**Submitter :** Dr. James Scully **Date:** 04/05/2005

**Organization :** THE AMERICAN PSYCHIATRIC ASSN.

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Attachment

Provisions of the Proposed Regulation

See Attachment

Regulatory Impact Analysis

See Attachment

Collection of Information Requirements

See Attachment

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CMS-0011-P-62-Attach-2.DOC

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April 7, 2005

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

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

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

## I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

### A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf computer software. Instead, much of the available software is proprietary and uses

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[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
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> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
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> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded voice messages, if relayed elsewhere, are also covered by this law. If electronically

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

### B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-prescribing. Compuware Corporation, Microsoft and Washington Publishing Company

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example. Instead they work solo or in small group practices that do not enjoy the ability to spread

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: "HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year. Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

### C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the Office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had

[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

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[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006. [22]

### D. E-prescribing and Federal Grants

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

### E. Manipulation of Physicians' Prescribing Choices

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

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[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

## II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins."[28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

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[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

[30] NCPDP is accredited by the American National Standards Institute (ANSI).

[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

> 1. "Fill status notification" and RxNorm clinical drug terminology functions of NCPDP SCRIPT. (RxNorm provides links from clinical drugs' names to their active ingredients, components and most brand names.);[34]
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> 2. Situational data elements and proper usage of functional acknowledgements of ASC X12N 270/271;[35]
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> 3. Structured and codified *signatura* (SIGs) for patient instructions; and[36]
>
> 4. National prescriber identifiers (NPIs) need to be chosen and issues dealing with elements of prescriber location and connection to individual prescribers should be part of pilot testing.[37]

NCVHS also recommended pilot tests to evaluate the economic and quality-of-care impacts of automating prior authorization communications. Prior authorizations will be a major utilization management tool for formularies of Medicare Part D plans, as of

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[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

[34] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.6.

[35] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.8.

[36] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.10.

[37] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.12.

January 1, 2006. If the prior authorizations are not processed smoothly, patients will have difficulty getting continuous prescription coverage on their drug regimens.

Pilot-testing the proposed standards would confer several essential advantages for psychiatrists and their patients. If pilot-testing is done in 2006, results would be evaluated, then the final standards would not be published until April 1, 2008.[38] This would have the beneficial effect of moving the effective date for compliance with the standards into a more manageable time frame, instead of rushing it to January 1, 2006. After all, this date is only a few months after the proposed rule will be finalized.

For pilot tests to be conducted in 2006, initial standards must be adopted no later than September 1, 2005.[39] However, CMS proposes to adopt three standards as final without any pilots, on the basis that they meet CMS' criteria for having "adequate industry experience." They are not proposing to adopt any initial standards that would then require pilot tests. According to NCVHS, fewer than 3% of all prescriptions are written by prescribers using an integrated e-prescribing system of some type, presumably not all with the proposed final standards. A portion of those are in the VA hospital system, which uses integrated medical records and prescribing systems with its own data-transmission standards and software that is in the public domain.

Of course, CMS is aware of the widespread use of other standards within the federal healthcare system. CMS emphasized in an Executive Summary of July 2004 that "(t)here have been considerable efforts by HHS, DoD, and VA to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector."[40] CMS has lauded VA's healthcare informatics systems and suggested that they could transfer into the public sector. Moreover, their software is in the public domain, so it is more accessible than proprietary copyrighted software for

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[38] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[39] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[40] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: ". . . As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector. Additionally, the Public Health Information Network (PHIN) and the National Electronic Disease Surveillance System (NEDSS), under the leadership of the Centers for Disease Control and Prevention (CDC), have made notable progress in development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and health information exchange. With HHS support, Health Level 7 (HL7) has also created a functional model and standards for the EHR." Retrieved March 29, 2005: http://www.healthpolicyohio.org/OHHIT/NHII_2004/HealthITStrategicFrameworkExecSummary.htm

companies that wish to develop products with it.[41] For these reasons, it is unclear what stands in the way of CMS adopting at least one standard in use within the federal system as an initial standard and pilot-testing it.

NCVHS noted in its letter to CMS that a standard from Health Level Seven, Inc. (HL7), is commonly used for medication orders in hospitals and clinical pharmacies and advocated coordinating HL7 with NCPDP SCRIPT. Many staff model HMOs and the VA use HL7 internally for most drug orders.[42,43] In July 2004, HL7 issued a press release announcing that the Board of Directors "had unanimously approved the Electronic Health Record System Functional Model (EHR-S) to move forward as a Draft Standard for Trial Use (DSTU). The EHR Draft Standard can now be registered with ANSI, beginning the draft standard's trial period of up to 24 months. . . An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records."[44]

Given their widespread use, it would appear that at least some of these aforementioned standards would meet the test for "adequate industry experience" and, at least, be under consideration for status as initial standards for pilot testing. However, none of these standards appear to be under consideration by CMS at this time for adopted as initial standards and this must be done by September 1, 2005, to be pilot tested in 2006.

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[41] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: "The VA's report, 'Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities' (Attachment 2), also highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain. These technologies may be suitable for transfer to rural and medically underserved settings. VA's primary health information systems and EHR (VistA and the Computerized Patient Record System [the current system] and HealtheVet-VistA, the next generation in development) provide leading government/public-owned health information technologies that support the provision, measurement, and improvement of quality, affordable care across 1300 VA inpatient and ambulatory settings. . . The VA is also incorporating the CHI approved standards into its next-generation HealtheVet-VistA. . . Finally, the VA's health information technologies, such as bar code medication administration, VistA Imaging, and telehealth applications, provide the VA with exceptional tools that improve patient safety and enable the increasingly geographically dispersed provision of care to patients in all settings."

[42] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265: "Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy."

[43] Consolidated Health Informatics: "Standards Adoption Report: Messaging Standards: Retail Pharmacy Transactions;" p. 5. Retrieved March 22, 2005: http://www.whitehouse.gov/omb/egov/documents/domain3.doc

[44] Health Level Seven, Inc. (HL7) Press Release: "Board of Directors Unanimously Approves EHR for Draft Standard Status;" July 27, 2004.

Presumably, any change to existing standards would require legislation to revise or add language to 42 C.F.R. Sec. 423.160. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) pre-empts state laws and prohibits them from enacting legislation that contravenes federal provisions as to e-prescribing standards.[45] So, once federal law mandates specific standards, state law cannot alter or affect physicians' compliance requirements.

APA's view is that it is unwise to forego a pilot test of the standards and technologies using them that is likely to bring to light glitches more easily worked out on a small scale than on a wide scale. It is particularly clear that integrated e-prescribing systems that communicate among prescribers, dispensers and health care plans have not been in widespread use across a variety of clinical settings. For that reason alone, it is unclear precisely what practical issues need to be resolved. Further, the extensive MMA requirements demands solid, seamless integration of multiple messaging, data translation, data transfer and data access functions using at least three standards, as well as file transfer protocols such as RxHub. The integration of these standards and technologies using them has yet to be accomplished and fully tested in the field, to ensure compliance with MMA and HIPAA. Moreover, there is the issue of how software incorporating these standards will interface with web-based applications and a variety of hardware combinations.

Unless and until sufficient pilot tests are done with physicians under real-life clinical conditions to identify and resolve e-prescribing problems, CMS' laudable goals will be impeded. More importantly, once physicians begin to experience difficulties using e-prescribing systems because functionality has not yet been perfected, their frustration may well reduce or cease the use of e-prescribing altogether. In addition, negative publicity about roadblocks in the systems will deter many others from adopting e-prescribing.

Apart from time they need to properly evaluate systems against their needs, physicians also require time to become familiar with the systems, alter practices to accommodate new processes and train staff. Feedback from pilot testing will assist companies in developing physician and patient-centered products, services, training and educational materials. This will ultimately make e-prescribing more attractive and effective across various dimensions, including the enhancement of patient outcomes.

The transition to using new technologies and equipment will take physicians' time and energy. This may be more of a demand for those who do not currently own a computer. To rush this process is to increase the risk of medication errors and suboptimal patient outcomes. Those results would contravene one of CMS' primary goals for advancing e-prescribing, which is to reduce negative patient outcomes due to errors in traditional prescribing systems.

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[45] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

Another positive result of pilot-testing is that it would move the compliance date away from January 1, 2006. That would give psychiatrists time to plan for the substantial financial outlay for an e-prescribing system. The expanded time window will also allow psychiatrists to apply for federal matching grants for e-prescribing systems. These grants will not be funded until 2007. In addition, legislators will get more time to implement the projected new Safe Harbor and the new Stark II exemption that are intended to allow physicians to accept non-monetary assistance for e-prescribing systems without violating current federal laws.

***Recommendations:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards with physicians, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

## III. "PROVISIONS:" The Secretary's Proposed Effective Date of January 1, 2006, for E-Prescribing Compliance is Premature and Carries Adverse Implications

### A. Prematurity of the Proposed Effective Date

The HHS Secretary has the discretion to choose a more practical and appropriate effective date for e-prescribing compliance than January 1, 2006, and APA urges him to do so. This date is premature for several reasons and adopting it will produce adverse effects for physicians and their patients. It will also discourage psychiatrists and other physicians from adopting e-prescribing, until many technological and practical issues area resolved. The following are some of the reasons why January 1, 2006, is not a judicious choice as an effective date for compliance with e-prescribing:

1. January 1, 2006, is the same effective date for transition of dually eligible Medicare/Medicaid patients into Medicare, which will already be burdensome for physicians and patients;

2. CMS admits that it may not be possible to issue a National Provider Identifier (NPI), as planned, for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline. In addition this date is earlier than the current HIPAA compliance date for using an NPI for covered e-prescribing transactions;

3. January 1, 2006, is premature and does not synchronize with the availability of federal matching grants for physicians' e-prescribing systems, which begin being funded in 2007;

4. January 1, 2006, does not allow sufficient time to finalize a new Safe Harbor and a new Stark II exception, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems, without rendering them vulnerable to federal prosecution under current anti-kickback and Stark II laws; and

5. CMS notes that it may not be possible to issue a National Provider Identifier (NPI) for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline, which would be earlier than the current compliance date for HIPAA covered transactions. Thus, it would be impossible for physicians to be in compliance in using a HIPAA-required NPI, if they are not issued one before the deadline. E-prescribing transmissions will make physician-prescribers covered entities for HIPAA compliance. We believe that psychiatrists should not be legally mandated to use an NPI until it exists and that confusion about which identifier will be required should be resolved prior to any compliance effective date. Alternative identifiers for e-prescribing could be the physician's medical license number, DEA number, EIN or Social Security number.

***Recommendation:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

## B. "IMPACT ANALYSIS:" Privacy Concerns

Patient privacy is particularly critical in ensuring high quality psychiatric care. Psychiatrists are also rightly concerned about how e-prescribing technologies, such as web-based portals, may compromise their patients' privacy, and hence impair the foundation of trust that is the core of the psychiatrist-patient relationship. It is not until pilot tests sort out these and other potential issues that psychiatrists are likely to gain sufficient comfort with adopting e-prescribing techniques. We remain concerned about the inadequate safeguards to potential breaches in the security of identifiable patient information, through electronic transmissions and databases. It is critically important to ensure the security of and to prevent hacking into electronic systems, especially as regards the confidentiality of patients' medications. As a consequence, CMS must address this e-prescribing issue directly.

Regrettably, confidentiality is too often overlooked as an essential element of high-quality health care. Out of fear of disclosure, some patients simply will not provide the full information necessary for successful treatment. Others refrain from seeking medical care or drop out of treatment, in order to avoid any risk that their records are not entirely private. With regard to e-prescribing and its use of the internet and other electronically accessible databases, this fear may be heightened for some psychiatric patients, especially those with paranoid features to their illness. A psychiatrist is hard-pressed to assure a patient about confidentiality when there are headlines about databank breaches.

A pharmacist can legally contact a list of his or her pharmacy's patients, who have been prescribed certain drugs, in order to inform them about alternative drug therapies. A pharmaceutical company can pay the pharmacist to do this, though it cannot directly obtain patient information and contact patients. This allows pharmaceutical companies to indirectly promote targeted drugs to patients. Also, pharmacies can promote their own financial interests by urging a patient to use medications that are more profitable for the pharmacy. Marketing communications do not necessarily need to disclose these compensation arrangements.

APA believes that patients need to be certain that there will be no downstream release of information to marketers and that the security of their health records will be safeguarded. A strong CMS policy to that effect would give vendors a clear message of CMS' expectations, as this applies to e-prescribing systems and security. It is critically important that CMS respond to the e-prescribing security concerns of psychiatrists, as well as all physicians, and their patients.

As mentioned above, mental health records are particularly sensitive to release and disclosure, partly due to the unfortunate, pervasive social stigma about mental disorders. A patient might not want family, neighbors, or even a postal delivery person to see a postcard from a pharmacy suggesting that he or she is on psychotropic medication. Such communications could undermine mental health care, as patients avoid or delay it, to avoid stigmatization.

## CONCLUSION AND RECOMMENDATIONS

APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing within the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach. Pilot testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. What may constitute "adequate industry experience" with standards within one context, i.e., intra-entity transmissions or within partial e-prescribing systems, may well not work as anticipated within a different environment. For instance, problems may arise when psychiatrists, or, indeed, any physicians, in a small group practice use a fully integrated e-prescribing system to communicate with managed care companies and external pharmacies using different systems.

Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings, will it be feasible to determine precisely which standards, process areas or technologies require adjustment. All standards to be used for e-prescribing must have the capability of being used within products that work seamlessly across different data-interchange platforms and among all entities involved in the prescribing process. Moreover, the standards ultimately adopted as final foundation standards to be embedded within software, used via web portals and within e-prescribing systems hardware must be efficiently inter-functional and meet the intended practical and legal requirements. It will take some time to discover how to perfect these systems and CMS must not foreshorten this process, or it will prove to ultimately be at the expense of patients.

Psychiatric patients on prescription psychotropics are especially vulnerable to delays, glitches, and errors that could be caused by premature adoption of standards, resulting in ineffective systems. Since medication adherence is already a serious issue for such patients, even delays of a day or two in receiving prescription fills could seriously and adversely affect them. It will be much easier to collect data, provide feedback loops, and create corrective interventions within a smaller pilot-test system of e-prescribing, than within a large one. Moreover, fewer physicians and patients will be negatively affected when something goes awry within a pilot test, than within a wider context of usage. It simply makes practical sense to evaluate a major change of this dimension on the prescribing mechanisms for physicians on a small scale, before expanding the process into a larger patient-care environment.

Successes within the pilot tests can then be used to encourage further adoption of e-prescribing, while physicians remain confident that obstacles to effective use will be resolved at the pilot stage, before they adopt the technologies. In this way, e-prescribing will become a more palatable alternative to physicians, who will have a more definitive set of reasons to adopt it, with solid evidence of its advantages and confidence in its practicality. Physicians also require reassurance from CMS that policies will be adopted

that send a clear message to companies that commercial messages and design bias in software and hardware for e-prescribing will not be tolerated.

Pilot testing in 2006 will automatically advance the effective date for compliance, which has the added benefit of allowing sufficient time to promulgate the new Safe Harbor and new Stark II exception that give physicians the freedom to accept assistance in establishing e-prescribing systems. It will also be in line with the timeframe that will ensure physicians' access to federal grants to underwrite such systems. APA's specific recommendations are reiterated, below:

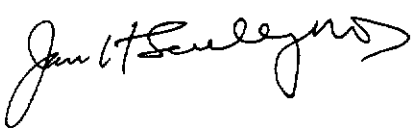
***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor for physicians to freely accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

***Recommendations-Pilot Testing:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

***Recommendation-Effective Date:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

Thank you for your consideration of these comments.



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April 7,

2005

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

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

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

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[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

## I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

### A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf computer software. Instead, much of the available software is proprietary and uses

[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
>
> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
>
> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded voice messages, if relayed elsewhere, are also covered by this law. If electronically

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

### B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-prescribing. Compuware Corporation, Microsoft and Washington Publishing Company

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example. Instead they work solo or in small group practices that do not enjoy the ability to spread

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: "HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year.
Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

### C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the Office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had

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[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

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[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006.[22]

### D. E-prescribing and Federal Grants

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

### E. Manipulation of Physicians' Prescribing Choices

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

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[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

## II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins."[28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

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[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

[30] NCPDP is accredited by the American National Standards Institute (ANSI).

[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

> 1. "Fill status notification" and RxNorm clinical drug terminology functions of NCPDP SCRIPT. (RxNorm provides links from clinical drugs' names to their active ingredients, components and most brand names.);[34]
>
> 2. Situational data elements and proper usage of functional acknowledgements of ASC X12N 270/271;[35]
>
> 3. Structured and codified *signatura* (SIGs) for patient instructions; and[36]
>
> 4. National prescriber identifiers (NPIs) need to be chosen and issues dealing with elements of prescriber location and connection to individual prescribers should be part of pilot testing.[37]

NCVHS also recommended pilot tests to evaluate the economic and quality-of-care impacts of automating prior authorization communications. Prior authorizations will be a major utilization management tool for formularies of Medicare Part D plans, as of

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[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

[34] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.6.

[35] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.8.

[36] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.10.

[37] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.12.

January 1, 2006. If the prior authorizations are not processed smoothly, patients will have difficulty getting continuous prescription coverage on their drug regimens.

Pilot-testing the proposed standards would confer several essential advantages for psychiatrists and their patients. If pilot-testing is done in 2006, results would be evaluated, then the final standards would not be published until April 1, 2008.[38] This would have the beneficial effect of moving the effective date for compliance with the standards into a more manageable time frame, instead of rushing it to January 1, 2006. After all, this date is only a few months after the proposed rule will be finalized.

For pilot tests to be conducted in 2006, initial standards must be adopted no later than September 1, 2005.[39] However, CMS proposes to adopt three standards as final without any pilots, on the basis that they meet CMS' criteria for having "adequate industry experience." They are not proposing to adopt any initial standards that would then require pilot tests. According to NCVHS, fewer than 3% of all prescriptions are written by prescribers using an integrated e-prescribing system of some type, presumably not all with the proposed final standards. A portion of those are in the VA hospital system, which uses integrated medical records and prescribing systems with its own data-transmission standards and software that is in the public domain.

Of course, CMS is aware of the widespread use of other standards within the federal healthcare system. CMS emphasized in an Executive Summary of July 2004 that "(t)here have been considerable efforts by HHS, DoD, and VA to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector."[40] CMS has lauded VA's healthcare informatics systems and suggested that they could transfer into the public sector. Moreover, their software is in the public domain, so it is more accessible than proprietary copyrighted software for

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[38] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[39] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[40] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: ". . . As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector. Additionally, the Public Health Information Network (PHIN) and the National Electronic Disease Surveillance System (NEDSS), under the leadership of the Centers for Disease Control and Prevention (CDC), have made notable progress in development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and health information exchange. With HHS support, Health Level 7 (HL7) has also created a functional model and standards for the EHR." Retrieved March 29, 2005: http://www.healthpolicyohio.org/OHHIT/NHII_2004/HealthITStrategicFrameworkExecSummary.htm

companies that wish to develop products with it.[41] For these reasons, it is unclear what stands in the way of CMS adopting at least one standard in use within the federal system as an initial standard and pilot-testing it.

