediately above, CMS should "immediately begin enumerating all prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans." If CMS begins performing this enumeration now, the NPIs should be available in plenty of time before the January 06 implementation of the Medicare Part D drug benefit.

NACDS does *not* recommend the use, short term or otherwise, of NCPDP's HCIdea number to be used for identifying prescribers because such a charge would incur additional costs for a very short term use of less than 2 months before providers may apply for NPI enumeration.

NACDS also recommends that CMS, after it adopts the NPI as the Medicare Part D e–prescribing programs' unique prescriber identifier, work with the State Medicaid Agencies to assure that they are *not* using federal dollars to support any other unique identifiers.

If the NPI is *not* available by 1 January 06, NACDS strongly recommends that community pharmacies be allowed to continue to use the pharmacy and prescriber numbers that they are using today. This recommendation would not only allow the time for CMS to do the necessary enumeration of providers, but it would *not* increase costs to community pharmacies. No other interim solution of an alternate unique provider identifier is necessary.

NACDS' Comments: "BACKGROUND"—NACDS recommends that the *new* formulary and medication history candidate standard which *may* be affirmatively voted upon by NCPDP's membership and approved by their Board of Trustees by sometime in July *at the earliest*, should *not* be considered by CMS as a *foundation* standard because there will *not* be sufficient time from July 05 to January 06 to meet one of CMS' proposed criteria... to demonstrate *adequate* industry experience, which is necessary to avoid being required to be included in the MMA 2006 pilots. The "*adequate* industry experience" must refer to the industry experience with the standard as approved by the SDO, *not* the RxHub protocol proprietary *candidate* standard that went through SDO modifications before being adopted as an SDO standard. The industry experience with the proprietary *candidate* standard must be viewed as irrelevant.

NACDS' Comments: "BACKGROUND"—We agree with CMS' proposed "critical characteristics for formulary and benefit data standards" set out in the 3rd column of F.R. page 6263. However, it is imperative that these proposed "critical characteristics" be combined with

CMS' three proposed criteria" to assess adequate industry experience, which are set out in the 1st column of F.R. page 6261.

Please see our comments on those proposed criteria at "Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program". Please see NACDS's 3rd comment under *"Background"— "G. Electronic Prescription Drug Program"*, which explains why NACDS recommends that the *new* formulary and medication history standard that *may* become a NCPDP standard later this year, should *not* be considered by CMS as a *foundation* standard.

H. Summary of Status of Standards for an Electronic Prescription Drug Program [F.R. at page 6264]

NACDS' Comments: "BACKGROUND"— We agree with the foundation standards and their specified application as proposed by CMS:

- NCPDP SCRIPT Standard Version 5;
- X12 270/271; and
- NCPDP Version 5.1.

For the reasons mentioned at NACDS' 3rd and 4th comments above at "Background"—"G. Electronic Prescription Drug Program", we do not believe that the adequate industry experience conditions have been met to include *any* formulary and medication history candidate standards as a foundation standard.

NACDS further agrees with CMS' proposed strategy to phase–in implementation of the MMA e–prescribing standards by requiring providers, dispensers, MA–organizations, and PDPs engaged in e–prescribing to comply with the proposed foundation standards, as set out in this NPRM, by no later than 1 January 2006 and at future dates as compliance with other e–prescribing standards are adopted in subsequent rulemaking. We also agree that pilot testing will be required for "candidate" standards *unless* they meet the exception for adequate industry experience criteria as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*.

NACDS' Comments: "BACKGROUND"— We agree with the three foundation standards that are proposed by CMS... please see our comments above at *"Background"—"H. Summary of Status of Standards for an Electronic Prescription Drug Program"*. NACDS also agrees that it is essential that foundation standards be ANSI–accredited *and* meet the adequate industry experience criteria, as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, which will facilitate interoperability with later industry–adopted standards for EHRs as well as interoperability across software and hardware products.

II. Provisions of the Proposed Regulation [F.R. at page 6264]

NACDS' Comments: "PROVISIONS"—NACDS is not aware of any reasons why Part D plans should be required to use the MMA standards for e–prescribing transactions within the enterprise. We are not aware of any potential negative implications or any disadvantages that might occur if these Part D plans in–house e–prescribing transactions were excluded from CMS requirements to comply.

E. **Proposed Standards** [F.R. at page 6265]

NACDS' Comments: "PROVISIONS"—We agree with CMS' decision to propose the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as foundation standards because there is adequate industry experience to forego pilot testing. NACDS also agrees with CMS' decision that the Prescription Fill Status Notification Transaction of SCRIPT lacks the necessary industry experience and thus may not be included as a foundation standard in this proposed rule, but will instead be required to go through the MMA 2006 pilot testing.

NACDS' Comments: "PROVISIONS"—In addition to the comments that NACDS has already made about e–prescribing transaction standard version change, the 2nd NACDS comment at *"Background"—F. Evolution and Implementation of an Electronic Prescription Program"*, we also recommend that CMS should coordinate the version updating process for the e–prescribing transaction standard with the maintenance and modifications of the applicable HIPAA transaction standard. This updating process could certainly be done by CMS by simply referencing the relevant HIPAA standard so that the e–prescribing transaction standard could be updated automatically in concert with any HIPAA standard modification. Keeping MMA e–prescribing transaction standard versions in sync with HIPAA transaction standards is critical.

III. Collection of Information Requirements [F.R. at page 6267]

NACDS' Comments: We do not find it necessary to comment on any of the information collection requirements (i.e., the *Paperwork Reduction Act* requirements).

IV. Regulatory Impact Analysis [F.R. at page 6268]

A. Overall Impact [F.R. at page 6228]

NACDS' Comments: "IMPACT ANALYSIS"—The proposed MMA e–prescribing transaction standards *must* be available for the January 2006 implementation of the Medicare Prescription Drug Program for use by the PDPs that are required to support e–prescribing. This PDP e–prescribing requirement can be expected to *greatly* accelerate prescribers' use of e–prescribing. In addition, an increased number of prescribers outside of the Medicare program can be expected to begin using e–prescribing based on the positive experiences of their Medicare colleagues.

NACDS' Comment: *"IMPACT ANALYSIS"—In addition to the comments NACDS made above at "Background"— "D. Current Prescribing Environment"*, about the federal law and state laws that already require community pharmacies to provide patient safety prospective drug utilization review (pro–DUR) before the medication is dispensed, we would also like to acknowledge that the e–prescribing standards that deliver relevant patient and medication information to the prescriber at the time of prescribing, *in a non–commercial message format*, will add another level of safety checks.

NACDS is very concerned that MMA e–prescribing could quickly be converted into another marketing media venture by commercial interests. When Congress enacted the MMA it gave the Secretary of HHS very clear instructions that electronic prescribing standards shall be adopted

that "allow for the messaging of information only if it relates to the appropriate prescribing of drugs..."

We recommend that CMS includes in its e–prescribing Final Rule, as a general e–prescribing format standard, that MMA e–prescribing must *not* include inappropriate messaging of information. Such inappropriate messaging certainly includes financial incentives that attempt to influence the prescriber's selection decision of medication or of dispenser. If commercial messaging is not strictly prohibited by CMS, as a general format standard, such messaging could have the undesired effect of slowing the implementation of e–prescribing by prescribers and dispensers.

Physicians should see the full range of pharmacy choices that the beneficiary has to obtain their covered Part D drugs, including obtaining extended supplies of medications at retail pharmacies as required by law. The information should include the different cost sharing requirements, but the presentation of the information should not be such that it directs or steers beneficiaries to a particular pharmacy.

Physicians should also not be provided incentives to steer beneficiaries to a particular pharmacy. The information should also include a notation that the beneficiary has the choice of obtaining an extended supply of covered Part D drugs at their local retail pharmacy, and is not required to use a mail order pharmacy.

NACDS also agrees with CMS that the Medicare Part D prescription drug benefits medication therapy management (MTM) programs will improve medication use and further reduce the risk of adverse events, including adverse drug interactions. NACDS believes that electronic prescribing will make available important information to the community pharmacy provider that will help them provide medication management services in the retail pharmacy, such as medication history, and eventually medical history.