NCVHS noted in its letter to CMS that a standard from Health Level Seven, Inc. (HL7), is commonly used for medication orders in hospitals and clinical pharmacies and advocated coordinating HL7 with NCPDP SCRIPT. Many staff model HMOs and the VA use HL7 internally for most drug orders.[42],[43] In July 2004, HL7 issued a press release announcing that the Board of Directors "had unanimously approved the Electronic Health Record System Functional Model (EHR-S) to move forward as a Draft Standard for Trial Use (DSTU). The EHR Draft Standard can now be registered with ANSI, beginning the draft standard's trial period of up to 24 months. . . An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records."[44]

Given their widespread use, it would appear that at least some of these aforementioned standards would meet the test for "adequate industry experience" and, at least, be under consideration for status as initial standards for pilot testing. However, none of these standards appear to be under consideration by CMS at this time for adopted as initial standards and this must be done by September 1, 2005, to be pilot tested in 2006.

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[41] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: "The VA's report, 'Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities' (Attachment 2), also highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain. These technologies may be suitable for transfer to rural and medically underserved settings. VA's primary health information systems and EHR (VistA and the Computerized Patient Record System [the current system] and HealtheVet-VistA, the next generation in development) provide leading government/public-owned health information technologies that support the provision, measurement, and improvement of quality, affordable care across 1300 VA inpatient and ambulatory settings. . . The VA is also incorporating the CHI approved standards into its next-generation HealtheVet-VistA. . . Finally, the VA's health information technologies, such as bar code medication administration, VistA Imaging, and telehealth applications, provide the VA with exceptional tools that improve patient safety and enable the increasingly geographically dispersed provision of care to patients in all settings."

[42] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265: "Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy."

[43] Consolidated Health Informatics: "Standards Adoption Report: Messaging Standards: Retail Pharmacy Transactions;" p. 5. Retrieved March 22, 2005: http://www.whitehouse.gov/omb/egov/documents/domain3.doc

[44] Health Level Seven, Inc. (HL7) Press Release: "Board of Directors Unanimously Approves EHR for Draft Standard Status;" July 27, 2004.

Presumably, any change to existing standards would require legislation to revise or add language to 42 C.F.R. Sec. 423.160. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) pre-empts state laws and prohibits them from enacting legislation that contravenes federal provisions as to e-prescribing standards.[45] So, once federal law mandates specific standards, state law cannot alter or affect physicians' compliance requirements.

APA's view is that it is unwise to forego a pilot test of the standards and technologies using them that is likely to bring to light glitches more easily worked out on a small scale than on a wide scale. It is particularly clear that integrated e-prescribing systems that communicate among prescribers, dispensers and health care plans have not been in widespread use across a variety of clinical settings. For that reason alone, it is unclear precisely what practical issues need to be resolved. Further, the extensive MMA requirements demands solid, seamless integration of multiple messaging, data translation, data transfer and data access functions using at least three standards, as well as file transfer protocols such as RxHub. The integration of these standards and technologies using them has yet to be accomplished and fully tested in the field, to ensure compliance with MMA and HIPAA. Moreover, there is the issue of how software incorporating these standards will interface with web-based applications and a variety of hardware combinations.

Unless and until sufficient pilot tests are done with physicians under real-life clinical conditions to identify and resolve e-prescribing problems, CMS' laudable goals will be impeded. More importantly, once physicians begin to experience difficulties using e-prescribing systems because functionality has not yet been perfected, their frustration may well reduce or cease the use of e-prescribing altogether. In addition, negative publicity about roadblocks in the systems will deter many others from adopting e-prescribing.

Apart from time they need to properly evaluate systems against their needs, physicians also require time to become familiar with the systems, alter practices to accommodate new processes and train staff. Feedback from pilot testing will assist companies in developing physician and patient-centered products, services, training and educational materials. This will ultimately make e-prescribing more attractive and effective across various dimensions, including the enhancement of patient outcomes.

The transition to using new technologies and equipment will take physicians' time and energy. This may be more of a demand for those who do not currently own a computer. To rush this process is to increase the risk of medication errors and suboptimal patient outcomes. Those results would contravene one of CMS' primary goals for advancing e-prescribing, which is to reduce negative patient outcomes due to errors in traditional prescribing systems.

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[45] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

Another positive result of pilot-testing is that it would move the compliance date away from January 1, 2006. That would give psychiatrists time to plan for the substantial financial outlay for an e-prescribing system. The expanded time window will also allow psychiatrists to apply for federal matching grants for e-prescribing systems. These grants will not be funded until 2007. In addition, legislators will get more time to implement the projected new Safe Harbor and the new Stark II exemption that are intended to allow physicians to accept non-monetary assistance for e-prescribing systems without violating current federal laws.

***Recommendations:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards with physicians, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

## III. "PROVISIONS:" The Secretary's Proposed Effective Date of January 1, 2006, for E-Prescribing Compliance is Premature and Carries Adverse Implications

### A. Prematurity of the Proposed Effective Date

The HHS Secretary has the discretion to choose a more practical and appropriate effective date for e-prescribing compliance than January 1, 2006, and APA urges him to do so. This date is premature for several reasons and adopting it will produce adverse effects for physicians and their patients. It will also discourage psychiatrists and other physicians from adopting e-prescribing, until many technological and practical issues area resolved. The following are some of the reasons why January 1, 2006, is not a judicious choice as an effective date for compliance with e-prescribing:

1. January 1, 2006, is the same effective date for transition of dually eligible Medicare/Medicaid patients into Medicare, which will already be burdensome for physicians and patients;

2. CMS admits that it may not be possible to issue a National Provider Identifier (NPI), as planned, for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline. In addition this date is earlier than the current HIPAA compliance date for using an NPI for covered e-prescribing transactions;

3. January 1, 2006, is premature and does not synchronize with the availability of federal matching grants for physicians' e-prescribing systems, which begin being funded in 2007;

4. January 1, 2006, does not allow sufficient time to finalize a new Safe Harbor and a new Stark II exception, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems, without rendering them vulnerable to federal prosecution under current anti-kickback and Stark II laws; and

5. CMS notes that it may not be possible to issue a National Provider Identifier (NPI) for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline, which would be earlier than the current compliance date for HIPAA covered transactions. Thus, it would be impossible for physicians to be in compliance in using a HIPAA-required NPI, if they are not issued one before the deadline. E-prescribing transmissions will make physician-prescribers covered entities for HIPAA compliance. We believe that psychiatrists should not be legally mandated to use an NPI until it exists and that confusion about which identifier will be required should be resolved prior to any compliance effective date. Alternative identifiers for e-prescribing could be the physician's medical license number, DEA number, EIN or Social Security number.

***Recommendation:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

## B. "IMPACT ANALYSIS:" Privacy Concerns

Patient privacy is particularly critical in ensuring high quality psychiatric care. Psychiatrists are also rightly concerned about how e-prescribing technologies, such as web-based portals, may compromise their patients' privacy, and hence impair the foundation of trust that is the core of the psychiatrist-patient relationship. It is not until pilot tests sort out these and other potential issues that psychiatrists are likely to gain sufficient comfort with adopting e-prescribing techniques. We remain concerned about the inadequate safeguards to potential breaches in the security of identifiable patient information, through electronic transmissions and databases. It is critically important to ensure the security of and to prevent hacking into electronic systems, especially as regards the confidentiality of patients' medications. As a consequence, CMS must address this e-prescribing issue directly.

Regrettably, confidentiality is too often overlooked as an essential element of high-quality health care. Out of fear of disclosure, some patients simply will not provide the full information necessary for successful treatment. Others refrain from seeking medical care or drop out of treatment, in order to avoid any risk that their records are not entirely private. With regard to e-prescribing and its use of the internet and other electronically accessible databases, this fear may be heightened for some psychiatric patients, especially those with paranoid features to their illness. A psychiatrist is hard-pressed to assure a patient about confidentiality when there are headlines about databank breaches.

A pharmacist can legally contact a list of his or her pharmacy's patients, who have been prescribed certain drugs, in order to inform them about alternative drug therapies. A pharmaceutical company can pay the pharmacist to do this, though it cannot directly obtain patient information and contact patients. This allows pharmaceutical companies to indirectly promote targeted drugs to patients. Also, pharmacies can promote their own financial interests by urging a patient to use medications that are more profitable for the pharmacy. Marketing communications do not necessarily need to disclose these compensation arrangements.

APA believes that patients need to be certain that there will be no downstream release of information to marketers and that the security of their health records will be safeguarded. A strong CMS policy to that effect would give vendors a clear message of CMS' expectations, as this applies to e-prescribing systems and security. It is critically important that CMS respond to the e-prescribing security concerns of psychiatrists, as well as all physicians, and their patients.

As mentioned above, mental health records are particularly sensitive to release and disclosure, partly due to the unfortunate, pervasive social stigma about mental disorders. A patient might not want family, neighbors, or even a postal delivery person to see a postcard from a pharmacy suggesting that he or she is on psychotropic medication. Such communications could undermine mental health care, as patients avoid or delay it, to avoid stigmatization.

## CONCLUSION AND RECOMMENDATIONS

APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing within the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach. Pilot testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. What may constitute "adequate industry experience" with standards within one context, i.e., intra-entity transmissions or within partial e-prescribing systems, may well not work as anticipated within a different environment. For instance, problems may arise when psychiatrists, or, indeed, any physicians, in a small group practice use a fully integrated e-prescribing system to communicate with managed care companies and external pharmacies using different systems.

Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings, will it be feasible to determine precisely which standards, process areas or technologies require adjustment. All standards to be used for e-prescribing must have the capability of being used within products that work seamlessly across different data-interchange platforms and among all entities involved in the prescribing process. Moreover, the standards ultimately adopted as final foundation standards to be embedded within software, used via web portals and within e-prescribing systems hardware must be efficiently inter-functional and meet the intended practical and legal requirements. It will take some time to discover how to perfect these systems and CMS must not foreshorten this process, or it will prove to ultimately be at the expense of patients.

Psychiatric patients on prescription psychotropics are especially vulnerable to delays, glitches, and errors that could be caused by premature adoption of standards, resulting in ineffective systems. Since medication adherence is already a serious issue for such patients, even delays of a day or two in receiving prescription fills could seriously and adversely affect them. It will be much easier to collect data, provide feedback loops, and create corrective interventions within a smaller pilot-test system of e-prescribing, than within a large one. Moreover, fewer physicians and patients will be negatively affected when something goes awry within a pilot test, than within a wider context of usage. It simply makes practical sense to evaluate a major change of this dimension on the prescribing mechanisms for physicians on a small scale, before expanding the process into a larger patient-care environment.

Successes within the pilot tests can then be used to encourage further adoption of e-prescribing, while physicians remain confident that obstacles to effective use will be resolved at the pilot stage, before they adopt the technologies. In this way, e-prescribing will become a more palatable alternative to physicians, who will have a more definitive set of reasons to adopt it, with solid evidence of its advantages and confidence in its practicality. Physicians also require reassurance from CMS that policies will be adopted

that send a clear message to companies that commercial messages and design bias in software and hardware for e-prescribing will not be tolerated.

Pilot testing in 2006 will automatically advance the effective date for compliance, which has the added benefit of allowing sufficient time to promulgate the new Safe Harbor and new Stark II exception that give physicians the freedom to accept assistance in establishing e-prescribing systems. It will also be in line with the timeframe that will ensure physicians' access to federal grants to underwrite such systems. APA's specific recommendations are reiterated, below:

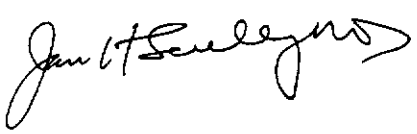
***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor for physicians to freely accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

***Recommendations-Pilot Testing:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

***Recommendation-Effective Date:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

CMS-0011-P-63

Date: 04/05/2005

**Submitter :** Ms. Ann Berkey

**Organization :** McKesson Corporation

**Category :** Health Care Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

Attached please find McKesson Corporation's Comments on CMS-001-P.

CMS-0011-P-63-Attach-1.DOC

McKesson Corporation
[redacted]

Ann Richardson Berkey
Vice President
Public Affairs

[redacted]

McKESSON

April 5, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

**Attention: CMS-0011-P**

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to provide our comments in response to the CMS proposed rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. As the world's largest healthcare information technology company, we are pleased to submit comments which reflect the unique breadth of our experience and expertise, our broad solution set and the range of our customers' perspectives on these important issues.

As a Fortune 16 corporation dedicated to providing information technology, care management services, automation, medical supplies and pharmaceutical products to virtually every segment of the healthcare industry, we understand the challenges as well as the opportunity for significant quality and efficiency improvements through the widespread adoption of e-prescribing. McKesson touches the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. With our technology solutions in 65% of U.S. health systems, McKesson is actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce cost and variability of care and improve healthcare efficiency. Our success in supply chain automation and electronic transaction processing and our experience in e-prescribing exemplify the benefits that can be derived from sustained efforts to improve stakeholder communication and to eliminate duplication of efforts in the healthcare delivery process.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the

successful Together Rx™ card and our subsequent introduction of the CMS-endorsed Rx Savings Access™ Card. The Together Rx™ card has delivered over $600 million in savings since June 2002 to more than 1.5 million low-income seniors. McKesson's Rx Savings Access™ Card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 236,000 Medicare-eligible seniors are enrolled in this card and have realized over $62 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In nine states where we provide disease management services to Medicaid patients, we estimate those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

CMS has invited comments on proposed foundation standards for electronic or e-prescribing and on the impact of those standards on various stakeholders. We believe these standards have significant implications and benefits for all stakeholders, including physicians and other prescriber organizations, health plans, pharmacy benefit managers, retail pharmacies and other dispensing organizations, technology vendors, federal and state governments, and patients. Our comments not only respond to many of the questions raised in these proposed regulations; they also provide our recommendations in areas related to the broader implementation of electronic prescribing from both a technology and a business perspective.

## Section I Background

### A. Statutory Basis

McKesson recognizes that the proposed regulations are designed specifically for use in the Medicare Part D program; however, to ensure that there is only one set of industry standards for e-prescribing, we strongly encourage CMS to develop and support generally accepted standards that can also be utilized throughout the entire healthcare system, including for those not eligible for Part D benefits.

### 1. Initial Standards versus Final Standards

We concur that there is adequate industry experience to proceed with initial implementation of these proposed standards without pilot testing. However, we would encourage formal monitoring of the process by CMS and ongoing evaluation of anticipated concerns as these standards are implemented. Specific areas of concern include:

- the use of proprietary standards that have not been placed into the public domain may create de facto monopolies;
- widespread deployment of e-prescribing transactions in the absence of a patient identifier may increase the risk of misdirected transactions;
- absence of a national standard for electronic signature may increase the cost of implementation;
- inefficiencies and additional costs may result from the absence of a pre-authorization standard;
- the use of NDC-11 codes to identify medications may cause delays in the ability to e-prescribe new medications or preparations; and
- the possibility that standards developed for the Medicare Part D program will not be extended to and scaled out for other populations, thus leading to the development of more than one industry standard for eligibility transactions.

While acknowledging these concerns, we continue to recommend that CMS deploy these foundation standards without pilot testing.

**2. State Preemption**

Currently, state regulations vary widely and could create significant barriers to entry and add unnecessary costs. Common state legal and regulatory hurdles that are encountered include:

- absence of or incomplete laws/regulations that authorize e-prescribing;
- requirements that e-prescribing be transmitted directly to a licensed pharmacy of the patient's choice, thereby limiting options for routing transactions;
- variability of "Dispense as Written" interpretations on a state by state basis;
- unclear and confusing electronic or digital signature requirements;
- requirements that e-prescribing entities be approved by State Boards of Pharmacy prior to implementation in the state; and
- DEA limitations and requirements for state controlled substance triplicate forms.

Since many medical "communities" extend beyond a single state's border, resolution of differences between state laws and federal policy will be required to speed the adoption and implementation of e-prescribing. To address that concern, McKesson supports federal preemption of state policies and standards that may be in conflict. Federal preemption of state e-prescribing laws will provide consistency between states. It will also promote adoption and reduce barriers to entry for prescribers, dispensers and vendors. The scope of the preemption outlined in the proposed rule promotes consistency relative to the foundation standards; however, the narrow scope still leaves room for continued variability from state to state in the adoption and regulation of e-prescribing.

**3. Anti-kickback Statute Safe Harbor and Stark Exception**

We strongly believe that the Stark safe harbor exceptions are critical to attain the provider adoption rates necessary to achieve the desired benefits of this e-prescribing initiative.

However, we believe that rapid and precise clarification of these exceptions is essential to ensure that provider organizations clearly understand and can utilize these exceptions to drive broad adoption.

**B. The NCVHS Process**

We have been favorably impressed with the effectiveness of the NCVVS process, and we strongly support ongoing use of this forum and process for obtaining industry expertise and guidance.

**C. Standards Design Criteria**

McKesson believes that the most significant factor in the rapid adoption of proposed standards by providers and information technology suppliers is ready, affordable access to all aspects of the standard necessary for its full implementation. Accordingly, key standards, including transaction standards (messages), data standards and identifiers (codes), and rules used for patient identification and patient matching, should be placed in the public domain and must not be the intellectual property of a single vendor. These standards may become the foundation of healthcare transactions, and once established, they will not be easily removed.

CMS should establish a clear policy that ensures any adopted standard is not burdened with intellectual property licenses that are royalty bearing or discriminatory. This royalty-free licensing policy should include the following elements:

1) disclosure of relevant existing or proposed patents by any participant recommending a standard; and

2) agreement by participants to license all essential claims to interoperability standards on a royalty-free, non-discriminatory and irrevocable basis. These measures will ensure that no one organization has the ability to exert undue control over the standards.

**F. Evolution and Implementation of an Electronic Prescription Drug Program**

McKesson supports the proposed criteria for determining foundation standards. It is critically important that foundation standards be developed through the consensus process used by ANSI-accredited Standards Development Organizations. Key industry stakeholders must recognize these as industry standards in order to ensure adoption and timely deployment throughout the industry. Upon designation of new or revised foundation standards, a compliance deadline of not less than two years from the designation date should be allowed for industry testing and deployment. Concurrent with the implementation of the initial standards, we recommend that pilot testing commence on other NCVHS recommendations that are not part of the foundation standards.

We also recommend that, for purposes of HIPAA compliance, e-prescribing should be considered within the categories of treatment, payment or operations when a determination is made as to the "minimum necessary information" required.

## G. Electronic Prescription Drug Program

We support NCVHS as the lead organization for review and recommendation of additional standards. We would also encourage NCVHS to organize forums and communicate with Standard Development Organizations to facilitate and expedite efficient and timely modifications to the initial standards. We support the use of an ANSI-accredited Standards Development Organization for the creation of new standards.

### Provider and Dispenser Identifiers

McKesson endorses comments from the Working Group on Electronic Data Interchange (WEDI) as noted below:

- NPI should be the primary identifier for prescribers and dispensers;
- current identifiers should be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access, are available;
- the required date for use of NPI in transactions in this proposed rule must not be sooner than the required date for use of NPI in HIPAA transactions. WEDI is concerned that there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before NPI can be mandated. The proposed date of January 2006 is unattainable because of non-availability of these NPI system capabilities. The NPI should not be required until the May 2007 deadline;
- legacy identifiers had capability for transaction routing that may not be provided by NPI or other data elements in standard transactions. This problem must be researched and solved. The solutions probably lie with adjustments to the data in the transactions, rather than adjustments to the NPI rules.

It is important to recognize that, irrespective of the value of the NPI for uniformly identifying healthcare providers, electronic prescribing requires that prescribers be additionally identified by an electronic "address" for the proper routing of transactions. Additionally, where the same prescriber operates out of more than one physical location, this routing information needs sufficient specificity to direct transactions to the correct prescriber location. The NPI alone cannot facilitate the routing of transactions. Accordingly, we recommend evaluation of alternatives for identification, including HCIdea, with the requirement that all standards be available in the public domain.

### Formulary and Medication History Standards

We support adoption of the RxHub file transfer protocol as the standard for medication history transmission and formulary transmission. As noted in our earlier comments, foundation standards, including codes and rules for patient identification, should be placed in the public domain. A pilot study should evaluate standards for communication of the "decision making process" (alerts and warnings received and over-ridden) from a prescriber to a dispenser.

Our support for RxNorm is reflected in the "Drug Information" section below; however, we want to emphasize its importance for formulary management as well.

**Drug Information**
In the absence of robust standards for identifying medications and therapeutic classes of medications, we support the use of the NDC-11 codes as a provisional medication identifier. We endorse the recommendations of the NCVHS advisory panel that the FDA accelerate and refine the process by which it creates, updates, and distributes the NDC-11 medication codes. We also recommend monitoring the effectiveness of the NDC-11 code as a means to identify dispensed medications.

We support evaluation of the RxNorm standard as a means to identify medications and therapeutic classes, and enable communication between prescribers, electronic health record systems, dispensing systems, vendors and the FDA. We recommend ongoing support for collaboration between the National Library of Medicine and the FDA.

**H. Summary of Status of Standards for an Electronic Prescription Drug Program**
McKesson supports efforts to establish these foundation standards rather than waiting until more comprehensive standards are accepted for patient medical histories and for electronic health records (EHRs). The adoption of foundation standards is a critical step in accelerating the broader adoption of e-prescribing and healthcare information technology. Long-term success will be contingent on the success of foundation standards, but will also be influenced by a multitude of other factors. Towards that end, we support the current activities of the Commission for the Certification of Healthcare Information Technology (CCHIT) relative to certifying EHR software and believe that the selection of these foundation standards will facilitate adoption of e-prescribing without compromising the EHR certification process. Furthermore, we encourage CMS to continue to explore additional means to minimize legal, regulatory and technical hurdles for prescribers and their solution providers, which will result in improved patient safety as well as lower costs.

**Section II Provisions of the Proposed Regulation**

**C. Proposed Requirements for Part D Plans**
We agree that internal standards need not be immediately revised to comply with these rules. In practice, we expect that internal standards will likely migrate to compliance with these rules as products are updated.

**E. Proposed Standards**

**1. Prescription**
McKesson concurs that prescription fill notification transactions be specifically excluded from the foundation standards until sufficient industry experience is determined, either through pilot program testing or by broad industry consensus on the business case for inclusion.

**2. Eligibility**
McKesson agrees with the proposed foundation standards that specify the NCPDP eligibility transaction standard for use by the pharmacies and the ASC X12N 270/271 eligibility standard for use by prescribers. The use of HL7 for e-prescribing eligibility verification should not be considered unless the matter is thoroughly reviewed and agreed upon by the various industry constituencies.

We concur with the proposal to use notice and comment rulemaking for substantive changes to the standards and to allow waiver of comments on minor modifications as long as "backward compatibility" with the previously adopted version is supported. However, the number of such minor modifications should be limited without requiring formal notice and comment. This would prevent a substantive change from "masquerading" as a series of minor changes. For substantive changes, we recommend a minimum of two years for implementation to ensure compliance by all industry participants.

**F. Compliance Date**
January 1, 2006 is a reasonable date for implementation of the foundation standards outlined in the proposed rule, provided that the transaction standards for formulary and medication history transactions are adopted by NCPDP and are accredited by ANSI.

**Section IV Regulatory Impact Analysis**

**A. Overall Impact**
While we support the establishment of foundation standards without waiting for more comprehensive medical history/EHR standards, increasingly hospitals and physicians are adopting integrated solutions that combine e-prescribing with other components of an EHR system. In fact, isolated e-prescribing applications in the ambulatory environment may not even exist by the time these standards are effective in 2009. To that end, we want to ensure that, if providers adopt an integrated EHR system, they will not lose the safe harbor provisions applied to e-prescribing that are noted in the Medicare Modernization Act.

We concur with CMS that the proportion of prescribers using e-prescribing will increase with the implementation of the Medicare Part D program; however, we believe widespread adoption could be rapidly achieved by removing two significant barriers. Exceptions to anti-kickback laws must be clearly defined and implemented prior to or concurrently with the proposed regulations on e-prescribing. Additionally, we encourage CMS to provide monetary incentives to encourage physicians to acquire and deploy e-prescribing technology.

**B. Impact on Health Plans/PBMs**
While many health plans automatically receive information from dispensing organizations via the telecommunications standard, they have limited or no experience

with the "front-end" transactions associated with formulary download and medication history. In fact, unless a health plan or PBM is part of RxHub, we are concerned that they may not have had the opportunity to appropriately test and gain adequate experience with the proposed standards in these areas. Furthermore, few health plans have actively participated in comprehensive e-prescribing programs like those in Massachusetts and Rhode Island and have little experience with the costs associated with supporting such programs, including labor and incentive costs for prescribers. While we concur with the potential benefit to payers and PBMs as outlined in the proposed rule, the cost impact may be larger than anticipated.

**C. Impact on Prescribers**

The potential benefits to prescribers from e-prescribing are well stated in the proposed rule. McKesson has successfully partnered with providers in Illinois and Iowa to achieve the following results:

- elimination of medical chart pulls related to medication questions or inquiries;
- 26% increase in nursing time spent with patients;
- 100% compliance with required prescription elements as compared to less than 60% compliance with paper prescriptions;
- reduced phone call volume related to formulary questions from pharmacies and pharmacy benefit managers;
- improved access to clinical information between care settings, especially the availability of information on outpatient medications in the hospital setting;
- 83% improvement in efficiency related to medication refills.

While early adopters have realized the benefits of e-prescribing, we believe that the adoption rates envisioned by CMS can be best achieved through a combination of economic incentives and exceptions from anti-kickback laws.

**D. Impact on Pharmacies and Other Dispensers**

The benefits outlined in the proposed rule are consistent with our customer experiences to date relative to e-prescribing and use of foundation standards for claims submission. However, dispensers may incur costs in training their staff to support inbound e-prescribing from area pharmacies. As area prescribers implement electronic systems, dispensers must work collaboratively with them to mitigate initial costs and ensure enhanced customer service, quick turnaround times, and greater patient safety.

E-prescribing provides pharmacies with opportunities to automate the medication process workflow. Pharmacists spend a significant amount of time on the telephone with refill and third-party payer issues. While patients can electronically request prescription refills from their pharmacy, pharmacies do not have similar processes for requesting pre-authorizations from physicians and third party payers.

Automating these processes will provide significant workflow benefits to pharmacies and other dispensers:

- saves time by automating the renewal/refill process and callbacks;
- provides the pharmacist more time for counseling;
- improves customer satisfaction and care: less waiting time and reduced potential for medication errors;
- provides more timely and effective response to medication recalls;
- provides more efficient formulary enforcement; and
- supports software integration with practice systems and a smooth workflow.

In addition to dispensing and distribution, a large part of the pharmacist's responsibilities is in the transcription, verification, translation, and communication of medication information. E-prescribing provides opportunities to enhance communications between physicians, nurses, pharmacists and patients by providing pharmacists with the ability to:

- monitor refill activity;
- monitor new written prescriptions filled;
- relay prescription fill and refill information to the prescribers; and
- monitor patient adherence to drug therapy.

**F. Impact on Others**

McKesson believes that all healthcare information technology vendors with ambulatory EHR products and all companies that currently offer or plan to offer e-prescribing applications will be impacted by the proposed rule. The cost of compliance with the provisions of the proposed rule for current e-prescribing vendors will vary based upon their current compliance with proposed standards. Future entrants to the marketplace should benefit from the adoption of clearly defined standards. As a vendor with established e-prescribing products, we believe that our own cost of compliance with the proposed regulations will not be excessive, as long as the proposed standards do not add additional royalty requirements or intellectual property barriers to our current implementation.

**Conclusion**

In conclusion, we would like to reiterate our support for the following:

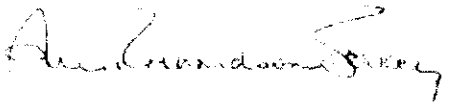
- implementation of the proposed foundation standards for e-prescribing without pilot testing;
- a requirement that standards not be proprietary or encumbered by intellectual property claims;
- federal preemption of state e-prescribing policies and regulations; and
- exceptions from Stark and other anti-kickback laws to expedite adoption of e-prescribing.

As a major healthcare supply management and information technology company, McKesson appreciates the opportunity to share its views on the proposed regulations to

adopt standards for an electronic prescription drug program under the Medicare Modernization Act. These initial regulations are critical and we applaud the agency's efforts to undertake this important first step. We look forward to working with CMS and the Administration as you implement this final rule and as you address other important issues that must be resolved to ensure widespread adoption of e-prescribing.

Please do not hesitate to contact me with any questions. I can be reached at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

**Date: 04/05/2005**

**Submitter :** Ms. Lisa Geiger

**Organization :** American Health Quality Association

**Category :** Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see the attached comments from the American Health Quality Association.

CMS-0011-P-64-Attach-1.DOC

Date: 04/05/2005

**Submitter :** Mrs. Diana Dennett

**Organization :** America's Health Insurance Plans

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-65-Attach-1.DOC

America's Health
Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

April 5, 2005

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

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

## Application of Standards Within Organizations

***Issue:*** The standards should not be applied to electronic prescribing communications within a "closed network."

***Discussion:*** The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan...." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity are not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

***Recommendation:*** AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS either reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103) or adopt the following language:

*A "closed enterprise" is:*

*1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider that share a common electronic health information system;*

*2. An organized system of health care in which more than one covered entity (as defined by HIPAA) participates and in which the participating covered entities:*

- *a. Hold themselves out to the public as participating in a joint arrangement; and*
- *b. Participate in joint activities that include at least one of the following:*
  - *i. Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; or*
  - *ii. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; and*
- *c. Share a common electronic health information system.*

**Pilot Testing**

***Issue:*** Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

***Discussion:*** The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. 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, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

***Recommendation:*** AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

**Standards for Formulary Representation and Medication History**

***Issue:*** The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

***Discussion:*** The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the

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[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).

RxHub protocol as a basis for these standards. 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.

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

***Recommendation:*** AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

**Process for Modifying the Standards**

***Issue:*** The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

***Discussion:*** The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, CMS should consider the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to 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 and implemented to allow any necessary changes to technology and business systems.

***Recommendation:*** AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

**The National Provider Identifier**

***Issue:*** Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

***Discussion:*** The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. 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 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification 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.

***Recommendation:*** AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.


**State Law Preemption**

***Issue:*** The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

***Discussion:*** The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

***Recommendation:*** AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

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[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

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

**Organization :** **American Academy of Pediatrics**

**Category :** **Other Association**

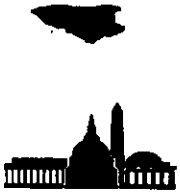
**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-66-Attach-1.DOC



American Academy of Pediatrics

**STATEMENT**

**FROM THE AMERICAN ACADEMY OF PEDIATRICS**

**IN RESPONSE TO THE**
**CENTERS FOR MEDICARE AND MEDICAID SERVICES MEDICARE PROGRAM**

# E-PRESCRIBING AND THE PRESCRIPTION DRUG PROGRAM PROPOSED RULE

**APRIL 5, 2005**

American Academy of Pediatrics
141 Northwest Point Boulevard
Elk Grove Village, IL 60007-1098
847/434-4000 (Phone)
847/434-8000 (Fax)

## Introduction

This response is submitted on behalf of the American Academy of Pediatrics (AAP), an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and surgical specialists who are dedicated to the health, safety, and well being of infants, children, adolescents, and young adults.

The AAP and its members have long been committed to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults. This commitment includes advocating for the design of health care systems to prevent errors. If designed with particular pediatric needs in mind, E-prescribing has demonstrated the ability to improve safety, efficacy, and efficiency in children's health care.

## CMS-0011-P BACKGROUND

With regard to State Preemption of the Proposed Rule, the American Academy of Pediatrics believes that the Federal standard for electronic prescribing should preempt state regulations prohibiting such transactions, particularly as they relate to controlled substance prescribing and digital signatures. Many states currently have their own requirements, including the use of special paper forms, for the prescription of controlled substances. As noted in the Proposed Rule (IMPACT ANALYSIS, Impact on Prescribers), prescribers spend a significant amount of time responding to requests for refills. In pediatrics, controlled substances are routinely prescribed as therapy for Attention Deficient Hyperactivity Disorder (ADHD) and related conditions. Such prescriptions require frequent provider approval of refill requests. State regulations requiring such prescriptions to be handled on paper limit the potential for error reduction through new technologies, such as e-prescribing. Similarly, states have proscribed multiple standards for signatures on controlled substance prescriptions, both in paper and electronic form. Multiple standards for signatures are a significant roadblock to broader adoption of e-prescribing.

## CMS-0011-P PROVISIONS

The American Academy of Pediatrics supports the Proposed Rule as a floor on e-prescribing functionality, above which many e-prescribing software vendors will provide additional functionality. As such, the proposed Standards are reasonable; however, the American Academy of Pediatrics would encourage the adoption of an additional functional standard related to interaction checking. Where drug-drug or drug-allergy interaction checking has been completed and overrides of resulting alerts have been allowed before transmission to the dispenser, a flag should be incorporated into the information to be transmitted to alert the dispenser that the potential interaction was recognized and overridden. This would further reduce the need for follow-up communications between the prescriber and dispenser. Such an event might occur where the pharmacy's record indicates a patient allergy to a particular medicine when the prescriber has determined the allergy is insignificant or erroneous.

In addition, the Rule seeks to establish the National Provider Identifier (NPI), an upcoming HIPAA standard, as the standard identifier for prescribers and dispensers, but it does not address a standard identifier for patients. The American Academy of Pediatrics believes that a uniform National Patient Identifier is necessary to allow interoperability in e-prescribing, electronic health records, and other health information technology applications. We would encourage the creation of a unique National Patient Identifier, as originally specified under HIPAA. This is particularly important for pediatrics, in which patients frequently present with no name (in the case of a newborn) or with changing names (which may or may not match that of the parents). The American Academy of Pediatrics recognizes the controversy surrounding the issue of a National Patient Identifier and recommends that use of such an identifier be restricted to communications covered by the HIPAA Privacy Rule.

Finally, the American Academy of Pediatrics believes that the new prescription transaction standard should include the following:

1. In addition to the patient's name, residential address, and birthdate, basic demographic information for pediatric prescribing should include the names and phone numbers (voice, cell) for both parents, the custodial parent, or other guardians, if appropriate. The parent's name may be different than the patient's name, and prescriptions might be filled by either of two separated parents from different addresses.

2. Standardized transmission of patient weight and weight units, the date on which the weight was obtained, should be included on the prescription. Systems should be able to calculate patient age from birthdate.

3. Diagnosis should be included (optionally) on the prescription or as part of the transmission, as it is required in some states for controlled substances, e.g. Attention Deficit Hyperactivity Disorder for prescriptions of methylphenidate.

4. The ability for dosages to be printed in fractions of dosage forms should be standard.

5. An optional note field is needed for the prescriber to communicate to the pharmacist any other special information or request. This note should print on the prescription or transmit electronically.

**CMS-0011-P IMPACT ANALYSIS**

Costs to implement e-prescribing may be much greater than estimated. Many providers do not have the office infrastructure to support e-prescribing. Costs to install computers, wireless routers (particularly for those in rural areas who may not have access to cable or DSL Internet connections), to set up networks, and to purchase personal digital assistants (PDAs) could incur costs above $2,000* per prescriber. For prescribers who are already using some technology in their practices, interfaces to practice management or electronic health record software, preferred formularies, and decision support, purchase of PDAs and wireless routers, etc., would also have additional start-up costs. Overhead costs may be in the range of 15-20% annually. Finally, the

impact on workflow efficiency of a different, unconnected system must be considered. This is particularly true for smaller practices that cannot afford an EMR system that contains e-prescribing.

It is also necessary to point out that financial incentives to providers through Medicare programs do not benefit most pediatricians. Incentive programs focusing solely on Medicare could therefore put pediatricians and other child health care providers at a disadvantage and restrict the quality improvement benefits of e-prescribing to the adult population. The American Academy of Pediatrics therefore recommends that any financial incentives approved for prescribers through the Medicare program also be extended equally to prescribers participating in Medicaid programs.

## CMS-0011-P ADDITIONAL COMMENTS

Finally, the AAP urges that practicing pediatricians be involved in the development of further e-prescribing standards. It is often the case that pediatricians have to modify standards and recommendations designed for adults when their patients have not been taken into consideration during the design and testing stage of health care technology, including E-prescribing systems. For example, the age and weight of a child can make a medically significant difference in selecting an appropriate dose. Specific medications may be contraindicated for particular diagnoses or for particular age groups. Awareness of these and other issues in the design stage of E-prescribing systems can help to reduce the error rate in prescribing medications for children. Because prescribing for a pediatric patient can be more complex than prescribing for an adult, it is important that the special pediatric considerations be factored in during the development of standards, not as an afterthought.

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* Calculation based on the following: $500 computer; $30/month ($360 for first year) for high-speed Internet access; $50 wireless router; $150 installation of computer, router, and security; $400 PDA; $500 e-prescribing software (including pharmacy database, formularies, decision support); $200 printer.

**Submitter :** **Mr. Ken Whittemore Jr,** **Date: 04/05/2005**

**Organization :** **SureScripts**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attached

CMS-0011-P-67-Attach-1.DOC

CMS-0011-P-67-Attach-2.DOC


April 5, 2005

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

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
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; 42 CFR, Part 423**

Dear Dr. McClellan:

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 70, Number 23, beginning on page 6256 on February 4, 2005. SureScripts appreciates the opportunity to comment on these proposed rules that call for the adoption of foundation standards that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. SureScripts has testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input throughout 2004 on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement these foundation standards and the proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

## Introduction

SureScripts was founded in August of 2001 by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), which together represent the interests of the 55,000 chain and independent pharmacies throughout the United States. The company is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is SureScripts Messenger™ Services, a healthcare infrastructure

that establishes electronic communications between pharmacists and physicians and enables the two-way electronic exchange of prescription information. You and your staff can find more information about SureScripts at www.surescripts.com.