The success of these MTM programs, however, will be dictated primarily by whether Part D plans provide these important MTM services through retail pharmacies–which is the preferred way of providing these services to achieve optimal health care outcomes–or whether plans will simply require beneficiaries to obtain these services through telephone services.

B. Impact on Health Plans/PBMs [F.R. at page 6269]

NACDS' Comments: "IMPACT ANALYSIS"—We cannot comment on this section because we do not have any information on the possible impact of e–prescribing on Health Plans/PBMs.

C. Impact on Prescribers [F.R. at page 6270]

NACDS' Comments: "IMPACT ANALYSIS"—Although the MMA e–prescribing programs consist of both prescribers and dispensers, all of CMS' attention to provide incentives to encourage e–prescribing has been focused only on one–side of this equation... the prescribers.

NACDS certainly supports providing incentives for prescribers, but believes that incentives for dispensers, including community pharmacies, should be provided as well. Not to provide incentives to dispensers could be viewed as financially penalizing them for doing the right thing

early by spending the necessary money to be prepared for e–prescribing when the prescribers are ready. In addition, community pharmacies pick up the entire e–prescribing transaction charge… prescribers don't pay any transaction charge. This positive early action by dispensers should be acknowledged by also providing them with incentives to quickly implement e–prescribing.

D. Impact on Pharmacies and Other Dispensers [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—Please refer to our comment immediately above at *"Impact Analysis"—C. Impact on Prescribers"*. In addition, we certainly agree with the e–prescribing benefits described in the testimony of four of our chain members before NCVHS on three separate occasions beginning in July 2004.

We are delighted to see that CMS used the information in the preamble to the e–prescribing NPRM that NACDS provided: "indicating that 75 percent of the 57,208 pharmacies in the U.S. already have e–prescribing capability."

It must be noted that the motivation for these pharmacies to become e–prescribing capable is *not only* the reduction in administrative costs (i.e., reduced time–consuming phone calls to physicians and improved prescription communication between prescriber and dispenser, for example, reduction in illegible handwritten paper prescriptions), but also the awareness that e–prescribing will improve patient safety.

Pharmacists, like other health care providers, are very concerned about patients' quality of care and are very eager to do what they can to improve it. E–prescribing is as much about increasing the opportunity for pharmacists to work more closely with the patient's prescriber and play an expanded role in patients' care. E–prescribing will present new opportunities to make pharmacists' professional roles more challenging and meaningful. CMS should be aware that these professional benefits to pharmacists are perhaps as much of a driving force to become e–prescribing capable as is the reduction in administrative costs.

F. Impact on Others [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—We can not comment because we do *not* have any first hand information on the impact of e–prescribing on the "others" that CMS listed (i.e., technology vendors, pharmaceutical and medical device manufacturers, public health organizations, research and academic institutions, and professional lay organizations).

G. Impact on Small Businesses [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—Some or NACDS' chain members may fit the definition of "small businesses" and therefore NACDS is especially sensitive to and agrees with CMS' statement that, " there will be a distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale." However, our comments above at *"Impact Analysis"—"D. Impact on Pharmacies and other Dispensers"* certainly apply to these small business members as well as all of our other chain pharmacy members.

H. Effects on States and Federalism Statement [F.R. at page 6272]

NACDS' Comments: "IMPACT ANALYSIS"—We agree with CMS that the annual expenditures for installing the capability of e–prescribing will *not* reach the *Unfunded Mandate Reform Act's* threshold of $110 million annually. NACDS addressed its concerns about federal preemption above at *"Background"—"A.2. State Preemption"*. We also agree with CMS, that its discussion in the *"State Preemption"* section and in this section constitute the Federalism summary impact statement required by Executive Order 13132.

I. Conclusion and Alternatives Considered [F.R. at page 6272]

NACDS' Comments: "IMPACT ANALYSIS"—Our comments above, at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, state that NACDS supports CMS' proposed foundation standards because, in part, that they were developed by an ANSI accredited SDO and that they have had adequate industry experience. Therefore, NACDS does *not* believe that the alternative of pilot testing the foundation standards is necessary or desirable. Pilot testing would be redundant at best. The "broad" industry experience provides much better evidence that these standards are accepted by the industry than would pilot testing, which would be of a much smaller scale.

However, NACDS is very sensitive that the word "adequate" in "adequate industry experience" must *not* be minimized. This concern is at least part of the reason behind our 3rd comment above at, *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, suggesting that the proposed formulary and medical history candidate standard must be included in the 2006 MMA required pilot tests.

NACDS would certainly *not* support CMS' adoption of MMA e–prescribing standards that were merely proprietary standards (i.e., not developed by an ANSI accredited SDO) even though they have adequate industry experience. Development by an ANSI accredited SDO and adequate industry experience must be evidenced before CMS should even consider that candidate standard as a MMA e–prescribing standard.

NACDS' Comments on the MMA Electronic Prescribing NPRM
5 April 05

Submitted electronically: http://www.cms.hhs.gov/regulations/ecomments

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)

File Code: CMS–0011–P

Dear Dr. McClellan:

The National Association of Chain Drug Stores (NACDS) appreciates this opportunity to comment on CMS' proposed e–prescribing "foundation" standards, which are the first set of final standards in your incremental approach to adopting final standards for an electronic prescription drug program under the MMA. NACDS' comments are organized, as CMS requested in this proposed rule, by the section of the proposed rule to which they apply, including the specific "issue identifier" that precedes that section. We have also included the *Federal Register* page numbers for convenient reference.

NACDS' chain members, Albertsons, Kerr Drug, Walgreens, and Wal–Mart, have testified on three separate occasions since July 04 at the e–prescribing standards hearings held by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security. NACDS and its chain members look forward to working with CMS to implement these foundation standards and to become actively involved in the MMA mandated 2006 pilots that will test candidate standards that may find their way into the Final Rule, which will be issued no later than April 1, 2008.

Founded in 1933 and based in Alexandria, Virginia, NACDS membership consists of more than 210 chain community retail pharmacy companies. Collectively, chain community retail pharmacy comprises the largest component of pharmacy practice, with 120,000 pharmacist positions and 110,000 FTE pharmacists. Chain community retail pharmacy operates over 35,000 community retail pharmacies with annual sales over $193 billion. Chain operated community retail pharmacies fill approximately 71% of the more than 3.2 billion prescriptions dispensed annually in the United States. For more information about NACDS visit www.nacds.org.

If you have any questions concerning NACDS' comments, please contact either:

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NACDS' Comments

I. Background

A. Statutory Basis [F.R. at page 6256]

NACDS' Comments: "BACKGROUND"—We agree that the HIPAA definition of "electronic media", defined at 45 CFR 160.103, should be applied to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e–prescribing standards.

"Electronic media" is defined at 45 CFR 160.103 to include both electronic storage media and transmission media, including the "internet (wide–open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media."

A. 2. State Preemption [F.R. at page 6258]

NACDS' Comments: "BACKGROUND"—The great variations in state laws and regulations, which negatively impact e–prescribing, have definitely slowed the expansion of e–prescribing. For this reason, NACDS supports an expansion of federal preemption of those state laws and regulations.

The reasons that most variations in state laws and regulations have negatively impacted e–prescribing were *not* by intent, but as a result of unintended consequences. Virtually all of these state laws and regulations were *not* intended to be barriers to e–prescribing, but many were not well enough crafted to withstand the passing of time and new technology and consequently have had that effect.

For example, some state laws and regulations use the term electronic and digital signature interchangeably. Today, many of the individuals who wrote those state laws and regulations would likely recognize the huge differences in the meaning of those terms and their very different impact on e–prescribing.

Realizing that a state educational effort was necessary to correct either the language of the laws and regulations or their interpretation, many entities, including chain pharmacies, initiated independent efforts to educate the states. This educational process was not only directed at trying to eliminate the negative impact of those laws and regulations, but also to offer specific suggestions on how to change those laws and regulations to retain the intent while eliminating the negative impact on e–prescribing.