SureScripts Comments Regarding the Prohibition of Inappropriate Messaging in Electronic Prescribing Systems and Transactions

Noticeably absent from this proposed rule is any language that effectuates the requirement in the MMA that prohibits the intrusion of inappropriate messaging into the electronic prescribing process at the point of care (defined as both the physician office and the pharmacy). Specifically, the MMA states that the electronic prescribing standards that the Secretary adopts shall "*allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse drug interactions, and to improve medication use.*" Congress was quite clear in stating in the MMA that inappropriate messaging at the point of care during the prescribing and dispensing processes must not be allowed in the Medicare electronic prescribing program.

SureScripts is acutely aware of the strong desire and intent that some entities, including but not limited to technology vendors, manufacturers, payers, pharmacy benefit managers (PBMs), pharmacies, laboratory service providers, and others in the clinical technology space have to inappropriately influence physicians' choice of medication therapy and patient's choice of pharmacy for Medicare beneficiaries. Inappropriate and misleading messages could be and, in some cases, are planned to be delivered with the intent to influence a physician's choice of therapy and/or a patient's choice of pharmacy by entities who financially or strategically gain from the message delivery, physician's decision of therapy, or patient's choice of pharmacy. Some plans are to (1) disguise this message as a "clinical alert" based upon biased research not published in the public domain nor sourced at the time of message delivery or (2) the alert would be positioned as saving a patient money when further investigation would prove the selection of pharmacy in fact costs the patient additional moneys in out-of-pocket costs. There is little question that these and other entities will engage in this inappropriate messaging unless CMS creates clear, specific, and unequivocal rules prohibiting such activities within the practice of electronic prescribing for the Medicare prescription drug program as provided for in the MMA.

SureScripts emphatically urges CMS to incorporate into its final MMA rule on electronic prescribing strong and specific prohibitions against the types of inappropriate messaging that are discussed in this response. Sample rules related to inappropriate messaging are attached hereto as possible model language for consideration by CMS. These guidelines have been developed and modified over the last two to three years by SureScripts, and have been agreed to by many technology vendors and multiple other stakeholders including health systems, pharmacies, physician groups, pharmaceutical manufacturers, and payers. We believe these messaging guidelines could serve as the foundation of policies related to inappropriate messaging. Doing any less will permit an environment of abuses to evolve that will surely impede the rapid

adoption of electronic prescribing and electronic health records that was contemplated by Congress as it created the MMA.

SureScripts Responses to CMS Requests for Comment on the Proposed Rule

(We have arranged our comments to follow the captions and overall organization of your requests for comments, which is consistent with the format requested in your notice of proposed rulemaking.)

BACKGROUND

A. Statutory Basis

*CMS: Electronic media is defined under HIPAA to include both electronic storage media and transmission media, including the ``internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media." (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards.*

**SureScripts Comments:** We agree that all of the electronic media described above can and often are used to transmit prescriptions electronically, which does make this definition useful in determining when prescribers and dispensers are electronically transmitting prescription and certain other information. To these media we would add secure wireless communication technologies, which are also used to transmit electronic prescriptions, especially when PDA and other handheld devices are employed by prescribers.

*CMS: Finally, we believe that we have met the statutory requirement for industry consultation because we actively participated in the NCVHS process, and we requested and received industry comments on adequate industry experience with existing standards through the Medicare Prescription Drug Benefit proposed rule. We are also requesting comments in this proposed rule. The need for pilot testing of future standards will be determined when additional standards are recommended.*

**SureScripts Comments:** SureScripts testified orally and in writing to NCVHS on a number of topics related to electronic prescribing throughout 2004 and into 2005. Our experience during this time was that both NCVHS and CMS personnel were keenly interested in learning about electronic prescribing standards that are being used effectively by the industry and with which of those standards the industry might already have adequate experience. Thus, we agree that CMS has met the statutory requirement for industry consultation as required by the MMA.

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

**SureScripts Comments:** SureScripts has had extensive experience with the adverse impact that state pharmacy laws and regulations and other local rules can have on the implementation of electronic prescribing, which is why we favor of a broad preemption of state rules that interfere with the adoption, implementation and/or operation of electronic prescribing standards or the elements of the electronic prescribing infrastructure.

SureScripts recognized from the start that the manner of issuance of prescriptions was governed by state board of pharmacy rules. The knowledge that these rules would apply to the creation and transmission of electronic prescriptions prompted us to make an across-the-board review of these rules throughout the states in 2002. This review indicated that electronic prescribing connectivity was, at least in theory, permissible in most states.

Over time, however, as SureScripts began planning in earnest to move forward with electronic prescribing in specific states, it became clear that additional regulatory due diligence was needed. It was not sufficient to know if electronic prescribing was permitted in theory, rather, experience taught us that the critical and truly pertinent question was: "Do the laws and regulations in a particular state permit electronic prescribing *the way in which SureScripts planned to implement it*?" Answering this question has not been easy, as it has involved a time-consuming process of researching and analyzing specific, in-depth technology and procedural issues, and it is a process that is still not complete even three years later.

Through this ongoing process, SureScripts has encountered a number of common state legal and regulatory hurdles, which include:

- An absence of laws and regulations that authorize electronic prescribing connectivity
- **Incomplete laws and regulations enabling electronic prescribing connectivity***
- **Laws and regulations that were created early on and thus don't "fit" the technology***
- **Highly specific dispense-as-written requirements that cannot be met using electronic technologies***
- **Unclear electronic or digital signature requirements***
- Requirements that electronic prescribing connectivity entities and prescribing technology vendors including stand alone prescribing applications and electronic health record solutions be approved by the board of pharmacy prior to implementation in the state

- **Extraneous laws and regulations that have been interpreted as applying to electronic prescribing connectivity***

SureScripts' Regulatory Affairs staff has successfully developed specific tactics for overcoming most of these hurdles and, where they remain, is working closely with the boards of pharmacy in those states to overcome them.

Of all of the state hurdles, though, the specific one that has proven to be most troublesome and widespread is language to the effect that:

> *All Prescription Drug Orders communicated by way of Electronic Transmission shall be transmitted directly to a Pharmacist or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice* ***with no intervening Person having access to the Prescription Drug Order*;***

This language is taken directly from the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act, and it has been adopted in various forms by most of the states. We have found time and time again that the underscored language above presents a barrier to the implementation of electronic prescribing in the states. Sometimes these barriers are a result of how this exact language is interpreted by state regulatory agencies, and other times it is the result of a particular state having embellished upon this language, thereby making it totally unworkable. While we understand that the intent of this language is to protect patient confidentiality and guarantee that electronic prescriptions are not altered during the transmission process, the effect of this broad language and the way that it has been interpreted in many states has been to prohibit the use of standard telecommunication protocols to implement the technology. These many variations and interpretations of this one small portion of the model act language clearly argue in favor of a broad preemption to this type of language.

With regard to CMS's specific questions regarding preemption, SureScripts believes that the examples listed above that are bolded and denoted with an asterisk should be preempted in order to enable electronic prescribing to move forward nationwide. However, following CMS's logic that there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted, it is hard to envision that any of them would be. For example, in what ways would the foundation standards recommended within this proposed rule conflict with any of the state rules summarized above? We at SureScripts are at a loss to think of any. In other words, if the MMA preemption provision cannot be used to eliminate any of the actual obstacles to the implementation of electronic prescribing listed above, then of what use to CMS or the industry is the MMA preemption provision? In order to be truly useful, the MMA preemption provision will have to preempt not just those state rules that conflict with electronic prescribing standards, but also those state rules that interfere with the actual operation of various components of the electronic prescribing infrastructure.

As to the breadth and depth of the MMA preemption provision, SureScripts believes that said preemptions must apply to the broadest set of transactions and entities. Only applying preemption to the

electronic prescribing program under Part D will create a bifurcated set of rules that will be difficult for providers to understand and follow. The boards of pharmacy realized ten years ago that this would be the case with the OBRA '90 rule, and therefore decided that the patient counseling and recordkeeping requirements of that Federal rule should apply to all patients. Hence, it is entirely appropriate and logical that CMS should acknowledge the problems inherent in a two-tiered electronic prescribing program and avoid said problems by applying the MMA preemption provision as widely as possible.

Lastly, though we at SureScripts (as well as others in the industry, we suspect) are coming close to the point where we have successfully navigated around the state regulatory obstacles to electronic prescribing in all states, such rules do change. Technology also changes and evolves over time. Both of these facts argue toward a broad MMA preemption, because electronic prescribing should not be subject to the shifting and variable influence of regulations. Innovation in the field should be supported, not stifled, by regulations, and only a broad MMA preemption can guarantee this.

D. Current Prescribing Environment

*CMS: Today, physicians and other health care providers make their drug-prescribing decisions using whatever medical, medication, and eligibility information that is known or available to them. Then they give a handwritten prescription to the patient or fax it to the patient's pharmacy of choice. At the pharmacy, tasks are somewhat more automated. Through electronic claims, eligibility, and benefits submission, the dispensing pharmacist may learn about drug interactions, disease management concerns, the need for prior authorization, or lower cost alternatives. The pharmacist may then contact the prescriber by phone for approval of changes, refills, or renewals. This process can be very repetitive and time consuming for both the pharmacist's and the prescriber's office staff. According to some estimates, almost 30 percent of prescriptions require pharmacy call backs, resulting in 900 million prescription-related telephone calls that are placed annually.*

**SureScripts Comments:** We encourage CMS to modify the *Current Prescribing Environment* section so that it also reflects the fact that community pharmacists gather and make use of significant patient clinical and medication information during the course of their practices. It is critical that local, regional, and national health information networks understand the value of including community pharmacies in their electronic information sharing networks as the national health care information technology network is built out.

In particular, Congress recognized that community pharmacists have a vital role in enhancing therapeutic outcomes and reducing medication errors and adverse drug interactions when it enacted the Omnibus Budget Reconciliation Act of 1990. While OBRA '90 applies only to Medicaid recipients, it was not long before all the state boards of pharmacy passed laws and/or regulations that assured that this higher standard of pharmacist care for Medicaid patients would be available for all of their citizens.

OBRA '90, and the state pharmacy practice rules that expanded OBRA '90's coverage to all state citizens, requires a set of prospective drug utilization review activities that are more extensive than those required by the MMA. In addition is the point that 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 patients' diseases, allergies, drug reactions, list of medications and relevant devices, will certainly need to be included with in patients' electronic medical records (EMRs) in addition to other electronic prescribing information required by the MMA in order for said records to deliver their full clinical value. Therefore, SureScripts strongly recommends that CMS acknowledge this fact in the *Current Prescribing Environment* section of this proposed rule.

F. Evolution and Implementation of an Electronic Prescription Drug Program

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

*The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

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

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

**SureScripts Comments:** As is mentioned above, SureScripts did provide testimony to NCVHS during its 2004-2005 hearings, and we specifically spoke to the issue as to which industry standards have been used to date to implement electronic prescribing on a nationwide basis. We believe we have an excellent intuitive understanding of which electronic prescribing standards have "adequate industry experience," and thus should not need to be piloted in 2006. We realize, however, that it is appropriate for CMS to formalize a definition of "adequate industry

experience" in order to give the industry an accurate yardstick with which to judge various standards. The solution at which CMS has arrived in offering these three criteria is useful, understandable, reasonable and elegant, and the use of these criteria yields an accurate, real-world assessment of the standing of standards in question. As such, the only qualifiers that we would add to these three criteria would be that:

(1) The first criteria should actually focus on the ANSI-accreditation status of the *standards development organization (SDO)* rather than the standard itself. In other words, the NCPDP SCRIPT Standard should be adopted as an MMA foundation standard because it was created by NCPDP, which is an ANSI-accredited body. We make this recommendation because we are concerned that in some cases, waiting until a *standard* itself has worked its way through the ANSI-accreditation process may well cause an unnecessary delay of months or even years before its adoption.

(2) We suggest expanding the scope of the second criteria so that it requires broad use by multiple different types of industry participants, such as pharmacies, prescribers, PBMs, payers, etc. Our reasoning here is that a standard must have widespread utility in order to be designated as an MMA foundation standard. High transaction volumes among a small number of like users should not satisfy this criterion.

If CMS takes these qualifiers into consideration, SureScripts will agree that the use of these three criteria is appropriate when seeking to determine if a standard does, in fact, have adequate industry experience, and we will support their use wholeheartedly.

*CMS: In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**SureScripts Comments:** We recommend that HHS adopt minimal version levels of foundation and final standards, that HHS depend on existing SDO enhancement processes for newer versions, and that health care organizations be permitted to use newer versions without delay provided there is backward compatibility. We further recommend that NCVHS hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS should recommend such changes to HHS in much the same way as it has made its MMA electronic prescribing standards recommendations thus far. If NCVHS considers said changes to be substantive, we suggest that HHS issue an NPRM within 90 days. If the change is not substantive, we suggest that notice and comment be waived.

G. Electronic Prescription Drug Program

*CMS: Provider and Dispenser Identifiers. The MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions. However, the NCVHS found that it was important to address the issue of provider identifiers for various e-prescribing standards it reviewed and, more generally, for an electronic prescription drug program. We agree. After assessing a number of candidate identifiers, the NCVHS further recommended the use of the National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available.*

*HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. We believe that it is necessary to have a unique identifier for these transactions. The NPI is the preferred option, because it is a standard that many entities will be required to use under HIPAA. If use of the NPI is required for e-prescribing transactions involving Medicare Part D drugs at the time the benefit is available in January 2006, prescribers, pharmacies, pharmacists, Part D sponsors and potentially other entities would be required to implement the NPI for e-prescribing transactions earlier than the current compliance date for the HIPAA covered transactions.*

*The NCVHS also urged HHS to accelerate the enumeration of all providers to support transition to the NPI for e-prescribing. We have been planning to enumerate HIPAA covered providers over the course of several years.*

*Accelerated NPI usage for e-prescribing, therefore, may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. Furthermore, there is a possibility that unforeseen system or budget concerns could delay provider enumeration, and, therefore, the date by which the NPI would be available for use in e-prescribing under Medicare Part D. We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**SureScripts Comments:** A prerequisite to the suggestion that the NPI be used as an identifier for Medicare Part D e-prescribing transactions is the absolute requirement that the NPI fully meet the needs of participants in the electronic prescribing industry. The two primary and essential functions that a provider identifier must fulfill in electronic prescribing transactions are to: (1) identify who the provider is and (2) tell how the message must be routed in order to reach the provider. There is no question that, by definition, the NPI will satisfy the first requirement, but it is our understanding that, as currently configured and being implemented, the NPI will not satisfy the second requirement. Having the first functionality without the second renders the NPI no more useful that other potential identifiers, and less useful than others currently in use. This functionality deficit of the NPI will require industry participants to create significant work arounds, which should not be the case and which means the NPI is a less-than-ideal choice of

identifier for electronic prescribing transactions. This clearly argues against requiring the use of the NPI for the electronic prescription program under Medicare Part D.

If on the other hand, CMS was to see to it that the NPI was changed to include routing information, it would make the NPI an excellent choice of a provider identifier for Medicare Part-D and other e-prescribing transactions. As we testified last year to NCVHS, the absence of a fully functional prescriber ID in the marketplace led SureScripts to create its own SureScripts Provider ID, or SPI. This has been an expensive, time-consuming endeavor, and it would not have been necessary if a product existed in the marketplace that met both of the primary requirements for an electronic prescribing ID discussed above. Therefore, we encourage CMS to make the changes necessary in order for the NPI to serve as a fully functional electronic prescribing identifier. If this is done, SureScripts will embrace, adopt and support the NPI.

Finally, should the NPI be transformed into a fully functional identifier that is completely useful to the electronic prescribing industry, its use should not be required sooner than the date for use of the NPI in HIPAA transactions, and there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before the NPI is mandated. In the interim, participants in the electronic prescribing industry should be allowed to continue to use whatever provider ID system(s) that they have been using, which in SureScripts' case would be our SPI. SureScripts would be opposed to CMS requiring the use of any other provider ID system during the interim.

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

**SureScripts Comments:** We agree that the NCPDP Provider Identifier should continue to be used to identify pharmacies until such time as the NPI is fully implemented and available for use. We do not agree, however, with the recommendation that the NCPDP HCIdea be used in the event that the National Provider System (NPS) cannot enumerate providers (prescribers) in time for Medicare Part D electronic prescription drug program implementation. Rather, as stated above, we recommend the continued use of existing network identifiers for prescribers, such as the SureScripts SPI, until such time as the NPI is in fact ready for general use.

*CMS: Formulary and Medication History Standards. The NCVHS noted that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange. In response to industry testimony, RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be*

*considered for adoption as an ANSI-accredited standard. NCVHS considered ANSI accreditation to be a criterion in their recommendations process, and HHS proposes to adopt this as a criterion for determining adequate industry experience.*

*The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocol as a basis, and indicated its belief that this appeared possible in time to adopt the standard as a foundation standard.*

*We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. We would consider adopting an NCPDP standard for formulary and medication history that are based on the RxHub protocol.*

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

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and point-of-care (POC) vendors.*

*The standards provide a uniform means for--*

*+ Pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via POC systems; and*

*+ POC vendors to receive a range of formulary and benefit information through these services.*

*The standards cover a range of formulary and benefit data, including information on the--*

*+ Formulary (for example, therapeutic classes and subclasses);*

*+ Formulary status (for example, drugs that the benefit plan considers to be ``on formulary'');*

*+ Preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and*

*+ Copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another).*

*We propose the following critical characteristics for medication history standards:*

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and POC vendors.*

*The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*

*The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe,*

*and may include the pharmacy that filled the prescription and the physician that wrote the prescription.*

**SureScripts Comments:** SureScripts understands and appreciates CMS's strong interest in adopting standards that would enable the transmission of formulary representation and medication history information within the MMA electronic prescribing program as soon as possible. Great progress has been made in this area over the last six months, and a proposed standard appears that it will be adopted by an ANSI-accredited SDO (NCPDP) in the near future. However, because this standard will not have had widespread usage among a broad variety of industry participants, CMS should carefully consider whether adequate industry experience exists with this new standard to warrant its quick adoption as an MMA foundation standard or whether it should first be pilot tested in 2006.