Needless to say, this state educational process was a very slow process because of the number of states and the wide variations in the wording of their respective laws and regulations. It must be realized that this educational process will need to be continued as long as new state laws and regulations that *could* possibly negatively impact e–prescribing are enacted or promulgated and/or new technology is developed, which would require revisiting the *possible* negative impact of current state laws and regulations.

However, after all of this is said about the negative impact of the variations of state laws and regulations on e–prescribing, it is essential to emphasize that e–prescribing has increased dramatically in that environment. It is very likely though, that e–prescribing would have increased even more dramatically if there was a "total" federal preemption of the state laws and regulations that had *any* adverse impact on e–prescribing.

NACDS believes that it is important to realize that there is an *assumption* by some that designing a federal preemption law, which would *only* preempt those state laws that adversely impact e–prescribing, would be an easy task. However, this task would require an educational effort directed at the federal government, which may be no easier or less time consuming than the state educational efforts.

In addition, the federal educational effort will also have to continue just as long as the state educational efforts… as long as new federal laws are enacted or promulgated that *could* possibly negatively impact e–prescribing and/or new technology is developed, which would require revisiting the *possible* negative impact of current federal laws.

NACDS suggests that CMS request NCVHS to hold a reasonable number of days of hearings… perhaps 5–10 days of hearings… concerning whether or not federal preemption should be expanded and if so, how best to expand that preemption. However, *before* CMS/NCVHS even announces its intent to hold such hearings, they must very carefully frame the issues(s) of that *possible* expanded federal preemption so that elected officials and their constituents are not unduly alarmed.

In addition, CMS/NCVHS must acknowledge that virtually all of the state laws and regulations negatively impacting e–prescribing were certainly well intentioned, but in many cases not crafted precisely enough to withstand the passage of time and the development of new technology, which lead to unintended negative impacts on e–prescribing.

One of the reasons some of the state laws and regulations are now perceived as not written well, is that the authors were writing these laws in the very early days of e–prescribing when no one could predict the future directions of e–prescribing. Many states did as good of a job drafting their laws as they could be reasonably expected to do at that time.

In addition, CMS/NCVHS must make it clear that any *possible* expansion of federal preemption is *not* aimed at politically sensitive issues (e.g., sharing HIV or mental health information). The narrow focus of any possible expansion of federal preemption must be e–prescribing between prescribers and dispensers.

Now, to answer the specific questions posed by this NPRM section. While NACDS agrees with the proposed rule to preempt state law and regulation provisions that conflict with federal electronic prescription program drug requirements that are adopted under Part D, we urge CMS to request that NCVHS hold hearings that would determine whether or not federal preemption should be expanded and if so, to determine specifically how that would be done.

NACDS agrees that the "Relation to State Laws" section of the Act mandates federal preemption of state laws and regulations that are either contrary to the federal e–prescribing standards, or that restricts the ability to carry out or stand as an obstacle to the Medicare Part D electronic prescription drug program requirements. Again, NACDS urges CMS to request that NCVHS

hold hearing that would determine whether or not that federal preemption should be expanded, and if so how.

NACDS also believes that this preemption provision, addressed in the paragraph immediately above, applies only to electronic prescription transactions.

NACDS believes that NCVHS federal preemption expansion hearings could be beneficial even if CMS does *not* now currently have the Congressional authority to expand federal preemption. Those same hearings could provide the essential information necessary for Congress to revisit the issue of expanding federal preemption of state laws and regulations that negatively impact e–prescribing. It will certainly be necessary for Congress to act to increase federal preemption to e–prescribing that exists beyond the MMA Part D program. The continued growth of e–prescribing is dependent upon the creation of *one* national set of e–prescribing standards for *all* e–prescribing.

D. Current Prescribing Environment [F.R. at page 6260]

NACDS' Comments: "BACKGROUND"—The *Current Prescribing Environment* should also reflect that community pharmacies have significant patient clinical medication information. This awareness is essential to local, regional, and national health information networks so that they understand the value of including community pharmacies in their electronic information sharing networks.

Specifically, Congress recognized that community pharmacies have a vital role in reducing medication errors and adverse drug interactions as well as improving medication use when it enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) Public Law 101–508. OBRA '90 applies only to Medicaid recipients, but it was not long before all the states passed laws that assured that this higher standard of pharmacy care for Medicaid patients would be available for all of their citizens.

OBRA '90, and the state laws that expanded OBRA '90's coverage to all state citizens, requires a set of prospective Drug Use Review (DUR) requirements that are more expansive than those required by the MMA. In addition, and more to the point of this comment, OBRA '90 also required that:

> "A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:
> "(aa) Name, address, telephone number, date of birth (or age) and gender.
> "(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
> "(cc) Pharmacist comments relevant to the individual's drug therapy."

The OBRA '90 required maintenance of information concerning patients' diseases, allergies, drug reactions, list of medications and relevant devices, certainly has value to be included within patients' electronic health records (EHRs) in addition to other e–prescribing information required by the MMA.

F. Evolution and Implementation of an Electronic Prescription Drug Program [F.R. at page 6261]

NACDS' Comments: "BACKGROUND"—We agree with CMS' proposed criteria to assess "adequate industry experience" as the rational for supporting CMS' proposed foundation standards without the need to be first pilot tested:

1. The standard is American National Standards Institute (ANSI) accredited;
2. The standard has been implemented by entities to which the final standard will be applied in multiple e–prescribing programs with more than one external health care partner; and
3. The standard is recognized by key industry stakeholders as the industry standard.

NACDS believes that the first of these CMS proposed criterion to assess "adequate industry experience" is an essential safeguard of broad industry input into the development of the candidate standard. The ANSI accreditation process of the standard runs largely parallel to the ANSI accredited standards development organizations (SDO) development of that standard. There is only about a 6–8 week lag in ANSI accreditation of the standard as an *American National Standard* to the SDO's adoption of that standard. Thus, while the ANSI accreditation process of the standard provides an independent verification of broad industry input into the development of that standard, it does not unduly slow the adoption and implementation of that standard.

In addition to these three CMS proposed criterion to assess "adequate industry experience", NACDS strongly suggests that the standard must also be developed and adopted by an ANSI accredited SDO such as NCPDP, HL7, and X12.

NACDS' Comments: "BACKGROUND"—CMS must adopt/acknowledge a standard development organization's (SDO) standards version control/management process that would be used to evolve currently adopted standards and to determine an appropriate implementation time sequence, consistent with the Administrative Procedures Act and other applicable legal requirements.

NACDS continues to believe that the ANSI accredited SDOs play the critical role of bringing together industry stakeholders and providing the forum to develop industry consensus standards, including standards for version control/management. NCVHS' role should continue to be one of holding hearings to assuring greater public input and debate on the SDO adopted standards and then to recommend those standards, supported by the information derived from its hearings, to the Secretary of HHS.

Specifically, CMS must adopt/acknowledge a SDO's process to support a range of standards that are backwards compatible. Backwards compatibility allows for "interoperability" over a range of standard versions. The range must be advanced as industry use dictates, which is best determined by the respective SDO. The result is a "moving range" of standard versions.

The SDO version control/management process, which NACDS described in the paragraph immediately above, would advance the industry as a whole, but does not force everyone to stay in lock–step in order to maintain interoperability. Naming only one version of a standard as the only acceptable version would impede progress and innovation. On the other hand, requiring the simultaneous adoption of a newer version could create disruptive and inefficient transitions. The solution is for SDOs to approve a moving range of standards, which would allow the use of a newer version while still supporting older versions.

Market forces, which are more perceptible to the SDO, will dictate the moving range of standard versions. Competition supports the moving range of standard versions, which allows entities to leapfrog from an older to a newer version when they perceive the time is right to maximize efficiencies. For leapfrogging to occur there must be a minimum of two newer versions. A moving range of standard versions also supports flexibility of decision making in a competitive market.