*CMS: Drug Information. Section 1860D-4(e)(2) of the Act specifies that an electronic prescription drug program will include information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments. Given that relevant e-prescribing standards must permit electronic exchange of drug labeling and drug listing information maintained by the FDA and the NLM, medication history standards should be compatible with those standards when they are adopted by the Secretary. While drug information standards will not be foundation standards, they will be supported in the future by the structured product label. While standards for providing this type of information on drugs have not yet been considered by the NCVHS and are not yet proposed, we anticipate proposing standards in the future through rulemaking because they are required by MMA and we believe that providing this information is essential to improving the safety and quality of medication management. We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*

**SureScripts Comments:** SureScripts does not have a recommendation to make at this time with regard to drug information standards, but we would like to be apprised of any such standards that CMS does propose in the future through the rulemaking process so that we might comment on them when appropriate. In addition, we strongly believe that any drug information standards recommended for use by CMS, either in proposed or final rules, should absolutely be thoroughly tested first in a wide variety of industry settings prior to being recommended.

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

*CMS: We recognize that the standards we are proposing do not provide all of the functions for which standards are required by section 1860D-4(e)(2) of the Act. At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience; otherwise, pilot testing is required by section 1860D-4(e)(4)(c) of the Act prior to the adoption of a standard as a final standard. We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In*

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

*The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*The ASC X12N 270/271--Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunication Standard).*

**SureScripts Comments:** SureScripts agrees with and wholeheartedly supports CMS's proposal to adopt the NCPDP SCRIPT Standard, the ASC X12N 270/271 Transaction, and the NCPDP Telecommunication Standard as foundation standards for the electronic prescribing program created by the MMA, provided that the versions listed above are considered minimal version levels, and business partners may utilize newer versions as described in our response on versioning that we provided above in Section F. We are particularly pleased with the recommendation that the NCPDP SCRIPT Standard be adopted as a foundation standard because of its near-universal acceptance and use by participants in the ambulatory electronic prescribing environment nationwide.

In addition, SureScripts is completely comfortable with the strategy that CMS is proposing of phasing in implementation of an electronic prescription drug program by requiring participants to comply initially with the proposed foundation standards listed above, and at a future date, to comply with other necessary standards, provided that they are adopted using a similar rulemaking process and are subject to pilot testing if they do not have adequate industry experience.

*CMS: We acknowledge that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive Electronic Health Record (EHR) system with decision support functionality and must be interoperable with other functions of an EHR. The need for interoperability between these*

*systems will become even more critical in the future when patient medical history standards are adopted. 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.*

**SureScripts Comments:** SureScripts agrees with the reasoning behind CMS's approach of adopting foundation electronic prescribing standards that are ANSI-accredited and have adequate industry experience as a means of facilitating interoperability with EHRs. SureScripts already is transmitting electronic prescriptions and refill renewal requests and authorizations back and forth between a number of EHR application providers and pharmacy partners. We believe that prescribers will continue to need to use a variety of portals to gain access to the electronic prescribing infrastructure, and we are committed to expanding the interoperability of all of these systems at every opportunity.

II. Provisions of the Proposed Regulation, C. Proposed Requirements for Part D Plans

*CMS: Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy. The e-prescribing standards that these ``closed'' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards.*

*It is important to note that the NCVHS recommendation differs from the HIPAA transaction requirements. The preamble for the Transactions Rule (65 FR 50316-50317) discusses transmissions within a corporate entity requires covered entities to use the adopted transaction standards when conducting covered electronic transactions with other covered entities. The Transactions Rule also expressly states that if a covered entity conducts a covered transaction using electronic media within the same covered entity, it must conduct the transaction as a standard transaction (45 CFR 162.923). Consequently, whether the transaction is conducted within or outside the entity is immaterial with respect to whether compliance with the HIPAA transactions is required.*

*This issue is relevant to Medicare Part D in situations where an MA-PD plan, for example, is a staff-model HMO using an internal pharmacy. We solicit comment on whether Part D plans*

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

**SureScripts Comments:** We agree that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise. However, NCPDP and HL7 have worked together to ensure that the content of NCPDP and HL7 transactions are compatible for outpatient prescriptions and we believe this to be a viable solution in the near term. The SureScripts electronic prescribing network is now able to receive HL7 prescription transactions and convert them into the NCPDP SCRIPT format for transmission to community pharmacies. We are pleased to offer this value-added service to our partners, because we believe it supports the earlier adoption of electronic prescribing particularly by inpatient clinical systems and ambulatory Electronic Medical Record (EMR) solutions. We would prefer that this not be considered a long-term solution for moving electronic prescribing messages "outside of the organization" (i.e. from EMR solutions in a clinic or hospital setting to community pharmacies). Rather, we would like this to be viewed as a transitional approach, one that should only be allowed for a reasonable period of time. We recommend that technology companies that have implemented electronic prescribing by January 1, 2006 using this exemption be allowed one additional year to bring their systems into compliance with the NCPDP SCRIPT standard.

E. Proposed Standards

*CMS: The Secretary has tentatively concluded that the proposed standards discussed below are not subject to pilot testing because adequate industry experience with these proposed standards already exists. Entities with electronic prescription drug programs would be required to comply with the proposed applicable standards no later than January 1, 2006.*

*1. Prescription*

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

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

*New prescription transaction*
*Prescription refill request and response transactions*
*Prescription change request and response transactions*
*Cancel prescription request and response transactions*
*The following ancillary messaging and administrative transactions:*
*+ Get message transaction*
*+ Status response transaction*
*+ Error response transaction*
*+ Verification transaction*
*+ Password change transaction*

*We do include, as part of the proposed foundation standards, the previously identified ancillary messaging and administrative transactions. These transactions are an integral part of the NCPDP SCRIPT Standard, providing the administrative functions to assure that prescription transactions are accurately exchanged. Industry experience with the adopted HIPAA transactions has shown the need for standard acknowledgement and error reports transactions. During the NVCHS hearings, the only transaction specifically mentioned as lacking industry experience was the Prescription Fill Status Notification Transaction and, thus, it has not been included in this proposed rule. Because these ancillary messaging and administrative transactions are an integral part of the NCPDP SCRIPT Standard, we believe that the industry has adequate experience with them, so as to be able to forego pilot testing. We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.*

**SureScripts Comments:** Again, SureScripts agrees with CMS's proposed adoption of the NCPDP SCRIPT Standard as a foundation standard for the MMA electronic prescribing program. There is no question that there is adequate industry experience with both the new prescription and the prescription refill request and response transactions, and though not used nearly to the same extent thus far, we are also comfortable with including both the prescription change request and response and the cancel prescription request and response transactions among the MMA foundation standard recommendations. Further, we do believe that there is adequate industry experience such that the associated ancillary messages should be able to forego pilot testing. (As an aside, it should be noted that the use of SCRIPT ancillary messages should not be required, because there are instances in which they are not necessary. For example, there are some implementations that do not require a GET message since mail boxing is not required.)

*CMS: If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which*

*provides for publication in the Federal Register of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

*When determining whether to waive notice and comment and whether to incorporate by reference multiple existing versions, we would consider the significance of any corrections or revisions to the standard as well as whether the newer version is ``backward compatible'' with the previously adopted version. In this context, we intend the term ``backward compatible'' to mean that the newer version would retain, at a minimum, the full functionality of the version previously adopted in regulation, and would permit the successful completion of the applicable e-prescribing transaction with entities that continue to use the previous version. We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

**SureScripts Comments:** SureScripts would agree with this procedure as long as the HIPAA standard modification would not cause electronic prescribing standards to be "locked in" or have to return to an older version. Our belief is that electronic prescribing standards will be more advanced than applicable HIPAA transaction standards due to the process required to change HIPAA transaction standards.

IMPACT ANALYSIS

A. Overall Impact

*CMS: We anticipate that the use of the standards proposed in this rule, and the fact that we are proposing that these standards be available for the January 2006 implementation of the Medicare Prescription Drug Program, will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used. While there are no detailed models predicting specific rates of adoption for this technology, based on our sense of the likely expert consensus, we think it likely that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years. The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of--*

*Publicity surrounding the Medicare Prescription Drug Program;*

*More publicity about the benefits of e-prescribing and the experience of prescribers who are participating;*
*Increased emphasis on health information technology in general;*
*Potential cost savings to providers using e-prescribing; and*
*The availability of incentives for participation.*

*We believe that as prescribers gain experience with e-prescribing, they will recognize the benefits and share those experiences with colleagues. We invite public comment on our expectations for prescriber participation.*

**SureScripts Comments:** We believe that CMS's expectations for prescriber participation in electronic prescribing are actually much too conservative. For example, a recent report released by the Pri-Med Research Group showed that among the primary care practitioners surveyed, more than one in five reported using e-prescribing systems now, and another 42 percent said they were planning to do so in 2005. In addition, a recent Medical Economics survey indicated that one in four prescribers plans to buy an EMR system soon, at least 70 percent of which already include electronic prescribing functionality.

*CMS: 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. We plan to publish a more complete impact analysis in the final rule, including an assessment of impacts on the Medicare program, the effect on Part D spending, annual savings to Medicare, costs to plans and providers, and estimated costs and savings for the private sector and other Federal programs.*

**SureScripts Comments:** SureScripts has created an Industry News Search Engine that can be found on our web site that will be of great assistance to CMS as it compiles data for all of the subjects of this Impact Analysis. Well over 100 news reports and articles can be searched using this engine, which is located at http://www.surescripts.com/MRRC/topic.asp

C. Impact on Prescribers

*CMS: We invite public comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing. We also anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance.*

**SureScripts Comment:** We do not have any direct information on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing (other than what

might be available through our Industry News Search Engine, which is discussed above), but we do believe in the benefits of incentives to prescribers such as pay-for-performance programs that have been contemplated by CMS and other private payers, so long as said programs do not include inappropriate messaging done with the intent of benefiting the provider of the incentive programs.

*CMS: There is anecdotal evidence of direct economic benefits that accrue to prescribers that implement e-prescribing, in addition to the previously discussed health benefits to patients. The following examples of these benefits have been reported:*

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

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

*A large practice in Lexington, Kentucky estimates that e-prescribing saves the group $48,000 a year in decreased time spent handling prescription renewal requests.*

*Prior to implementation of e-prescribing, a large practice in Kokomo, Indiana with 20 providers and 134,000 annual patient office visits was receiving 370 daily phone calls, 206 of which were related to prescriptions. Of the 206 prescription-related calls, 97 were prescription renewal requests. The remainder consisted of clarification calls from pharmacists or requests for new prescriptions. Staff time to process these calls included 28 hours per day of nurse time and 4 hours per day of physician time. Chart pulls were required in order to process half of the renewal requests. Implementation of an e-prescribing system produced dramatic time savings that permitted reallocation of nursing and chart room staff.*

*Potential reductions in malpractice insurance because of improvements in the quality of patient care resulting from better tracking of patients' drug regimen and a reduction of ADEs, which may occur with e-prescribing.*

*These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.*

**SureScripts Comments:** We again direct you to our Industry News Search Engine on our web site, which should provide you much additional information on actual and potential savings to prescribers who use electronic prescribing: http://www.surescripts.com/MRRC/topic.asp

D. Impact on Pharmacies and Other Dispensers

*CMS: Testimony from pharmacists and professional pharmacy organizations provided to the NCVHS (available on the Web at http://www.ncvhs.hhs.gov reported the following benefits of e-prescribing for pharmacies:*

*Reduced time-consuming phone calls to physicians.*

*Improved accuracy and less time for refill authorizations.*

*Additional time available for patient contact and services.*

*Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).*

*Improved turnaround time for refill authorizations.*

*We do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing. While we expect to see the efficiencies (discussed at the beginning of this section) at pharmacies with some possible reductions in administrative staff time, we do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program. The industry has provided information indicating that 75 percent \8\ of the 57,208 pharmacies in the U.S. already have e-prescribing capability which suggests that pharmacies already find this a beneficial investment. In this respect, we note that the great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small. For example, as indicated earlier in this preamble, we believe that over 95 percent of pharmacy systems are already compatible with the NCPDP retail pharmacy drug claim standard. Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**SureScripts Comments:** We agree with CMS's assessment of the benefits of electronic prescribing for pharmacies. On the other hand, we believe that CMS has underestimated the cost for pharmacies to adopt and utilize electronic prescribing capabilities. The cost to add electronic prescribing functions to a community pharmacy involves both upfront costs and ongoing transaction fees. While it is true that most chain pharmacy organizations and the pharmacy software vendors that serve independent pharmacies have absorbed these upfront costs in order support the development of the electronic prescribing infrastructure, there still will be significant ongoing costs involved when pharmacies actually use the infrastructure. SureScripts has observed transaction fees in the community pharmacy marketplace ranging from $0.215 to $0.35 (note that one fee is charged when a pharmacy receives an electronic prescription and just one fee is charged for a message to the prescriber and any response on refill renewal requests). It is important to understand that community pharmacies are paying all transaction costs related to electronic prescription messages. We are not aware of any business models that require physicians to share in the transaction costs associated with electronic prescribing. Thus, though it is difficult to make highly accurate predictions at this time, it is quite reasonable to suggest that the average community pharmacy might incur electronic prescribing transaction fees that total $4,000 to $5,000 per year.

I. Conclusion and Alternatives Considered

*CMS: For the reasons given above, we are not preparing analyses under the RFA, section 1102(b) of the Act, or the Unfunded Mandates Reform Act. We have, nevertheless, considered the alternatives discussed below. We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

*Two sets of standards that we are proposing in this rule already are required standards under the Administrative Simplification provisions of HIPAA. The ASC X12N270/271--Health Care*

*Eligibility Benefit Inquiry and Response and NCPDP Telecommunication Standard are adopted standards and required when conducting standard transactions. We are proposing these standards for e-prescribing because they are already adopted standards for HIPAA transactions and meet some of the requirements specified in Title I, section 1860D-4(e) of the Act, as amended by section 101 of the MMA.*

*The NCPDP SCRIPT Standard is in widespread use and meets many of the e-prescribing requirements outlined in section 1860D-4(e) of the Act. Also, NCPDP is developing NCPDP SCRIPT transactions to meet other MMA requirements for future consideration or pilot testing. The NCVHS did not recommend any viable alternatives for e-prescribing foundation standards because testimony presented by the industry during the NCVHS hearings strongly supported the NCPDP SCRIPT Standard (available on the Web at http://www.ncvhs.hhs.gov).*

*An alternative to adopting these particular standards as final foundation standards for e-prescribing would be to pilot test the recommended standards. The NCVHS did not recommend pilot testing for these foundation standards because they are already adopted standards with adequate industry experience.*

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

**SureScripts Comments:** As noted above, SureScripts commends CMS for proposing to adopt the NCPDP SCRIPT Standard, the ASC X12N 270/271 Transaction, and the NCPDP Telecommunication Standard as foundation standards for the electronic prescribing program created by the MMA. We strongly believe that this was the appropriate course for CMS to take given the current state of the industry and the requirements made by the MMA. We see no valid reasons to consider the alternatives of first pilot testing these proposed foundation standards, and we would discourage CMS from delaying the timely adoption of these standards in order to so.

## Conclusion

SureScripts appreciates the opportunity to continue to provide advice and assistance to CMS as it works to implement the electronic prescription program requirements of the MMA through this proposed rule. We hope CMS will continue to take advantage of the experience that SureScripts can share with respect to the real-world implementation of electronic prescribing for the purposes of improving the safety, efficiency, and quality of the overall prescribing process. Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above or if the are any other ways that we can assist them in this important work.

Sincerely,

Ken Whittemore, Jr.
VP, Professional and Regulatory Affairs

ken.whittemore@surescripts.com
(703) 921-2114

Attachment

**SureScripts Recommended Rules to Prohibit Inappropriate Messaging in Electronic Prescribing Systems and Transactions**
**MMA Electronic Prescribing NPRM**

(a) *General.* Part D sponsors and their subcontractors, pharmaceutical manufacturers, pharmacies, and vendors of e-prescribing technology shall neither permit nor engage in inappropriate messaging in the establishment, maintenance, and operation of e-prescribing technology or an electronic prescription drug program.

(b) *Penalties.* Violations of this section shall be subject to Intermediate Sanctions as described in section 423.750.

*c) Definitions and Guidelines*

1. *Definitions*
   a. "Prescribing decision" means a physician's decision to prescribe a certain Part D drug or direct the patient to a certain pharmacy.
   b. Point of care refers to the time, commencing upon the physician's review of a patient's medical record and terminating upon the physician's signature on the prescription, during which a physician or his/her agent is engaged in the act of prescribing a Part D drug for a patient.
2. Except as specified paragraphs (4) and (5), Technology Vendors shall not use, alter, or modify their systems in any manner that would direct, influence, or encourage a physician or patient, at the point of care, to prescribe, select, or use a specific Part D drug or pharmacy, as compared to other Part D drugs or pharmacies.
3. Technology Vendors shall not use any means, program, or device, or knowingly permit any other person to use any means, program, or device, including, but not limited to, advertising, instant messaging, and interruptive messaging (e.g., "pop up" ads), to direct, influence or attempt to direct or influence, through economic incentives or otherwise, the prescribing decision of a physician at the point of care, or to make more difficult or unduly burden a physician's or patient's selection of a particular pharmacy or Part D drug as compared to another pharmacy or Part D drug if such means, program, or device (as described above) is triggered by, initiated by, or in specific response to, the input, selection, and/or act of a physician or his/her agent prescribing a Part D drug or selecting a pharmacy for a patient
4. Notwithstanding the above, Technology Vendors may display or present information regarding a Part D plan's formulary and benefit design, including lower cost Part D drug and pharmacy options, the tier placement of Part D drugs, prior authorization, step therapy, coverage status, and co-payment information, even if such information influences the patient or physician's choice of pharmacy or other prescribing decisions, so long as (i) such display or presentation is neutral and unbiased and the source of the information is identified, (ii) the End User may access all Part D drugs known through generally available sources used in the industry, and all pharmacies including all retail and mail service pharmacy options available, and (ii) nothing is designed to preclude a physician or patient from selecting any particular pharmacy or Part D drug.
5. Additionally, any lists created and maintained by End Users within a Technology Vendor's software product including, but not limited to, (i) an individual End User's list

of most frequently prescribed Part D drugs, (ii) an individual End User's list of most frequently used pharmacies, (iii) an individual End User's most frequently used SIGs (i.e., instructions for the use of medications), would not be considered a violation of this Section.

**Date: 04/05/2005**

**Submitter :** Mr. Rich Johnson
**Organization :** Texas Medical Association
**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-68-Attach-1.DOC

CMS-0011-P-68-Attach-2.DOC

-The involvement of state and specialty societies in the development of a formulary for this program will be essential. By identifying and engaging physicians with expertise in this area from such state and specialty organizations, CMS could address problems with a potential lack of both transparency and specificity of process in inventorying best practices and the most current standards of care. Additionally, physicians from state and specialty organizations, working with Medicare Quality Improvement Organizations, are in the best position to assist CMS in developing strategies for physicians to use in promoting patient safety and liability risk reduction overall in the implementation of Medicare Part D.

Again, thank you for the opportunity to comment. TMA will be actively engaged on behalf of Texas patients and their physicians in advocating for regulatory policies that truly reflect the intent of Congress in the largest expansion of Medicare since it's inception in 1965. We look forward to opportunities to work with you and CMS to that end.