The many positives of CMS adopting or acknowledging the above described SDO version controlled/managed process for MMA standards, strongly suggests that CMS consider that same process for the HIPAA named standards. It is NACDS' understanding that the community pharmacy SDO, NCPDP, is willing to sit down with CMS and work out the particulars of developing and coordinating such an SDO controlled/managed version process for both the MMA and HIPAA named standards.

G. Electronic Prescription Drug Program [F.R. at page 6261]

NACDS' Comments: "BACKGROUND"—We agree with NCVHS and CMS that it is very important to adopt national unique pharmacy and prescriber *identifiers* for e–prescribing program transactions *as well as the HIPAA transactions*. NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D

However, CMS must understand that e–prescribing not only requires a unique provider identifier, but also requires a unique routing number that can be used to route an e–prescription to one of a prescribers' multiple practice sites. The NPI, being a *unique* identifier, can only be used to route to one practice site.

It would be much more efficient, and far less costly, to be able to use the unique provider identifier as also the number for routing to one of a prescribers' multiple practice sites. To this end, NACDS strongly suggests that CMS ask NCVHS to hold hearings to determine whether or not the NPI 's functionality could be increased to include routing to multiple prescriber sites.

If these hearings determine that such multiple routing functionality is *not* possible, CMS must do everything it can to make it as easy and as cost effective as possible to facilitate that multiple routing, including allowing the continued use of the different methods being used today.

Again, NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D, and for that matter, also for all the HIPAA transactions.

Congress thought that these unique identifiers were critical when it enacted HIPAA in 1996 and at that time required the Secretary of HHS to adopt them. The NPI Final Rule states that the effective date that providers may apply for a NPI is 23 May 05 and that the compliance date for the NPI is "no later than" 23 May 07.

The implementation date for the Medicare Part D drug benefit (i.e., 1 January 06) falls between the date that providers may become enumerated with the NPI and the "no later than" compliance deadline. Therefore, NACDS strongly recommends that CMS immediately begin enumerating all

prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans. This NACDS recommendation is consistent with NCVHS' urging that HHS accelerate the enumeration of all providers to support transition to the NPI for e–prescribing. CMS should require the use of the NPI in the Medicare Part D drug benefit e–prescribing programs beginning 1 January 06.

NACDS strongly recommends that CMS *not* consider an alternative unique identifier to the NPI, including in the short term, because such implementation would create additional and unnecessary expenses for our chain pharmacy members with *no* benefit. Specifically, the "short term" would have to represent the time frame of the less than two months that remain before the NPI effective date of 23 May 05 when prescribers may begin requesting NPI enumeration by CMS. We strongly recommend that CMS focus its NPI enumeration on Medicare Part D prescribers.

NACDS' Comments: "BACKGROUND"—CMS' question, with an invitation for the public to comment, concerns the possible use of the HCIdea number as an alternative for identifying prescribers, which was based on the NPI *not* being available. As NACDS recommended in our comment immediately above, CMS should "immediately begin enumerating all prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans." If CMS begins performing this enumeration now, the NPIs should be available in plenty of time before the January 06 implementation of the Medicare Part D drug benefit.

NACDS does *not* recommend the use, short term or otherwise, of NCPDP's HCIdea number to be used for identifying prescribers because such a charge would incur additional costs for a very short term use of less than 2 months before providers may apply for NPI enumeration.

NACDS also recommends that CMS, after it adopts the NPI as the Medicare Part D e–prescribing programs' unique prescriber identifier, work with the State Medicaid Agencies to assure that they are *not* using federal dollars to support any other unique identifiers.

If the NPI is *not* available by 1 January 06, NACDS strongly recommends that community pharmacies be allowed to continue to use the pharmacy and prescriber numbers that they are using today. This recommendation would not only allow the time for CMS to do the necessary enumeration of providers, but it would *not* increase costs to community pharmacies. No other interim solution of an alternate unique provider identifier is necessary.

NACDS' Comments: "BACKGROUND"—NACDS recommends that the *new* formulary and medication history candidate standard which *may* be affirmatively voted upon by NCPDP's membership and approved by their Board of Trustees by sometime in July *at the earliest*, should *not* be considered by CMS as a *foundation* standard because there will *not* be sufficient time from July 05 to January 06 to meet one of CMS' proposed criteria... to demonstrate *adequate* industry experience, which is necessary to avoid being required to be included in the MMA 2006 pilots. The "*adequate* industry experience" must refer to the industry experience with the standard as approved by the SDO, *not* the RxHub protocol proprietary *candidate* standard that went through SDO modifications before being adopted as an SDO standard. The industry experience with the proprietary *candidate* standard must be viewed as irrelevant.

NACDS' Comments: "BACKGROUND"—We agree with CMS' proposed "critical characteristics for formulary and benefit data standards" set out in the 3rd column of F.R. page 6263. However, it is imperative that these proposed "critical characteristics" be combined with

CMS' three proposed criteria" to assess adequate industry experience, which are set out in the 1st column of F.R. page 6261.

Please see our comments on those proposed criteria at "Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program". Please see NACDS's 3rd comment under *"Background"— "G. Electronic Prescription Drug Program"*, which explains why NACDS recommends that the *new* formulary and medication history standard that *may* become a NCPDP standard later this year, should *not* be considered by CMS as a *foundation* standard.

H. Summary of Status of Standards for an Electronic Prescription Drug Program [F.R. at page 6264]

NACDS' Comments: "BACKGROUND"— We agree with the foundation standards and their specified application as proposed by CMS:

- NCPDP SCRIPT Standard Version 5;
- X12 270/271; and
- NCPDP Version 5.1.

For the reasons mentioned at NACDS' 3rd and 4th comments above at "Background"—"G. Electronic Prescription Drug Program", we do not believe that the adequate industry experience conditions have been met to include *any* formulary and medication history candidate standards as a foundation standard.

NACDS further agrees with CMS' proposed strategy to phase–in implementation of the MMA e–prescribing standards by requiring providers, dispensers, MA–organizations, and PDPs engaged in e–prescribing to comply with the proposed foundation standards, as set out in this NPRM, by no later than 1 January 2006 and at future dates as compliance with other e–prescribing standards are adopted in subsequent rulemaking. We also agree that pilot testing will be required for "candidate" standards *unless* they meet the exception for adequate industry experience criteria as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*.

NACDS' Comments: "BACKGROUND"— We agree with the three foundation standards that are proposed by CMS... please see our comments above at *"Background"—"H. Summary of Status of Standards for an Electronic Prescription Drug Program"*. NACDS also agrees that it is essential that foundation standards be ANSI–accredited *and* meet the adequate industry experience criteria, as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, which will facilitate interoperability with later industry–adopted standards for EHRs as well as interoperability across software and hardware products.

II. Provisions of the Proposed Regulation [F.R. at page 6264]

NACDS' Comments: "PROVISIONS"—NACDS is not aware of any reasons why Part D plans should be required to use the MMA standards for e–prescribing transactions within the enterprise. We are not aware of any potential negative implications or any disadvantages that might occur if these Part D plans in–house e–prescribing transactions were excluded from CMS requirements to comply.

E. **Proposed Standards** [F.R. at page 6265]

NACDS' Comments: "PROVISIONS"—We agree with CMS' decision to propose the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as foundation standards because there is adequate industry experience to forego pilot testing. NACDS also agrees with CMS' decision that the Prescription Fill Status Notification Transaction of SCRIPT lacks the necessary industry experience and thus may not be included as a foundation standard in this proposed rule, but will instead be required to go through the MMA 2006 pilot testing.

NACDS' Comments: "PROVISIONS"—In addition to the comments that NACDS has already made about e–prescribing transaction standard version change, the 2nd NACDS comment at *"Background"—F. Evolution and Implementation of an Electronic Prescription Program"*, we also recommend that CMS should coordinate the version updating process for the e–prescribing transaction standard with the maintenance and modifications of the applicable HIPAA transaction standard. This updating process could certainly be done by CMS by simply referencing the relevant HIPAA standard so that the e–prescribing transaction standard could be updated automatically in concert with any HIPAA standard modification. Keeping MMA e–prescribing transaction standard versions in sync with HIPAA transaction standards is critical.