Sincerely,

Bohn D. Allen, M. D.
President

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Again, thank you for the opportunity to comment. TMA will be actively engaged on behalf of Texas patients and their physicians in advocating for regulatory policies that truly reflect the intent of Congress in the largest expansion of Medicare since it's inception in 1965. We look forward to opportunities to work with you and CMS to that end.

Sincerely,

Bohn D. Allen, M. D.
President

**Submitter :** **Mrs. Diana Dennett** **Date: 04/05/2005**

**Organization :** **AHIP**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-0011-P-69-Attach-1.DOC

America's Health
Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org


April 5, 2005

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

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

## Application of Standards Within Organizations

***Issue:*** The standards should not be applied to electronic prescribing communications within a "closed network."

***Discussion:*** The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan...." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity are not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

***Recommendation:*** AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS either reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103) or adopt the following language:

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


**Pilot Testing**

***Issue:*** Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

***Discussion:*** The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. 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, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

***Recommendation:*** AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

**Standards for Formulary Representation and Medication History**

***Issue:*** The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

***Discussion:*** The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the

[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).

RxHub protocol as a basis for these standards. 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.

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

***Recommendation:*** AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

**Process for Modifying the Standards**

***Issue:*** The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

***Discussion:*** The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, CMS should consider the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to 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 and implemented to allow any necessary changes to technology and business systems.

***Recommendation:*** AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

**The National Provider Identifier**

***Issue:*** Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

***Discussion:*** The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. 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 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification 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.

***Recommendation:*** AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.

**State Law Preemption**

***Issue:*** The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

***Discussion:*** The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

***Recommendation:*** AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

---

[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

**Submitter :** Mr. Anthony Schueth **Date:** 04/05/2005

**Organization :** Point-of-Care Partners, LLC

**Category :** Other

**Issue Areas/Comments**

**GENERAL**

GENERAL

We have attached our response to the NPRM.

**POINT-OF-CARE PARTNERS**
eHealth Management & Marketing Consultants

April 5, 2005

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

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

Dear Centers for Medicare and Medicaid Services:

Point-of-Care Partners, LLC (POCP) is pleased to submit the following comments to the Medicare Prescription Drug Benefit notice of proposed rule-making (NPRM) for the E-prescribing and Prescription Drug Program that was published in the Federal Register on February 4, 2005.

POCP is a network of independent consultants with one common characteristic – we have developed, executed on, evaluated and studied electronic prescribing and point-of-care strategies and tactics, in some cases for more than 20 years. With this experience level, POCP brings a wealth of lessons learned to this NPRM response.

Our model is to focus on a subject matter, providing whatever consulting services a given client might need relative to it. If we do not have the resources or skillset to complete a desired assignment, we will reach out to our vast network of affiliates to find the desired talent.

More than 80% of our current business is related to electronic prescribing. Our clients include five clinical software companies that specialize in electronic prescribing, three clinical content database companies, the National Library of Medicine, a connectivity company, a health plan, two pharmacy benefit managers and three pharmaceutical manufacturers. Because of this breadth of experience in E-prescribing, we must be highly objective so that we don't alienate any one of our potential stakeholders. For that reason, our testimony will always take the "high ground," focusing on what is best for E-prescribing, in general, instead of that of a given stakeholder.

## I. Background (F. R. page 6257)

### *A. Statutory Basis*

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

*electronically transmitting prescription and certain other information, and therefore, should be required to comply with the E-prescribing standards.*

## POCP Recommendations:

In the outpatient world, nearly all prescriptions flow over mature networks through reputable intermediaries. We believe that is the most effective model for electronic prescribing. Should prescriptions flow via the open Internet, other security measures would have to be put in place, such as public-key/private-key infrastructure (PKI). Because of the cost of implementing that technology and the fact that experts do not believe that it is ready for prime time, we do not advocate it.

We publish a free electronic newsletter on electronic prescribing. In our October 10, 2003 issue, we advocated mandating E-prescribing for all prescriptions, not just Medicare. Here is our rationale:

> *We unequivocally believe that electronic prescribing represents a "win" for all constituents and we're all about "a rising tide raising all ships." To that end, encouraging E-prescribing is good, mandating it is better.*
>
> *Adoption has always been the greatest challenge to electronic prescribing. Anyone who believes that government grants to physicians will fix that problem is clearly not aware that acquiring free E-prescribing technology has never been a problem for physicians, yet adoption is only estimated to be from 6% to 10%. In our experience, most people do not appreciate anything they don't pay for themselves, physicians included.*
>
> *To be sure, E-prescribing is highly interrelated, and its value increases exponentially as independent parties cooperate with each other. For example, two-way interfaces between the practice management system and electronic medical record or E-prescribing application are better than a one-time data dump. In addition, transmitting a prescription electronically to the pharmacy is better than faxing it.*
>
> *There are many factors that lead to cooperation, the most important of which may be prioritization of resources. To that point, it's important to note that enhancing software and "integration" lead to the assignment of information technology (IT) or development resources, and there isn't a well-run pharmacy chain, insurance company, software concern or physicians group with IT or development staff members sitting around playing Solitaire. The efforts of these expensive resources need to be prioritized. If E-prescribing is just encouraged, we believe it will be too easy to say, "The marketplace isn't ready, so let's wait." If it becomes mandated, we think it will create a sense of urgency that would move integration and development to the top of the list.*
>
> *It will also get organizations on the same timetable. Throughout the history of E-prescribing, one interrelated constituency tends to be ready before the others. In the mid-1990s, retail pharmacy, lead by Walgreens, was ready for electronic prescriptions but there were few front-end software systems that could generate them. In the late 1990s, software companies counted on the revenue from retail pharmacy, but found that many of them weren't ready to receive EDI transactions.*
>
> *Associations will advocate on behalf of their members, but lawmakers should make decisions based on what's best for their constituents. The biggest winners with E-prescribing will be patients -- and society -- in the forms of reduced medication errors and lower costs. We encourage lawmakers to keep that in mind as they deliberate about "encouraging vs mandating." We think encouraging is good, mandating better.*

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

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

**POCP Recommendations:**

In our view, state boards of pharmacy (BOP) have been one of the consistently biggest barriers to E-prescribing. There are many reasons for this.

Over the years, stakeholders who are against electronic prescribing have used their influence to confuse and, in many cases, play to the fears of state board of pharmacy members, who are not educated on ePrescibing technology. For example, for years the National Association of Boards of Pharmacy had model regulations that prohibited an intermediary to come between the prescriber and pharmacy. That model is simply not practical. While the NABP has modified its model rules, confusion persists. For example, recently enacted laws in Georgia do not permit an intermediary.

Let us be clear: members of the state boards of pharmacy are good people with good intentions. In some cases, the "law of unintended consequences" is a factor; in others we believe that state BOP members are being manipulated by those who see E-prescribing as disadvantaging them.

Opponents of E-prescribing will use scare tactics such as raising privacy concerns and pointing out that, should an intermediary be permitted, the prescription could be rerouted or changed enroute. Since HIPAA, the privacy concerns are less of an issue today, so they focus on the latter. The fact is that all state laws dictate that the prescription must be routed to the pharmacy of the patient's choice, so that concern has already been addressed. Furthermore, it is unlawful to change the prescription enroute, so that should not be a concern.

The reality is that opponents to E-prescribing are concerned that they will be disadvantaged in the marketplace, possibly because they do not have E-prescribing capabilities or do not feel they can afford them. In the latter part of our NPRM response, we discuss impact on various stakeholders. In summary, we believe that CMS has misinterpreted the impact on some stakeholders. We sympathize with them, but strongly believe that the benefits of E-prescribing outweigh the negative impact on a few stakeholders.

SureScripts, ProxyMed, eRx Networks and other switch companies assign high-level staff members to educate, petition, get clarification on and sometimes lobby state boards of pharmacy at considerable and unnecessary cost to the industry. In its testimony in December 2004, the National Association of Boards of Pharmacy testified that all 50 states permitted electronic prescribing yet in its February 2005 Newsletter, SureScripts said that just 37 states were "good to go." In our view, if a state is not "good to go" with SureScripts, ProxyMed or eRx Networks, it doesn't *really* permit E-prescribing.

There are also issues of inconsistency between rules, as well as rules that are out of date. In her December 8, 2004 testimony to the National Committee on Vital and Health Statistics (NCVHS), Mary Ryan, RPh, Vice President, Medco Health Solutions testified

that "eSignature standards can vary at the state level and are just one of the myriad of such variances in the functional requirements of E-prescribing. Unless we have a national standard for all aspects of E-prescribing, prescribers and pharmacies will encounter barriers to implementing the technology needed to meet the expectations of all states." We agree.

Ms. Ryan points out that medicine, including pharmacy, is practiced across state lines, with 18% of prescriptions filled in mail order pharmacies and a growing segment using specialty pharmacies. According to a presentation by IMS at NCPDP in March, 2005, mail service and specialty pharmacy are the two fastest growing areas of pharmacy. The challenge, as Ms. Ryan points out, is that the prescription must be legal where it's written, and the prescribers have an expectation that a legal prescription will be honored in a receiving state.

In some states, E-prescribing is permitted but requires board approval. It's the E-prescribing software companies that must send high-level people to board meetings to lobby for this approval. These cost must be passed on to the prescriber, or other stakeholders, creating additional barriers to adoption.

Because of these state variances, the software companies must monitor all 50 states. Their applications must be modified for state variances, for example some states require the exact words "dispense as written" and a check box next to it, and others require the exact words "substitution permitted" and a check box next to that. Figuring out the state BOP rules and regulations can be quite a challenge.

Therefore, we agree with the recommendations provided by WEDI (in which we were participants). Changing "WEDI" to "POCP" and making a few tweaks to the language, we submit the following recommendations:

- POCP recommends Federal preemption of state board of pharmacy (BOP) rules and regulations relative to electronic and paper prescriptions, so that paper and electronic rules are complementary and synergistic. (We do not believe it is practical to just preempt ePrescriptions, in general.)

- POCP recommends that Federal preemption apply to <u>all</u> electronic and paper prescriptions, not just those covered under Medicare Part D.

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

POCP is concerned that Federal preemption that will reconcile BOP rules of the 50 states is highly complex and will take considerable time; so POCP recommends that the deadline for implementation of this aspect be in 2009.

There are some who will argue that they will have all of the state BOPs on the same page by then. We are not so optimistic. We think education will still be an issue, as the good people who serve on these boards tend to be practicing pharmacists who may not have the time to keep up with changing technology. We think state BOPs are still subject to scare tactics. And, as technology changes, state BOPs have historically been slow to keep up. Because of all of this, state BOPs are subject to enacting rules with unintended consequences, and manipulation by individuals and organizations that are against progress because they are selfishly and short-sightedly looking at E-prescribing as hurting them or their peers individually, not as what's best for the country as a whole.

**E. Current E-prescribing Environment (F.R. page 6260)**

## POCP Recommendations:

As we stated in the preamble, 80% of our business is in E-prescribing. We work with nearly all stakeholders and we have been involved in E-prescribing for 20 years, in one case. With those credentials, we would submit that your observation of the E-prescribing environment is accurate but not complete.

Over the years, E-prescribing has been plagued by fits and starts. In the mid-1990s, pharmacies were ready but physician software companies had no marketshare. In the late 1990s at the end of the dot-com boom, a number of software companies were building E-prescribing applications, but many pharmacies had lost their appetite for E-prescribing and were not EDI-enabled.

This timing issue is a barrier that you do not note. Focusing on overcoming barriers is in your best interest, and that of the country.

As you point out, one of the greatest barriers to E-prescribing is "the costs of buying and installing the system, the training involved, time and workflow impact, lack of reimbursement for costs and resources," which we place in the same bucket.

The reality is, the cost of buying and installing software is a major barrier to electronic health records (EHRs) or computerized prescriber order entry (CPOE) systems. Money is set aside for grants directly to prescribers. The problem is that there isn't nearly enough money to supplement purchases. It is also contemplated that Stark provisions could be modified so that third parties could purchase hardware and software for prescribers. We think that is a more practical solution than paying providers directly through grants. We are also wondering, however, if tax breaks could be given to providers who purchase EHRs or CPOE systems. Furthermore, we recommend that the Federal government look at ways to encourage medical malpractice insurance companies to give providers breaks on their malpractice insurance rates in exchange for purchasing an EHR or CPOE system. Their challenge is that they cannot yet tie E-prescribing and EHR use to reduced medication errors and other liabilities. This effort can be encouraged by including measurement of such impact as part of the 2006 pilot programs.

We focus on EHRs and CPOE because it isn't actually that expensive to purchase a stand-alone E-prescribing system. Furthermore, managed care organizations have been willing to provide E-prescribing hardware/software solutions to providers for years. This strategy has not, however, been as effective as the marketplace would have liked because there have been no strings attached to the hardware/software give-aways. To that end, we recommend that the Federal government adopt the principle that the industry is starting to

adopt; that is, that utilization needs to be a string attached to any hardware/software give-away.

On the subject of lack of reimbursements of costs, we agree with pay-for-performance initiatives that are being implemented by payers in the marketplace. It is our observation that health plans are following a process of paying for resources, activities and results. "Resources" means putting the foundation in place. In E-prescribing, "activities" means utilization, and "results" means outcomes. At a minimum, we would recommend encouraging the marketplace to pay for utilization for, it is our greatest challenge and, without it, no one derives value. While the MMA suggests that Medicare prescription drug plans (PDPs) could pay for formulary compliance, reduced medication errors and reduced hospitalizations (outcomes), that must come after utilization.

Relative to these outcomes, it is important that CMS understand that the only outcome easily measured is formulary compliance. The means to measure reduced medication errors and fewer hospitalizations needs to be developed through the creation of databases that have both pharmacy and medical claims, and a means to derive such information. This must be a part of any E-prescribing system enacted by CMS.

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

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

## POCP Recommendations:

We believe that CMS is spot-on with their requirement that standards be implemented by the industry and recognized by key industry stakeholders. On the subject of ANSI-accreditation, we think it should be a balloted standard of an ANSI-accredited standards development organization (SDO) vs. accreditation by the American National Standards Institute (ANSI) itself. This last step -- ANSI-accreditation -- takes time and doesn't add much. What's important is completing the standards development process of an ANSI-accredited SDO.

We also agree with the Secretary, who has determined that pilot testing is not required for the standards proposed in this regulation because they meet the criteria for adequate industry experience. We do have caveats about each standard, which we will go into in another section.

We also agree that standards should be vendor neutral and technology independent.

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

## POCP Recommendations:

We are active members of NCPDP, HL7, X12 and ASTM, and have either attended or listened into each of the NCVHS hearings on E-prescribing. As CMS knows, each of these SDOs impacts E-prescribing.

As active NCPDP members, we have been part of its task group that developed a recommendation on how to address the issue of versioning. We fully support NCPDP's recommendation.

On the topic of SDOs, we have some observations. First, the cost of participating in three different standards development organizations and attending NCVHS hearings is virtually cost-prohibitive. The only organizations that are able to do so are those with deep pockets. It is possible the result could be a skew toward those organizations, and that may not be in the best interest of E-prescribing, in general.

For example, two key E-prescribing stakeholders are physicians and patients. While their representatives testified at NCVHS, we rarely see them at other NCVHS hearings or standards development organization meetings. Another example are the E-prescribing software companies. While some of them testified and are able to attend some of the meetings, they do not have resources to cover the direct or opportunity costs of sending someone to all standards development organization meetings and NCVHS hearings.

What can CMS do about this? We recommend that CMS encourage SDOs to work together more directly. For example, they all have 3 to 4 workgroup meetings a year. Why couldn't they be in the same physical location?

All NCVHS meetings have been held in Washington, DC at the HHS office. This location has its advantages, such as the ability for CMS and HHS staff to sit-in on the meetings, and record and transmit meeting minutes. Could NCVHS have a hearing during a NCPDP Workgroup meeting, for example? Either NCPDP could go to Washington or NCVHS could go to wherever NCPDP was holding its meeting.

Yet another problem is that some SDOs are better at coordinating than others. NCPDP, HL7 and X12, for example, recently signed a memo of understanding (MOU) regarding their organizations' respective work on standardizing the automated adjudication of prior authorization. Our managing partner, Tony Schueth, is leading an NCPDP task group on automated prior authorization that includes members of HL7 and X12.

However, the SDO ASTM seems to do its own thing, duplicating that which is being done in other SDOs. A good example is the continuity of care record (CCR) that could have easily been handled through HL7. We don't think there is a conspiracy here, and we think good people run ASTM. We suspect that ASTM either isn't aware of what other SDOs are doing, they are not in a position to facilitate progress in that SDO, they do not have the resources to participate in more than one SDO or they are impatient.

We recommend that before taking on a new standards development project, SDOs should be encouraged to reach out to other SDOs to determine if another SDO has already built a standard relative to that topic.

The NCVHS Security and Standards subcommittee could coordinate all of this activity.

Finally, while we understand that this is radical, another suggestion would be to have just one healthcare SDO. Only an entity such as the Federal government could pull off something like this. At a minimum, HHS could bring in the leadership of each of the healthcare SDOs to a summit to discuss how they could work together.

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

### POCP Recommendations:

POCP supports the proposed rules, in that the NCPDP standard supports the National Provider Identifier (NPI).

Like NCPDP, we support pilot projects using the NPI, and do not believe it should be required before the deadline of May 2007. However, whatever date is chosen for adoption of the NPI, it must be certain that all participating entities have a NPI and that a process be in place that an entity be able to secure an NPI in less than 24 hours (similar to the NCPDP Provider ID process).

We should continue to use the identifiers used today until the NPI is available. This approach could also streamline the change from NCPDP identifier to NPI if the two were cross-matched.

Other identifiers that are used today within the routing of transactions (outside of the actual prescription) should remain. The E-prescribing networks today have these in place and have been using them for a number of years. The effort to change this would cause significant cost and delay.

### (F.R. page 6263)

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

### POCP Recommendations:

See previous and subsequent comments.

### (F.R. page 6263)

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

### POCP Recommendations:

POCP believes that standard identifiers are critical to E-prescribing, and that the NPI is as good a solution as any. Our concern is that individual prescribers are not required to have an NPI. For E-prescribing, individual prescribers should be required to have an NPI. If they do not, then other identifiers will have to be used to identify a prescriber and the NPI will simply become an add-on instead of a solution.

HCIdea is contemplated to be a bridge between where we are today and the NPI. While there may be uses for HCIdea, we don't believe it should be required for Part D prescriptions. The industry currently uses other means of identifying a prescriber, and that can continue until such time as the NPI is fully available.

POCP recommends that the required date for use of the NPI in transactions in this NPRM must not be sooner than the required date for use of the NPI in HIPAA transactions. There must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before NPI can be mandated. The NPRM date of January 2006 is too soon because of non-availability of these important NPI-related system capabilities.

## Formulary And Medication History Standards (F.R. page 6263)

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

### POCP Recommendations:

Please see our responses below.