III. Collection of Information Requirements [F.R. at page 6267]

NACDS' Comments: We do not find it necessary to comment on any of the information collection requirements (i.e., the *Paperwork Reduction Act* requirements).

IV. Regulatory Impact Analysis [F.R. at page 6268]

A. Overall Impact [F.R. at page 6228]

NACDS' Comments: "IMPACT ANALYSIS"—The proposed MMA e–prescribing transaction standards *must* be available for the January 2006 implementation of the Medicare Prescription Drug Program for use by the PDPs that are required to support e–prescribing. This PDP e–prescribing requirement can be expected to *greatly* accelerate prescribers' use of e–prescribing. In addition, an increased number of prescribers outside of the Medicare program can be expected to begin using e–prescribing based on the positive experiences of their Medicare colleagues.

NACDS' Comment: *"IMPACT ANALYSIS"—In addition to the comments NACDS made above at "Background"— "D. Current Prescribing Environment"*, about the federal law and state laws that already require community pharmacies to provide patient safety prospective drug utilization review (pro–DUR) before the medication is dispensed, we would also like to acknowledge that the e–prescribing standards that deliver relevant patient and medication information to the prescriber at the time of prescribing, *in a non–commercial message format*, will add another level of safety checks.

NACDS is very concerned that MMA e–prescribing could quickly be converted into another marketing media venture by commercial interests. When Congress enacted the MMA it gave the Secretary of HHS very clear instructions that electronic prescribing standards shall be adopted

that "allow for the messaging of information only if it relates to the appropriate prescribing of drugs..."

We recommend that CMS includes in its e-prescribing Final Rule, as a general e-prescribing format standard, that MMA e-prescribing must *not* include inappropriate messaging of information. Such inappropriate messaging certainly includes financial incentives that attempt to influence the prescriber's selection decision of medication or of dispenser. If commercial messaging is not strictly prohibited by CMS, as a general format standard, such messaging could have the undesired effect of slowing the implementation of e-prescribing by prescribers and dispensers.

Physicians should see the full range of pharmacy choices that the beneficiary has to obtain their covered Part D drugs, including obtaining extended supplies of medications at retail pharmacies as required by law. The information should include the different cost sharing requirements, but the presentation of the information should not be such that it directs or steers beneficiaries to a particular pharmacy.

Physicians should also not be provided incentives to steer beneficiaries to a particular pharmacy. The information should also include a notation that the beneficiary has the choice of obtaining an extended supply of covered Part D drugs at their local retail pharmacy, and is not required to use a mail order pharmacy.

NACDS also agrees with CMS that the Medicare Part D prescription drug benefits medication therapy management (MTM) programs will improve medication use and further reduce the risk of adverse events, including adverse drug interactions. NACDS believes that electronic prescribing will make available important information to the community pharmacy provider that will help them provide medication management services in the retail pharmacy, such as medication history, and eventually medical history.

The success of these MTM programs, however, will be dictated primarily by whether Part D plans provide these important MTM services through retail pharmacies–which is the preferred way of providing these services to achieve optimal health care outcomes–or whether plans will simply require beneficiaries to obtain these services through telephone services.

B. Impact on Health Plans/PBMs [F.R. at page 6269]

NACDS' Comments: "IMPACT ANALYSIS"—We cannot comment on this section because we do not have any information on the possible impact of e-prescribing on Health Plans/PBMs.

C. Impact on Prescribers [F.R. at page 6270]

NACDS' Comments: "IMPACT ANALYSIS"—Although the MMA e-prescribing programs consist of both prescribers and dispensers, all of CMS' attention to provide incentives to encourage e-prescribing has been focused only on one-side of this equation... the prescribers.

NACDS certainly supports providing incentives for prescribers, but believes that incentives for dispensers, including community pharmacies, should be provided as well. Not to provide incentives to dispensers could be viewed as financially penalizing them for doing the right thing

early by spending the necessary money to be prepared for e–prescribing when the prescribers are ready. In addition, community pharmacies pick up the entire e–prescribing transaction charge… prescribers don't pay any transaction charge. This positive early action by dispensers should be acknowledged by also providing them with incentives to quickly implement e–prescribing.

D. Impact on Pharmacies and Other Dispensers [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—Please refer to our comment immediately above at *"Impact Analysis"—C. Impact on Prescribers"*. In addition, we certainly agree with the e–prescribing benefits described in the testimony of four of our chain members before NCVHS on three separate occasions beginning in July 2004.

We are delighted to see that CMS used the information in the preamble to the e–prescribing NPRM that NACDS provided: "indicating that 75 percent of the 57,208 pharmacies in the U.S. already have e–prescribing capability."

It must be noted that the motivation for these pharmacies to become e–prescribing capable is *not only* the reduction in administrative costs (i.e., reduced time–consuming phone calls to physicians and improved prescription communication between prescriber and dispenser, for example, reduction in illegible handwritten paper prescriptions), but also the awareness that e–prescribing will improve patient safety.

Pharmacists, like other health care providers, are very concerned about patients' quality of care and are very eager to do what they can to improve it. E–prescribing is as much about increasing the opportunity for pharmacists to work more closely with the patient's prescriber and play an expanded role in patients' care. E–prescribing will present new opportunities to make pharmacists' professional roles more challenging and meaningful. CMS should be aware that these professional benefits to pharmacists are perhaps as much of a driving force to become e–prescribing capable as is the reduction in administrative costs.

F. Impact on Others [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—We can not comment because we do *not* have any first hand information on the impact of e–prescribing on the "others" that CMS listed (i.e., technology vendors, pharmaceutical and medical device manufacturers, public health organizations, research and academic institutions, and professional lay organizations).

G. Impact on Small Businesses [F.R. at page 6271]

NACDS' Comments: "IMPACT ANALYSIS"—Some or NACDS' chain members may fit the definition of "small businesses" and therefore NACDS is especially sensitive to and agrees with CMS' statement that, " there will be a distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale." However, our comments above at *"Impact Analysis"—"D. Impact on Pharmacies and other Dispensers"* certainly apply to these small business members as well as all of our other chain pharmacy members.

H. Effects on States and Federalism Statement [F.R. at page 6272]

NACDS' Comments: "IMPACT ANALYSIS"—We agree with CMS that the annual expenditures for installing the capability of e–prescribing will *not* reach the *Unfunded Mandate Reform Act's* threshold of $110 million annually. NACDS addressed its concerns about federal preemption above at *"Background"—"A.2. State Preemption"*. We also agree with CMS, that its discussion in the *"State Preemption"* section and in this section constitute the Federalism summary impact statement required by Executive Order 13132.

I. Conclusion and Alternatives Considered [F.R. at page 6272]

NACDS' Comments: "IMPACT ANALYSIS"—Our comments above, at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, state that NACDS supports CMS' proposed foundation standards because, in part, that they were developed by an ANSI accredited SDO and that they have had adequate industry experience. Therefore, NACDS does *not* believe that the alternative of pilot testing the foundation standards is necessary or desirable. Pilot testing would be redundant at best. The "broad" industry experience provides much better evidence that these standards are accepted by the industry than would pilot testing, which would be of a much smaller scale.

However, NACDS is very sensitive that the word "adequate" in "adequate industry experience" must *not* be minimized. This concern is at least part of the reason behind our 3rd comment above at, *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, suggesting that the proposed formulary and medical history candidate standard must be included in the 2006 MMA required pilot tests.

NACDS would certainly *not* support CMS' adoption of MMA e–prescribing standards that were merely proprietary standards (i.e., not developed by an ANSI accredited SDO) even though they have adequate industry experience. Development by an ANSI accredited SDO and adequate industry experience must be evidenced before CMS should even consider that candidate standard as a MMA e–prescribing standard.

CAHIT E-PRESCRIBING IMPLEMENTATION WORK PLAN

Project/Task Description	Lead Agency	Partners	Start Date	Milestones/Deliverables	End Date
MEDICATION and PRESCRIBING INFORMATION STANDARDS					
Physician Labeling Rule	FDA	HHS		• Final rule (8/04)	•
Electronic Drug Listing Rule	FDA	HHS		• NPRM – 11/04 • Final rule –11/05	•
Guidance document on electronic labeling	FDA	HHS		• Draft published 2/04 • Standards on HL7 ballot 5/04 • Final guidance 6/04	•
ELIPS (Electronic Labeling Information Processing System)	FDA	AHRQ/ASPE		• Initiate software development 2004 • Approved Rx products started 12/04 • Approved Rx products completed 12/05 • Extend to other drug products 12/06	•
ELIST (Electronic product listing)	FDA			• Initiate software development 12/04 • Implement system – 12/06 • Inventory completed – 7/08	•
Substance Registration System (to generate unique ingredient identifiers –UNII)	FDA	AHRQ, ASPE, NLM	Ongoing	• UNII publicly available via NLM 12/04	•

Structured product label (enable drug to drug interactions, drug to allergy checking, drug to laboratory results checking, dosage checking against patient's weight)	FDA	VA and NLM		• HL7 standards 5/04 • SPL extended to meet requirements of highlights section of prof. Labeling rule—Start 03/04 • HL7 committee level ballot by 1/05 • SPL with highlights standard 10/06	•
Rx Norm	NLM			Federal adoption pending, first release in April 04, updated version available?	
Other Medication terminology (VA reference terminology)	FDA/ VA			FDA to use in labeling starting 12/05 (Depends on Prof. Labeling Rule)	
Knowledge/evidence representation standards	AHRQ	NCVHS, FDA, CMS, ASPE, outside consultants	03/01/04	Scope defined Initial inventory created	09/01/04 6/01/05
NCPDP messaging standard for prescribing information	CMS	NCVHS	03/01/04	Recommendations	11/01/04
Electronic Signature standards	CMS	DEA	05/01/04		06/01/05
ELIGIBILITY AND BENEFITS INFORMATION STANDARDS					
	CMS		03/01/04		
NCVHS hearings and private sector initiatives	NCVHS	E-Health Initiative	03/01/04		09/01/05
MEDICAL HISTORY INFORMATION	CMS	OGC, OCR	03/01/04		
Analysis of what information can be	NCVHS	OCG, OCR,	03/01/04		09/01/05

exchanged under current law (state and federal)		CMS, ASPE			
HL7 data interchange standards project	ASPE				
Generate and prioritize e-prescribing requirements and communicate to HL7 SIG	CAHIT				
REGULATORY STRATEGY FOR PROMULGATION OF E-PRESCRIBING STANDARDS					
	CAHIT	MMA (Medicare Council)	03/01/04	Final standards promulgated	04/01/08
Develop timeline for rule making process based on OGC interpretation of statute	CMS	OGC	05/01/04		07/0104
DEMONSTRATION PROJECT TO TEST INITIAL STANDARDS					
	CMS	FDA/NLM/AHRQ MMA	06/01/05	Launch 1/2006 and report to Congress on 4/2007	04/07
Recommend adoption of initial standards for e-prescribing	NCVHS	CAHIT	03/01/04	Interim report to Secretary Final recommendations	FALL 2004 08/01/05
Plan scope and stakeholders to participate in demonstration project	CMS	CAHIT/MMA	09/01/04	2004-2005	
Plan evaluation component of demonstration project	CMS	AHRQ	09/01/05	2004-2005	
Launch demonstration project	CMS		01/01/06	1/01/06	1/01/06

Date: 04/05/2005

Submitter : Mrs. Lorraine Doo

Organization : CMS

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Issues

Background

This is the background

Provisions of the Proposed Regulation

yes

Regulatory Impact Analysis

yes

Collection of Information Requirements

yes

CMS-0011-P-57-Attach-1.DOC

CAHIT E-PRESCRIBING IMPLEMENTATION WORK PLAN

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MEDICATION and PRESCRIBING INFORMATION STANDARDS					
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NCVHS hearings and private sector initiatives	NCVHS	E-Health Initiative	03/01/04		09/01/05
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exchanged under current law (state and federal)		CMS, ASPE			
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Launch demonstration project	CMS		01/01/06	1/01/06	1/01/06

Submitter : Ms. Theresa Doyle

Date: 04/05/2005

Organization : Healthcare Leadership Council

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-0011-P-58-Attach-1.DOC

April 5, 2005

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

Re: Comments on E-Prescribing of Drugs and Preemption of State Laws

Ladies and Gentlemen:

The undersigned organizations, members of the Confidentiality Coalition, chaired by the Healthcare Leadership Council ("HLC"), appreciate the opportunity to comment on the views expressed by the Department of Health and Human Services ("Department") on the scope of federal preemption when it issued the proposed electronic prescribing ("e-prescribing") regulation under the new Medicare Part D prescription drug benefit. 70 Fed. Reg. 6256 (Feb. 4, 2005) (the "Regulation")

HLC is a not-for-profit membership organization comprised of chief executives of the nation's leading health care companies and organizations. In 1996, HLC began chairing the "Confidentiality Coalition," a broad-based group of organizations who support workable national uniform privacy standards. Through the years, the Confidentiality Coalition has played a leadership role in this area as we work with Members of Congress and the Administration to promote this goal. The Confidentiality Coalition includes physician specialty and subspecialty groups, nurses, pharmacists, hospitals, nursing homes, medical colleges, biotechnology researchers, employers, health plans, clinical laboratories, pharmaceutical companies, and PBMs.

The Confidentiality Coalition supports widespread adoption of e-prescribing to improve quality of care, reduce medical errors and achieve greater administrative efficiencies. However, we are concerned that the Department's narrow views on preemption will needlessly undermine the efficient electronic administration of the new Part D benefit because prescribing health care professionals, pharmacies, and claims administrators will find it difficult to determine when state laws governing e-prescribing apply and when they are preempted. Given the lack of a broad bright-line preemption standard, we expect that many providers in particular will continue to utilize paper prescriptions, thwarting Congress' intention to foster electronic prescriptions for the Part D benefit.

This comment letter requests that the Department adopt a broader view of preemption. First, consistent with the settled view of conflicts preemption, the Department should confirm that federal law preempts any state law that would frustrate

Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D. As explained herein, a variety of state laws would be preempted under this standard. Second, we ask that the Department confirm that federal preemption extends to any prescription issued for any person eligible to enroll in the Part D benefit. Both of these interpretations are fully consistent with the applicable statutory language.

Ultimately, we believe that preemption of state laws affecting e-prescribing for enrollees in all private and public plans will be necessary to meet Congress' goal of widespread adoption of e-prescribing to improve quality of care, reduce medical errors and achieve greater administrative efficiencies. However, given the limited timeline for affected parties to implement the standards, we ask that the Department provide immediate and bright-line guidance on the scope and application of preemption consistent with this analysis. The Department should continue to consider and receive comment on the broader interpretation of the language for future rulemaking.

I. Background

The Medicare Modernization Act of 2003 ("MMA"), Pub. L. 108-173, created a new Medicare Part D benefit which will provide prescription drug coverage for Medicare eligible beneficiaries. Section 1860(e) of the Social Security Act ("Act"), as added by the MMA, generally requires that prescriptions and other information pertaining to covered Part D drugs prescribed for Part D eligible persons comply with uniform federal standards promulgated by the Secretary of Health and Human Services whenever such prescriptions are transmitted electronically.

At the same time Congress directed the Department to develop these mandatory federal standards for persons who e-prescribe under Part D, it also adopted an express preemption standard. Specifically, section 1860D-4(e)(5) provides that the Secretary's e-prescribing standards:

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

In the preamble to the Regulation, the Department stated its view that that for a state law to be preempted the state law must implicate both the requirements of paragraphs (A) and (B). The Department further expressed its view that there would have to be an express Federal standard adopted that creates a conflict for a state law to be

preempted. 70 Fed. Reg. at 6258. The Department also noted that this narrow construction was consistent with a presumption against preemption of state law.