### (F.R. page 6263)

*We propose the following critical characteristics for formulary and benefit data standards:*

### POCP Recommendations:

In the NCPDP Formulary & Benefits Implementation Guide that is currently out for ballot, RxHub indicates that their formats went into production in the Fall of 2003. The reality is that those proprietary formats are based on those that their founding PBMs have utilized since the mid-1990s. Furthermore, this is a batch file format data transfer, not a real-time transaction, so the risks associated with the "adequate industry experience" requirement are not really applicable. Therefore, we think Formulary & Benefits has more than adequate industry experience.

We applaud RxHub for taking this standard through the NCPDP standards development process to get industry consensus. We also applaud MediMedia, EDS, ProxyMed and others participating in the standards development process, rather than fighting it, improving the standard so that it is not just one that works for PBMs. For this reason, we think that it merits being named a foundation standard. If RxHub had not taken its formats through the standards development process, we would not be as supportive.

CMS should be less concerned about the format, than its content. For example, the standard allows for co-payment information; however, most PBMs and plans today do not supply this data. CMS should require that Medicare prescription drug plans (PDPs) do so. Another example is prior authorization flags. Currently only one PBM that works with RxHub provides these flags, and it's only for a small percent of its business. CMS should minimally require its PDPs to provide a flag on drugs that require prior authorization, and optimally provide a notes about restrictions and a resource link to the PDP's prior authorization forms. Co-paymentsg and prior authorization flags are two components of formulary & benefit data that we believe are absolutely critical to a successful E-prescribing program.

Rather than go through all of the data elements, we recommend that CMS review the fields available in the standard and determine which are critical to keeping the costs of the Medicare prescription benefit in check and reducing medication errors. Those fields should then be required to be provided by Medicare PDPs. If they are not required, they probably won't be included.

Why? Because there are costs and complexity surrounding putting this data into the hands of ePrescribers. Within plans and PBMs, work is prioritized based on a number of factors that vary by plan and PBM. Plans, for example, may not see a financial benefit to them for providing copayment information to prescribers, or not enough of one to justify the development effort that may be required. While they may be supportive of E-prescribing, in general, they may not be as supportive as CMS. Therefore, CMS needs to take the lead in facilitating that this get done. If CMS assumes it will, compliance will be spotty, at best.

**(F.R. page 6263)**

*We propose the following critical characteristics for medication history standards:*

**POCP Recommendations:**

POCP believes that the medication history format going through the NCPDP accreditation process meets appropriate criteria, and should be a foundation standard. Our only concern is with the contents of a medication history transaction. For appropriate reasons, many fields are optional (conditional). To improve the quality of health c are, r educe m edication e rrors a nd di minish f raud, M edicare p rescription dr ug plans (PDPs) should be required to include the following data elements: date written, date filled, prescriber, drug name, dosage, quantity and days supply. If these data elements are not required of PDPs, compliance will be uneven, at best, and the value of medication history will be constricted.

## Drug Information (F.R. Page 6264)

*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.* (SPL discussion)

## POCP Recommendations:

POCP recommends (a) including the evaluation of SPL coded data into the future development of common E-prescribing/EHR coded data standards, and, (b) as SPL components are finalized and fully implemented by pharmaceutical manufacturers, providing prescriber access to drug SPL labeling information via E-prescribing systems.

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

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

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

**POCP Recommendations:**

We agree that by January 2006, providers, dispensers, MA-organizations and Medicarae prescription drug plans (PDPs) engaged in E-prescribing should be compliant with NCPDP SCRIPT (sans Fill/NoFill) and NCPDP Telecommunication. We think they should also be compliant with NCPDP's Drug History and Formulary & Benefit standards, as well.

On ASC X12N 270/271 Health Care Eligibility Benefit Inquiry, we agree with WEDI and its NPRM response, as our managing partner, Tony Schueth, was a volunteer that helped with that response. Here is its recommendation:

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

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

In addition, POCP recommends that CMS support the standards evolving for E-prescribing Prior Authorization that are being developed through the NCPDP Prior Authorization Task Group. This Task Group, working under the direction of POCP's managing partner Tony Schueth, is composed of representatives from across the healthcare industry that are interested in promoting an automated end-to-end E-prescribing prior authorization process.

The standards impacted by prior authorization, and the solutions being implemented, are:

- NCPDP Formulary & Benefit – by including a PA indicator that will alert prescribers that a drug requires prior authorization by the patient's health plan.

- NCPDP SCRIPT – by including the PA approval # on the script sent from the prescriber to the pharmacy, acknowledging that prior authorization has been obtained.

- NCPDP Telecommunications – by including the PA approval # on the claim between the pharmacy and health plan, acknowledging that prior authorization has been obtained.

- X12N 278; X12N 275; & HL7 PA Attachment – by outlining the patient, prescriber, and drug information that will be transmitted by X12N 278 & 275 and developing a new PA Attachment that will transmit specific patient medical information required for a prescriber to obtain drug prior authorization from the patient's health plan.

**(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.*

## POCP Recommendations:

POCP does not recommend postponing of the establishment and adoption of E-prescribing standards or postponing the implementation of E-prescribing functionality until all standards, common to both E-prescribing and the EHR, are fully aligned.

Two reasons to support our position:

1. Postponing the adoption of E-prescribing standards and the implementation of functionality would also postpone the gains that will come from improving the quality of patient care by reducing medication errors and by reducing costs associated with manual processes.

2. E-prescribing does require "technical interoperability" to be implemented, which is currently being addressed by all SDOs with standards associated with E-prescribing and EHRs, but *does not require full* "semantic interoperatibility" to work effectively.

   E-prescribing is available today with a combination of coded and text data that can be effectively transmitted between all parties to communicate information. SDOs will still need to engage in a continuous process of working to reach consensus on coded data standards that are common to E-prescribing and EHRs and plan for the ongoing adjustment and alignment of their individual standards.

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

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

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

**POCP Recommendations:**
We recommend that the last bullet above be modified as follows: "Prescribing-related information means information regarding eligibility for drug benefits, medication history, drug and/or personal allergies, or related health or drug information for a Part D eligible individual enrolled in a Part D plan." We support all of the other bullets as stated.

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

**(F.R. Page 6265)**
*We solicit comment on whether Part D plans should be required to use the standards for E-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted*
*E-prescribing standards.*

**POCP Recommendations:**
We agree with NCVHS that transactions conducted internally should not necessarily be required to use the named standards (only when going outside).

However, there may be value to strongly encouraging use the same standards. There may be instances where those practicing in a "closed network" may also practice in "non-closed networks". The activity of going between different types of systems can present the possibility of error. There will also be situations where a patient who normally participates in a "closed network" will seek care outside of that network and the sharing of information (medication/ medical history) will be advantageous. In addition, the use of the same standards would encourage the same degree of care that those exposed to the E-prescribing standards would have.

The disadvantages would be similar to any entity entering E-prescribing for the first time – education of standards, system changes, user learning, and cost. In addition, these entities would require a later deadline to incorporate changes.

It could become an issue where certain providers of care are held to a higher standard of care given their required use of E-prescribing standards.

### E. Proposed Standards (F.R. Page 6265)
*We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

**POCP Recommendations:**
POCP agrees that there is not adequate industry experience with Fill/NoFill transaction set at this time, and we recommend caution in moving forward with pilot programs to test the transaction. We believe strongly that E-prescribing can ultimately have a tremendous impact on patient persistency and compliance with medication therapies, but there are many operational challenges to making this dream a reality.

Improving patient safety and quality of care are two of the key objectives for the E-prescribing standards to be established by NCVHS. The funding for prescription drugs for seniors is expected to keep patients healthier and prevent the progression of chronic diseases that can be managed with medication therapy. E-prescribing will provide a safer mechanism for ordering and managing these prescription drug therapies.

Persistency and compliance is a particular problem in the senior population who may be easily confused about how to take their medication therapies, or hesitant to initiate discussion with their physicians about side effects or other problems that may be impacting compliance. According to SureScripts, approximately 400 million prescriptions go unfilled each year. Polypharmacy (multiple pharmacies per patient) is another problem in the senior population who may be continuing with drug therapies that the physician intended to be discontinued. Physicians are typically unaware of what the patient is actually taking.

One of the great promises E-prescribing offers is the opportunity to monitor the prescriptions that actually get filled, and more importantly, picked up by the patient. Today, the physician writes the initial prescription, but rarely gets information that confirms the patient actually got the initial prescription filled, and is persisting with chronic medications as prescribed. Two aspects of E-prescribing can potentially support healthcare providers in monitoring patient compliance. The drug history from the pharmacy benefit manager provides the physician with an on-demand record of prescriptions that have been filled. The Fill/NoFill status transaction also has great potential to provide the physician or other providers with valuable information.

We are encouraged to see that NCVHS is supporting the need for a pilot project for the Fill/Nofill transaction, as there is not yet adequate industry experience to prove it will be a success. Fortunately, an NCPDP standard already exists for this transaction. However, there are significant operational challenges for implementing this transaction effectively. The action of a pharmacy filling a prescription is independent of the patient actually claiming it. Most pharmacies do not have a workflow process in place today to support recording when the patient picks up a particular prescription. Additionally, the process for returning an unclaimed prescription back to stock varies by pharmacy, so it is difficult to know when to assume a prescription has been officially declared as unclaimed. Another challenge is defining a workflow process for receiving and processing Fill/Nofill information that is useful, but not overly burdensome to the physician practice. It may be overwhelming and unproductive for physicians to monitor Fill/NoFill status on all prescriptions. One solution might be to encourage monitoring on specified drug classes only, or identify rules engines or 3rd parties to help identify potential compliance problems. We urge CMS and NCVHS to support demonstration projects to work through these complex issues so that the potential benefits can be realized.

Retail pharmacies are an integral part of the E-prescribing equation. There can be no E-prescribing, or Fill/Nofill transactions without full pharmacy participation in the E-prescribing standard transactions. MMA would require Medicare prescription drug plan (PDP) sponsors and MA organizations to support E-prescribing programs in accordance with the final E-prescribing standards. Although it maybe implied, there is no similar specific requirement for pharmacies dispensing Medicare prescription to support E-prescribing transactions. We would encourage CMS to make this specific requirement.

NCVHS is also recommending that the existing proprietary Drug History transaction go through a formal standards accreditation process via NCPDP. This is also a positive step. Again, a demonstration project is needed to determine how this data can be effectively used by healthcare providers to facilitate the monitoring of persistency and compliance in a way that isn't overly burdensome. It is feasible that the Drug History transaction may ultimately be more useful in improving patient persistency and compliance than the Fill/NoFill transaction set.

We would like to encourage CMS to sponsor financial grants for retail pharmacies, physician groups, technology vendors and PBMs in support of these demonstration pilots. The potential benefits for patient safety and quality of care are great, but the effort to define workable solutions is substantial and must be facilitated.

**(F.R. Page 6265)**

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

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

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

**POCP Recommendations:**

We agree with this list. Our managing partner, Tony Schueth, was co-chair of NCPDP's Workgroup 11 from 1997 to 1999, and did a great deal of work on these standards.

**(F.R. Page 6266)**

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

**POCP Recommendations:**

In our view, there is adequate industry experience with ancillary messaging and administrative transactions, so they would not have to be pilot tested.

**2. Eligibility (F.R. Page 6266)**

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

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

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

**POCP Recommendations:**

We agree with adopting the ASC X12N 270/271 transaction for eligibility inquiries between prescribers and Part D sponsors. We think, however, that it should not be used

for benefits. Benefits should be transmitted through the Formulary & Benefits formats that are in the NCPDP accreditation process.

We recommend that CMS adopt the NCPDP Implementation Guide for the standard card. In 1997 NCPDP adopted an Implementation Guide based on the INCITS 284 standard for a health care identification card for prescription drug plans. The NCPDP Implementation Guide complies with regulations mandated in more than two dozen states. INCITS 284, revised for NCPDP in 2004-2005, is designed to support health care identification for any type of health plan.

We recommend, however, that a formulary identifier be created for every Part D formulary, and that it be included on the card. This will allow manual linking of the patient to the appropriate formulary. E-prescribers must be able to link to a formulary without having to go through an MPI. Today there is only one MPI that works in the payer world for E-prescribing, and not every plan will want to use the services of that company.

We support using the NCPDP Telecommunication Standard for conducting eligibility transactions between dispensers and Part D sponsors.

**(F.R. Page 6267)**

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

**POCP Recommendations:**

We were part of the NCPDP task group that drafted a recommendation to address this, and we agree with their recommendations. They are, in summary:

> *It is important to allow the evolution of the industry. The support of a new version takes time as products are developed and rolled out to the industry.*
>
> *One overarching philosophy ... is that the industry stakeholders collectively offer the best source for knowing the optimal range of capabilities within the industry. Thus, we need a mechanism for advancing the industry as a whole that doesn't force everyone to stay in lock step with each other in order to maintain interoperability. Naming one version of a standard as the only acceptable version for use impedes progress and innovation; requiring simultaneous adoption of newer versions can create disruptive and inefficient transitions that are prone to error rather than a more natural evolutionary process; allowing for newer versions of a standard while still supporting older versions helps to alleviate some of these problems, but has a secondary effect of creating inefficiencies over time as backward compatibility must be maintained to the oldest version in order to retain some level of interoperability.*
>
> *The strategy we propose attempts to address all these issues while maintaining an open process that allows all stakeholders to voice their opinions during the decision-making process.*

**Submitter :** Dr. Judith Kashtan **Date:** 04/05/2005

**Organization :** Private Practice

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

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

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

**Issues**

Background

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

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

*Version Management Process for Advancing a New Version:*

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

*Version Management Process for Retiring an Old Version:*

1. *The SDO works through its normal consensus process to discuss the retirement of an older version of the standard. At least two newer versions must have been approved through the process outlined above. Conditions for retirement may include:*
    a. *Industry consensus that maintaining active use of an older version would no longer be cost effective or would not support what are considered to be current best practices*
    b. *Industry consensus that the older version is no longer in wide-spread use*
2. *SDO achieves internal consensus (at the workgroup level) that a version should be retired and prepares to put this recommendation to an SDO-wide vote.*
3. *While preparing for the full-SDO vote, the SDO presents their proposal to retire the version to NCVHS to allow for public comment and invites interested stakeholders to participate in the voting.*
4. *NCVHS sends a letter of notification to HHS within 15 days of the hearing with its recommendation to retire the version/release of the standard should the SDO ballot b e s uccessful and no tes any s ubstantive c omments r eceived fr om t he hearing.*
5. *The SDO conducts an SDO-wide vote on retiring the version.*
6. *Upon passage, the SDO submits to HHS (and copies NCVHS on) a request to retire the version, with an implementation timeframe that does not cause undue burden on implementers.*
7. *Upon review, HHS announces retirement of the version in the Federal Register.*

POCP will go further than NCPDP. We recommend that this process be followed for all standards named as part of the MMA or named in the future. POCP also recommends that HHS consider using this process for advancing HIPAA standards.

We also like the idea of a predictable cycle for holding hearings on submitting or retiring versions of a standard. In that way, the industry knows that at whatever time of the year is suggested, we will be taking recommendations to NCVHS. We think the best time to do this would be in the summer, as things tend to be less hectic at this time because of vacations. Regardless of when it is, if this were at a predictable time, impacted individuals could schedule around it.

### (F.R. Page 6267)

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

### POCP Recommendations:

POCP is in support of coordinating HIPAA standard modifications with E-prescription transactions, adopted under under 45 CFR parts 160 through 162, but is not in favor of mandating the automatic update and use of the latest standard versions across the industry.

In addition, we are aware that many prescribers comply with HIPAA by allowing a clearinghouse to put a non-standard claim into the required standard. While that may be acceptable for claims, we do not advocate that for E-prescribing. The reason: we will lose a great deal of the value anticipated to come from E-prescribing. POCP recommends that a prescription only be allowed to be written from an MMA E-prescribing standards-compatible E-prescribing application.

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

*We invite public comment on our expectations for prescriber participation.*

### POCP Recommendations:

POCP would like to point out the following:

1. Physicians are feeling current pressures to purchase and use electronic health records (EHRs), which could be seen as a higher priority than E-prescribing. Not all EHRs have an E-prescribing component, so a physician could be faced with having to worry about an interface between the newly purchased (at no small expense) EHR and a free-standing E-prescribing tool. This can be more trouble than it s p erceived w orth. Al so, m any E HR c ompanies a re r eluctant t o b uild interfaces because of their plans to build their own E-prescribing module. The challenge is that, for more than 10 years, they have had these plans as E-prescribing never quite gets high enough on their priority lists. The unfortunate results is inertia.

   **Recommendation:** Require that EHRs adhere to the same technical standards that are being put in place for E-prescribing. Those EHRs that do not adhere to those standards would either have to make it known to the consumer and/or bear

the cost of the interface to an E-prescribing tool that has been built to the standards.

2. There is generally a lack of trust between physicians and health plans. Physicians may be reluctant to change over to E-prescribing, just because they know that the health plans will reap a significant benefit from it. There may be a tendency to hold the health plan hostage over the issue.

   **Recommendation:** Medicare prescription drug plans (PDPs) should pay physicians a fair amount in recognition of the disruption to the practice and the cost of making the change. Compensation can take the form of technology and support, monthly stipend, capitation, or some combination. Ideally, there would be a certain amount paid for the start up costs to the practice and then an ongoing amount that recognizes the savings to the health plan(s).

3. Much must be done to convince the physician that s/he will also receive enough of a benefit to offset the operational issues of initiating E-prescribing in the office. Some attention needs to be given to the very real problem of physician adoption and utilization of the technology.

   **Recommendation:** Additional studies documenting E-prescribing-related savings to physician practices must be done by objective entities (perhaps research institutions) in order to convince physicians of its value. Also, some research should be done on the problems impeding physician adoption to discover the best strategies for overcoming them.

4. If health plans are allowed to provide hardware, software and web service to physicians, it must also be understood and accepted that the physicians will use it for all patients from all plans. It may be necessary for health plans in a given locale to find a cooperative way to handle this issue.

   **Recommendation:** As a part of state licensure requirements and with coordination from the state licensing body, require that health plans pay a pro-rated share (based on number of covered lives within the state) of E-prescribing start up costs (i.e. $1500 per physician) and a subsequent minimum monthly stipend or rate for physicians who use E-prescribing for a majority (percentage to be determined) of their monthly prescription writing.

5. Accommodations must be made for situations when the technology fails (poor coverage, hardware failure, software bugs, etc.) or where it is totally unfeasible to use.

   **Recommendation:** A standard for technology and service performance for E-prescribing and web service companies should be established. Physicians should not be required to use the technology in a given area if those standards cannot be met. When failures occur, the physician should be allowed to use a paper prescription without penalty, provided the incident is documented.

## 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.*

## POCP Recommendations:

In our experience, making impact assessment estimates is a very difficult undertaking, at best. Limited data and/or the lack of sound predictive models often results in both intermediate and final estimates being subject to considerable, potential error. Moreover, many assumptions must be made in the course of arriving at these estimates. When assumptions are subsequently found to be mis-leading or incorrect, estimate validity is quickly called into question. Does this mean we should declare defeat before even beginning? POCP does not think so.