The Department's interpretation is the narrowest possible view of federal preemption. First, it limits preemption to only those prescriptions written for persons actually enrolled in Part D at the time the prescription is issued, rather than all Medicare beneficiaries. Second, it limits preemption to only those prescriptions actually covered by the Part D benefit, even though Medicare beneficiaries may receive drug coverage from multiple sources (including different parts of the Medicare program itself). Finally, the Department's interpretation would trigger preemption only where the state law actually conflicts with a federal standard promulgated by the Department, rather than a broader range of state laws that frustrate the policy objectives of uniform federal e-prescribing standards.

Although it adopted a narrow view of preemption, the Department specifically requested comments concerning the breadth of section 1860D-4(e)(5)'s preemptive force, specifically asking whether it applied only to transactions and entities that are part of an electronic prescription drug program under Part D, or to some broader set of transactions and entities. This letter responds to that request.

II. Problems Created by the Department's Interpretation

As noted above, the Department's proposed interpretation under section 1860D-4 limits preemption only to: (1) persons actually enrolled in Part D, (2) prescriptions actually covered by the Part D benefit, and (3) state laws that create an actual conflict with an adopted federal standard. This interpretation is needlessly narrow and will make it virtually impossible for providers, pharmacies and claims administrators to know when state laws are preempted by the federal e-prescribing standards.

The following examples illustrate how the Department's preemption standard will frustrate effective e-prescribing in connection with the Part D program:

- A physician e-prescribes a drug to a Part D enrolled patient believing that Part D covers the drug.[1] The physician did not obtain the patient's consent to e-prescribe as required by state law,[2] assuming that federal preemption applied. However, the administrator determines that Part B should be billed for the drug

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[1] Some drugs for the treatment of cancer are covered under Part D, while others are covered under Part B. Preamble to the Final Rule on the Prescription Drug Benefit, 70 Fed. Reg. 4194, 4233 (Jan. 28, 2005).

[2] *E.g.*, Wis. Stat. Ann. § 450.11(1m), Mich. Admin. Code § 338.3162a(2), Nev. Admin. Code § 639.7105(2)(b).

because, although Part D often provides coverage for that drug, Part B provides coverage when individuals have the particular condition that this patient has. As such, the state law consent requirement was not preempted.

- A physician e-prescribes a certain inhalation drug to a Part D enrolled patient, thinking that it is covered by Part D. However, since the patient uses a nebulizer, not a metered dose inhaler, the drug is actually covered by Part B. Again, the physician did not obtain consent to e-prescribe and thus failed to comply with non-preempted state law.

- A physician e-prescribes an oral cancer treatment drug to a Part D enrolled individual. However, the administrator determines that since oral administration in this case was a substitute for the intravenous administration of a Part B drug, Part B (not Part D) still should be charged. Once more, the physician did not obtain consent to e-prescribe and failed to comply with non-preempted state law.

- A patient, age 78, recently disenrolled from Medicare Part D, but still carries her Part D identification card with her. She shows the card to Physician X, who e-prescribes her a drug since he believes that she is still covered by Part D and that state law requiring patient consent for e-prescribing does not apply. Later, when the claim is processed, it is discovered that the patient was no longer a Part D enrollee. The consent requirement was not preempted.

- A physician e-prescribes a drug to a Part D enrolled patient, believing that it is on his Part D plan's formulary. However, the drug was not on the formulary and the patient's request for a formulary exception is denied. Again, the state law e-prescribe consent requirement mistakenly was not met.

- A physician writes five prescriptions for a Part D enrollee, two of which are covered by Part D, one of which is covered by Part B, one of which is covered by private insurance and one of which must be paid directly by the enrollee. Since the physician does not know whether and which drugs are covered by Part D, the physician writes paper prescriptions for all five prescriptions to avoid state law consent and other standards.

III. Proposed Interpretation

The examples described above will be commonplace. As a result, we are concerned that few providers, pharmacies and administrators – all of whom are essential to the efficient implementation of the new Part D benefit – will undertake the e-

prescribing that Congress intended to foster. If so, the Department's interpretation could render the statute's express preemption rule a nullity – an interpretive result to be avoided at all costs. *See, e.g., Park 'n Fly, Inc. v. Dollar Park and Fly, Inc.*, 469 U.S. 189, 196 (1985) (statutory language cannot be interpreted such that it is left meaningless).

To avoid such undesirable consequences, we ask that the Department adopt an interpretation providing that federal law broadly preempts any state laws that are contrary to or that stand as an obstacle to Congress' objective in creating the federal e-prescribing standards. This interpretation is consistent with the settled view of conflicts preemption and the statutory language. We also ask that the Department confirm that this preemption standard applies to any prescription issued to any person eligible for Part D coverage. This interpretation is consistent with the statutory language and is necessary to give life to Congressional intent regarding e-prescribing.

As a starting point, our interpretation begins with the assumption that the Department will continue to interpret the statute to require that both paragraph (A) and paragraph (B) be satisfied before a state law is preempted. However, we believe that a careful parsing of the requirements of both paragraph (A) and paragraph (B) of the two-part preemption provision reveals that a broader preemption interpretation is supportable and appropriate.

Paragraph (A) of section 1860D-4(e)(5) provides that the federal e-prescription standards preempt any state law that "is contrary to the standards *or restricts the ability to carry out this part.*" (Emphasis added.) While we agree with the Department that paragraph (A) reflects "conflicts" preemption, we disagree with the narrow cast the Department gives traditional conflicts preemption. The Department's interpretation of section 1860D-4(e)(5) emphasized the first prong of paragraph (A) – that the statute preempts state laws that actually "conflict with" or are directly "contrary" to the federal standards promulgated by the Department. But physical impossibility is not the only situation in which a state law must give way under section 1860D-4(e)(5). The second prong of paragraph (A) indicates that state law is preempted where it merely stands as an obstacle to promoting e-prescribing.[3] Indeed, Congress was clear in stating that its purpose was to foster the widespread development and utilization of e-prescribing systems in order to promote patient safety, improve quality of care, and create cost and other efficiencies in health care delivery. § 1860D-4(e)(3).

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[3] The two prongs of paragraph (A), when read together, are completely consistent with the settled view that conflict preemption occurs "when compliance with both state law and federal law is impossible [physical impossibility], *or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.*" *United States v. Locke*, 529 U.S. 89, 109 (2000) (internal quotations and citations omitted; emphasis added).

In addition to satisfying the requirements of paragraph (A), a state law must also satisfy paragraph (B) in order to be preempted. But paragraph (B) is quite broad, and is more reflective of "field" preemption rather than "conflicts" preemption. Under this paragraph, a state law must only "*pertain*[] 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" in order to be preempted. This "pertains to" clause is quite expansive. Under its ordinary meaning, "to pertain" is "to have some connection with or relation to something." Webster's Third Int'l Dictionary (1981). *See also* Black's Law Dictionary (6th ed. 1990) ("pertain" means "to belong or relate to"). In other preemption contexts, the Supreme Court has broadly interpreted statutory language providing that federal law preempts state laws that "relate to" a topic of federal interest. *E.g., Dist. of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 129-30 (1992) (the Employee Retirement Income Security Act ("ERISA")); *Morales v. Trans World Airlines*, 504 U.S. 374, 383-87 (1992) (the Airline Deregulation Act). In *Greater Washington Board of Trade*, for example, the Court explained that "relates to" meant to have "a connection with or a reference to" an ERISA-covered benefit plan, and the phrase was "deliberately expansive." 506 U.S. at 129.

Together, the second prong of paragraph (A), which looks to whether a state law creates obstacles for the federal goals, and the "pertains to" language of paragraph (B), operate to preempt a broad array of state laws. For example, the laws described above that would require patient consent before e-prescribing can be used clearly are an obstacle to the efficient implementation of a federal e-prescribing system. Other state laws that would be preempted include:

- State laws preventing the use of transmission intermediaries by requiring that prescriptions be "directly" delivered from the prescribing providers to the dispensing pharmacists; *e.g.*, Ga. Code Ann. § 26-4-80(c)(1); N.C. Admin. Code tit. 21, § 46.1813;

- State laws that restrict the release of medication information concerning specific conditions (*e.g.*, mental health) absent permission from the patient (note that federal law envisions that broad medication history will be available via e-prescription to assist providers and pharmacists in detecting potential drug interactions); *e.g.*, Md. Code Ann., Health-General § 4-307(d); and

- Substantive state law requirements for prescription format and context that may not be required under federal law (*e.g.*, requirements that: (1) prescriptions address whether interchanges are permissible, or (2) dispensing pharmacists initial

prescriptions to acknowledge they handled the matter). *E.g.*, N.J. Stat. Ann. § 24:6E-7; Rev. Code Wash. § 69.41.055(1)(a); Code Me. Rules § 02-393019-3.

Furthermore, the language of section 1860D-4 clearly supports the view that federal preemption extends to state laws that would apply to any prescriptions (including prescriptions for non-covered Part D drugs) for any person who is eligible for Part D. As highlighted by the examples, it will be commonplace for prescribing physicians to have no way of knowing whether a particular drug ultimately will be covered by Part D. Similarly, physicians will not know for sure if Medicare beneficiaries are actually enrolled in Part D at the time prescriptions are issued. Unless clearly preempted, the potential application of state law in these common circumstances will lead providers to simply default to compliance with state law rules and use paper prescribing systems in all cases rather than carefully attempting to identify when they can e-prescribe free from the application of state law. However, this need not be the result since the requirements of both paragraphs (A) and (B) should be satisfied. Applying paragraph (A), it is clear that the application of state laws in these circumstances will frustrate the policy objectives of Congress to promote the widespread use of e-prescribing in connection with the Part D benefit to be realized. Applying paragraph (B), it is clear that the application of state laws would "pertain" – *i.e.*, have a relationship with – prescriptions for covered Part D drugs.

* * * * *

We strongly encourage the Department to adopt a bright-line preemption interpretation at least as expansive as that requested herein. It is only through the adoption of a broad preemption standard that e-prescribing will be administratively practicable for providers, pharmacies and claims administrators. As such, a broad standard is the only route to accomplishing Congress' policy goal of promoting e-prescribing under Part D. We appreciate the Department's consideration of our comments.

ACA International
Aetna Inc.
American Hospital Association
American Medical Group Association
America's Health Insurance Plans
Association of American Medical Colleges
Blue Cross Blue Shield Association
The ERISA Industry Committee
Federation of American Hospitals
Healthcare Distribution Management Association
Healthcare Leadership Council
Medical Group Management Association
McKesson Corporation
National Association of Healthcare Access Management
National Association of Health Underwriters
National Association of Manufacturers
Premier, Inc.
Quest Diagnostics
U.S. Chamber of Commerce
VHA Inc.
Wellpoint

Submitter : Ms. Karen Eckert **Date:** 04/05/2005

Organization : Wolters Kluwer Health/Medi-Span

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Comments relating to background and regulatory impact analysis are included in the attachment.

CMS-0011-P-59-Attach-1.DOC

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

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

Dear Centers for Medicare and Medicaid Services:

Wolters Kluwer Health is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Wolters Kluwer Health is a global leader in providing healthcare information. Through our numerous product lines – Medi-Span, SKOLAR, Clin-eguide and Facts & Comparisons – professionals have access to immediate, trusted information at the point of care to help them make the best medical decisions for their patients.

Wolters Kluwer Health fully endorses the recommendations noted by NCPDP in their response, especially in the areas of versioning and pre-emption.

Wolters Kluwer Health fully endorses the recommendation of NCPDP's SCRIPT and Telecommunications Standards for the transmission of a prescription and claim between parties in the Medicare Part D Drug Program.

We will limit our comments to the areas that we are most familiar with in the e-prescribing process, the vocabularies and terminologies, and the content of the messaging.

I. Background

Table of NCVHS recommendations compared to the Standards in the NPRM (F.R. Page 6262)

Wolters Kluwer Health Response:

We are pleased that formal recommendations for RxNorm and drug-drug interaction information were not included in the NPRM at this time.

The RxNorm terminology is suitable to test as a drug terminology in the pilot tests to see if it can meet the prescriber's intent of the drug to be ordered/dispensed. To date, the RxNorm terminology is untested and there has been no opportunity to adopt or implement it until very recently in the private sector.

As to the drug-drug interaction information, there is a place in the electronic interchange of a prescription between parties to note that an interaction has been identified, yet the prescription should still be dispensed. However, there is not a need to include all the supporting documentation for that interaction between parties. As standards are identified, we need to make sure that they support the interchange of a prescription between parties, not what should be done within the prescriber system in the act leading up to and through the creation of a prescription.

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.

Wolters Kluwer Health Response:

Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. The e-prescribing process should be limited to the exchange of an electronic drug order and patient medical and drug information. The e-prescribing process should not include the exchange of electronic drug referential data. 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.

Medical History (F.R. Page 6264)

Wolters Kluwer Health Response:

We support the need for a standardized allergy terminology. Through our testimony to NCVHS and subsequent discussions, we asked for an allergy terminology standard to be identified so that we can map our proprietary terminologies to the standard terminology to facilitate interoperability and the exchange of allergen information between and across systems.

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

Wolters Kluwer Health Response:

We support the adoption of e-prescribing as a stepping stone to a full EHR. We can see no benefit to impeding the momentum driving t he ado ption o f e- prescribing no r t he 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.

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

We invite public comment on our expectations for prescriber participation.

A. Overall Impact (F.R. Page 6268)

We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.

Wolters Kluwer Health Response:

In the third column of page 6268, we caution that the advantages and benefits noted for "e-prescribing" and "e-prescribing programs" relate more to the electronic s ystem t o capture patient history, medication history, and medications; to run electronic, real-time alerts; and to access on-line information resulting in better care than the actual process and benefits of transmitting the drug order electronically between two sites as noted in the e-prescribing definition on page 6273.

F. Impact on Others (F.R. Page 6271)

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

Wolters Kluwer Health Response:

Other costs not noted in this section include the cost of the knowledge-base providers to incorporate mappings of their vocabularies to standardized vocabularies and distribution and maintenance of these mappings for terminologies noted in future regulations. Additionally, the cost for all sites to incorporate these "standardized" terminologies will require additional work for pharmacy system vendors, pharmacies, and e-prescribing/EMR system vendors.

Conclusion

Wolters Kluwer Health supports this electronic prescribing initiative and offers its assistance to CMS with issues that relate to terminologies as noted in the MMA.

Sincerely,

Karen Eckert
Director, e-Prescribing, Regulations, and Standards
Wolters Kluwer Health
Medi-Span product line
8425 Woodfield Crossing Blvd, Suite 490
Indianapolis, IN 46240
317/735-5308
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Submitter : **Mr. John Jones** **Date: 04/05/2005**

Organization : **Prescription Solutions**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-0011-P-61-Attach-1.DOC

PacifiCare®

April 5, 2005

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

RE: CMS-0011-P

Dear Sir or Madam:

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

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

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

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

Sincerely,

Steve Tucker,
Vice President
Regulatory Affairs

SMT:jlh

Attachment: Detailed Comments on CMS 0011-P

Medicare Part D Commentary

CMS-0011-P

Medicare Program
E-Prescribing and the Prescription Drug Program

Submitted by
PacifiCare Health Systems
and Prescription Solutions

OVERVIEW:

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

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

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

I Background

"BACKGROUND"

Compliance Date

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

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

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

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

Initial Standards Versus Final Standards

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

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

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

State Preemption

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

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

Anti-kickback Statute Safe Harbor and Stark Exception Section

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

Evolution and Implementation of an Electronic Prescription Program

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

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

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

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

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

Provider and Dispenser Identifiers

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

Formulary and Medication History Standards

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

II. Provisions of the Proposed Regulation

"PROVISIONS"

Eligibility

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

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

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

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