Unfortunately, the NPRM acknowledges the "lack of adequate data", and "no detailed models predicting specific rates of adoption" for E-prescribing. It is also acknowledged "we cannot predict how fast all of these savings will occur, nor their precise magnitude..." It also seems that many of the studies being done have shortcomings with respect to statistical soundness and validity. Many other difficulties are cited in the document, as well. When faced with so many obstacles, yielding to the weight of these challenges often becomes attractive. Once again, POCP believes there are alternatives.

In evaluating large programs and determining effectiveness, precisely measuring overall program impact immediately at the macro level is often next-to-impossible. Trying to do so can often be divisive, and even destructive. In our judgment, in planning and developing the pilots, it would be wise to build in a thoughtful and thorough evaluation strategy, for each, from the beginning, carefully attending to measurement issues. To our knowledge this is not currently being done. In so doing, estimates based on sound data, rigorous methodology and fewer assumptions could be developed, and agreed to via consensus. By then doing careful extrapolation, building in uncertainty using measures of estimate stability, better component estimates could be derived. These components could ultimately be combined to potentially provide better estimates at the desired macro level.

While POCP supports the naming of foundation standards and, in so doing, understands that pilots will not be required, we strongly recommend that foundation standards be included in pilot tests, not to test whether they should be E-prescribing standards but to validate previous studies and assumptions that are being made about the value of E-prescribing in general.

One aspect of E-prescribing that would enhance its impact on each stakeholder is the inclusion of diagnosis with the prescription. This would permit diagnosis-to-drug checking, the analysis of whether a prescription is being written for on- or off-label, and other forms of clinical evaluation.

Currently only two E-prescribing solutions accommodate diagnosis – Wellinx, which requires it, and Allscripts, which used to require it but now makes it optional. Why? Because adding it is an extra step that slows down prescribers.

For this reason, we do not advocate diagnosis code be required for E-prescribing, but we do believe it should be pilot tested to determine its impact. We recommend that the inclusion of diagnosis code be part of the 2006 pilot programs.

## B. Impact on Health Plans / PBMs (F.R. Page 6269)

*The final rule on the Medicare Prescription Drug Benefit estimates that 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program. Testimony presented to the NCVHS indicated that because most health plans/PBMs currently have ePrescribing capability, any additional cost associated with hardware/software connectivity would be minimal. Since the great majority of health plans contract with PBMS for pharmacy benefit administration, we do not consider the fees associated with these contracts to be an additional cost for plans conducting electronic prescription drug programs... The only expense attributable to health plans by this impact analysis are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct ePrescribing.*

### POCP Recommendations:

We believe that the CMS impact analysis is in error in this section. In particular, most health plans/PBMs *do not* currently have ePrescribing capability (specifically, they are presently unable to support eligibility-driven formulary and prescription claims history transfer to ePrescribing application vendors), and the costs associated with acquiring it are noteworthy. Moreover, these costs will not occur as incentives paid out to drive adoption. Rather, they will largely occur as a result of participating in the ePrescribing connectivity infrastructure.

For health plans/PBMs, RxHub is presently the only viable option for broad-scale connectivity that enables eligibility-based formulary services and prescription claims history transfer to point-of-care ePrescribing vendors.

RxHub was founded in 2001 by the three largest PBMs at the time – Medco, ESI, and AdvancedPCS (now part of Caremark). The biggest gaps in RxHub coverage, other than uninsured patients, are in Medicaid (other than in managed care Medicaid lives managed by one of the participating PBMs), several large commercial insurers that manage their own prescription benefits (Aetna, Cigna, Wellpoint/Anthem), and most of the "2nd tier" PBMs (Prime Therapeutics, MedImpact, Pharmacare, Prescription Solutions, etc.). Notably, RxHub began distributing CAQH formulary data last year, but CAQH plans are *not* eligibility-based, and are not coupled with the ability to transfer prescription claims history.

While many of the non-participating health plans/PBMs have shown an increase in interest in connecting to RxHub in recent months, there are many reasons why non-founding plans have been slow to connect to RxHub. Initially, mistrust and lack of certainty about RxHub's future were the biggest factors. As RxHub's role in the industry has solidified, these issues have become less important. Today, both startup and maintenance costs are the biggest factor. Non-participating plans typically estimate that the initial technical engineering to participate with RxHub will cost in the neighborhood of a quarter of a million dollars, so this would be what a Medicare prescription drug plan (PDP) would have to invest, were it not already connected to RxHub.

Apart from dollar cost, there are human / technical engineering / project management resource availability barriers both on the RxHub and the health plan/PBM side. While it is a good problem to have, RxHub will have to ramp up to meet demand. Other players may emerge, but it will take time for them to be in a position to compete with RxHub.

For this reason, POCP recommends that CMS implement a sliding scale for PDP compliance with foundation standards. POCP also recommends that CMS require PDPs to print a formulary identifier on drug cards so that a manual link can be made to CAQH and other formulary providers.

## C. Impact on Prescribers (F.R. Page 6270)

*After this proposed rule becomes final, once a prescriber decides to conduct e-prescribing for Part D drugs, for Part D enrolled beneficiaries, the prescriber would be required to comply with the standards being proposed in this regulation. However, we have no reason to believe that the use of these particular proposed standards would increase costs for new adopters, compared to what costs otherwise would have been. Even for those (and we think they are few) who are currently using systems that may be in some respects incompatible with these standards, we would expect vendors to upgrade those systems at no or nominal cost as part of their normal version updating process.*

### POCP Recommendations:

As with section B above (Health Plans/PBMs), we believe CMS has underestimated the impact on prescribers and the vendors that provide ePrescribing services to them.

As it relates to the eligibility, formulary, and medication history foundation standards, it may be instructive to look at the current status of ePrescribing vendor connectivity to RxHub and examine costs and barriers for those vendors that are not connected.

Contrary to the assertion in the NPRM, most major ePrescribing applications are *not* connected to RxHub today and are thus incompatible with the proposed rules.

There are tens of thousands of physicians (probably 30-50,000) who are creating prescriptions today in two EMR systems alone – EpicCare and Centricity (owned by Epic and GE, respectively). To the best of our knowledge, neither vendor has contracted with RxHub. Prescribers using either of those systems to create prescriptions for Part D patients will certainly be out of compliance next January.

Other systems vendors whose ambulatory EMR products are beginning to get some traction in their integrated delivery network customer bases are in the same disconnected boat: PowerChart Office (Cerner), RxPad (IDX/CareCast), LSS (Meditech), and Eclipsys all come to mind.

Moreover, many of the vendors that dominate the mid-sized and small practice markets are also not connected to (or contracted with) RxHub. These vendors' products tend to be quite mature, with thousands of users. These E-prescribing / EMR products include Practice Partner (Physicians Micro Systems), Elysium (Axolotl), SOAPWare (DOCS), and others. Prescribers using any of these systems will also be out of compliance next January.

Connectivity to RxHub is no minor undertaking for an ePrescribing / EMR vendor. While the X12 270/271 prescription benefit eligibility transaction engineering is relatively straightforward, application changes needed to properly handle formulary data structures, displays, and related prescriber workflow can be quite challenging and involve significant vendor R&D costs. The same can be said for engineering related to transfer of medication claims history from a PBM into an E-prescribing vendor's application. Actually, once the eligibility transaction engineering is complete, the additional work required to enable prescription claims history transactions is relatively minor. However, the application modifications required to properly store and display prescription claims data structures is considerable, and even more so for the development of medication list maintenance workflow screens. In fact, there is typically at least a 6- to 12-month lag between the time when a vendor begins eligibility transactions and when that vendor is ready to start transacting prescription claims.

Connecting to RxHub can easily cost a vendor over $100,000. While large vendors can readily absorb these costs, they have been slow to commit to connecting because of competing priorities. Some smaller (even startup) vendors have moved more quickly in spite of the relative impact of the engineering costs on their overall operating budget.

There is some cost offset for vendors if they no longer need to license InfoScan Formulary data from MediMedia. However, RxHub-mediated access to formulary data is far from complete, and varies considerably by region so many vendors have chosen to continue licensing InfoScan data even after connecting to RxHub. The addition of CAQH data to RxHub's formulary data pool has made coverage less of an issue; however, because the CAQH formularies are not integrated into RxHub's MPI and eligibility-checking services, vendors must engineer a separate process for handling formulary matching for patients covered by CAQH formularies. This redundant engineering requirement further adds to vendor costs.

Besides actual transaction engineering and application development costs, there are three other major sources of vendor costs that should be factored into an impact analysis: contracting, connectivity, and code migration. These factors play a major role in determining how long it actually takes a newly connecting vendor to bring RxHub services to its customers, and can thus be considered "gaiting" factors.

The first of these three gaiting factors is contracting. In the past, vendors connecting to RxHub were required to contract separately with (and be certified by) each participating PBM. To RxHub's credit, the contracting process has been greatly simplified with a new direct contracting model, where the vendor only has to contract with RxHub. This should make it much easier (and quicker) for vendors to complete the connection process.

The second gaiting factor is connectivity. RxHub's security model is built around E-prescribing vendors serving as the central connectivity point to RxHub for all of that vendor's clinic customers. Some RxHub-connected vendors had to create this capability from scratch, which further added cost and time to deployment. Some vendors – particularly those that service the integrated delivery network market – will be unwilling to build a central connectivity infrastructure for their customers. This means that RxHub would have to build and manage connectivity to individual provider organization customers of that vendor, adding significant resource requirements (and delays) on both the RxHub and provider organization sides.

The last of the three gaiting factors is code migration. Even after contracting, transaction engineering, application development, and connectivity issues have been successfully resolved, a vendor needs to migrate the new application code to its existing customer base. For vendors that don't deliver their application and services via an ASP model, this process takes a minimum of 6 to 12 months and can take much longer (e.g., some customers may not be able or willing to handle upgrades).

We believe that the market will resolve many, if not all, of these issues over time. We recommend, however, that CMS embrace a more complete view of the constraints and timing factors noted above, and monitor the market to ensure that one or more of these factors don't unduly slow down compliance with the ePrescribing rules.

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

*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**POCP Recommendations:**

We agree with NCPDP that naming of standards should not negatively impact current efforts. Considerable time and money has been spent to date and the momentum that is currently in place should be used as a positive force. The standards process should be flexible and timely so as to allow for changing business needs and the incorporation of new participants.

We also agree that ultimately the net effect will be positive. However, there may a slight negative effect early in the process as learning curves are overcome and business processes migrate to primarily e-prescribing.

We do acknowledge that the smallest, most financially weak pharmacies may suffer a negative and even catastrophic business impact as a result of capital cost for a new system to participate, or competitive pressure resulting from not participating, but this will impact a small fraction of the total number of small pharmacies. And those that are able to participate will likely experience some savings and competitive advantage.

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

**POCP Recommendations:**

POCP agrees with the CMS view that "E-prescribing has the potential for improving beneficiary health outcomes." This is particularly true of the Medicare population, where a beneficiary typically has a larger than average number of active prescriptions at any time. In addition, in many areas of the country care delivery is very fragmented, with the result that Medicare beneficiaries often are treated by multiple providers who are unaware of each other's prescribing activities. And it is not unusual for a Medicare beneficiary to bring to a doctor's appointment a brown bag containing all of the medications they are currently taking, so that the doctor or nurse can make or update a medication list for them. And finally, because of the cost of prescription drugs, it has not been unusual for Medicare beneficiaries to "half their dosage" so as to make their medication last longer. While E-prescribing does not directly eliminate these dangerous situations, it can create an environment where these situations no longer need occur.

The rapid rate of advances in medical technology, treatment protocols and development of new medications make it virtually impossible for a provider to stay ahead of the information curve. This can have a direct impact on any individual patient's health outcome, particularly when several medications are involved. Use of electronic prescribing can help fill the provider's information gap at the point of care, and help prevent adverse drug events, by detecting drug-drug, drug-allergy and drug-disease interactions.

As previously mentioned, fragmentation of care can result in parallel medication therapies, and the potential for dangerous interactions. Were all providers to have access to a patient's medication history, duplicate prescriptions could be eliminated. In addition, prior tried and failed prescriptions would not be tried again.

While use of E-prescribing will not directly guarantee patient compliance with a provider's medication therapy plan, it does create an environment that fosters improved compliance. Today, a physician typically handwrites a script and hands it to the patient. The patient walks away with the script, and may or may not actually have that script filled. E-prescribing can have that script electronically transmitted to the patient's pharmacy of choice, and put subtle pressure on the patient to actually have the script filled. Rarely today, does a provider contact a pharmacist to verify that a patient filled their script. While POCP understands the CMS rationale for not initially implementing the NCPDP SCRIPT Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction--Filled; Prescription Fill Status Notification Transaction--Not Filled; and Prescription Fill Status Notification Transaction--Partial Fill), to truly manage patient compliance, this transaction or robust drug history needs to be in place.

As mentioned previously, medication cost can significantly impact a patient's compliance with medication therapy. Where appropriate, E-prescribing can impact the cost by making it easier for a patient to have prescriptions filled via mail-order pharmacy, and/or by allowing physicians to make appropriate formulary choices.

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

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

### POCP Recommendations:

POCP agrees that this proposed rule would not have a significant economic impact upon a substantial number of small entities including small businesses, nonprofit organizations, and small governmental jurisdictions. This includes small hospitals, small retail pharmacies, and physicians in small private practices.

The majority of small physician practices will not be impacted because E-prescribing is still voluntary, and the recent releases of the most common physician practice computer systems are or will shortly be capable of supporting E-Prescription transactions which will support the standard transaction set. A few practices may find that either the capital requirement for a new system, or the competitive pressures of not prescribing result in a negative and potentially catastrophic impact to the business aspects of their practice, but this will be a very small minority of the very smallest practices. For the most part, those practices able to begin E-prescribing will experience a neutral or positive impact. Few small practices will experience changes in their labor costs because small-practice staffing patterns are relatively inflexible, but there may be some positive impact due to reduction in malpractice insurance rates as insurers recognize the positive impact of E-prescribing on medication errors.

Certain other small businesses, those in the computer systems support and consulting arena, may experience a positive impact from this rule due to increased demand for their services by helping practices and pharmacies implement and effectively utilize E-prescribing.

Taken as a whole, POCP agrees that there will not be a significant economic impact on a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required.

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

**POCP Recommendations:**
Please see POCP's response at ***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259).***

**I. Conclusions and Alternatives Considered (F.R. Page 6272)**
*We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

**POCP Recommendations:**
In our view, the industry needs a push from the Federal government, so we would have no sympathy for any stakeholder who might foresee a burden on them from these proposals. The inefficiency in our healthcare system and number of medication errors are absolutely unacceptable.

**(F.R. Page 6273)**
*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*

**POCP Recommendations:**
We do not have a problem with this on a case-by-case basis.

**Conclusion**

In conclusion, POCP would like to complement CMS for its understanding of the E-prescribing marketplace. If any of our comments require clarification, please do not hesitate to contact us. We are available to assist CMS in any way it may deem necessary.

Sincerely,

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Bob Elson, MD, Affiliated Consultant
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CMS-0011-P-73

**Submitter :** Dr. Clement McDonald

**Date:** 04/05/2005

**Organization :** Regenstrief Institute

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-73-Attach-1.DOC

Response to NPRM April 5, 2005 – 6:15 p.m. McDonald, CJ

In general there is much to like in this NPRM and I am supportive of most of it. In the following, as an ex-NCVHS'er and a long-term proponent of electronic medical record systems I would like to comment on a number of points.

Page 6258

I would not favor any abbreviation of the testing proposed for these standards. E-prescribing is really a new thing for physician's offices. In such complex undertakings there are always surprises. The better the testing and tuning the better the final product.

Page 6263

The NPI has been under development for more than 8 years in one form or another. Not having a single identifier will be a real problem to this project as well as many other medical informatics developments. So think we should push hard to get the NPI done as a requirement for part D prescribing.

There is not enough information given about the two alternatives proposed in the NPRM- and no statement about cost and who is covered. So hard to comment.

Who is covered by the numbering system could be VERY important. In most offices nurses help with refills and much prescribing management. So what ever approach to prescriber numbering is taken should not prevent office staff from entering refills and / or prescriptions—with some kind of identifier (perhaps local) to identify them and another (national) to identify the prescriber.

Page 6260

Middle column footnote 5

The arguments about the errors and prescribing are quite mixed up. Most of the IOM's death figures related to drugs come from reference 9 on page 1 of the IOM report[1]. This is actually the rate of deaths coded in the death certificate as accidental (not definitely suicide or homicide) related to medications and other noxious substances. One could construe prescribing errors to be some part of the cause. However, the demographics of the people who die in this class are men more than women with 80% between ages 25-49. While those most likely to be injured by prescribing errors would be those who get the most prescriptions – woman and elderly. A recent MMR[2] suggest that 80% of the drugs involved in accidental poisoning as defined above are narcotics and narcotic analogues and the rest are sedatives and antidepressants. A major portion of these cases probably involve acquisition of prescription drugs by illegal means.

The illegible handwriting has not been shown in any large series to be significant contributor to errors—in part because of the 900 million phone calls mentioned in the NPRM that pharmacists make to check such illegible prescriptions.

Finally, regarding 3rd column, 2nd paragraph, just about any of the safety checks that could be done in the office computer can also be done by the pharmacy computer. The big trick is getting the data regarding all other drugs prescribed – relevant diagnoses and lab tests in a unified medical record system.

I bring this up because the one big value a physician (and his/her patients) will get from electronic prescriptions- is a community medication profile, and the problems of linking one patient's prescriptions from many sites have not yet been solved. (See below).

Page 6263 – Medication history

Pharmacies themselves have a very poor infrastructure for creating a medication history. They do not collect enough information routinely to identify the same patient across different pharmacy companies and in some cases between different visits to the same pharmacy. There are better opportunities at the PBM level because they carry much more complete data. The RxHub solution is possible because of PBMs. Having a useful active medication profile—(the way I would like to see the medication history conceived) would be a great value to physicians and an incentive to adopt e-prescribing and medical record systems. As it stands now- physicians will have to load the initial medication profile by hand for every patient they care for. That is a shame when the same data is sitting in pharmacies – but just not inter-connected.

CMS will have to attend to the problem of aggregating the same patient across different prescription providers to provide a really useful medication profile. The best current bet is through PBMs. But with proper attention to a Medicare patient identifier (as contrasted to the beneficiaries' identifier), pharmacies could do better. Be aware of many leakage points. PBMs only know about drugs that they cover. They also only tend to provide information about patients who are currently their members. Given the 30% rate of plan switches per year- this can leave many gaps.

Finally, the NLM RxNorm vocabulary standards with full tie-ins to NDC codes must be part of the medication history standard to produce a useful active medication profile for many reasons.

I support the general direction of the RxHub medication history— as long as a universal clinical drug code, i.e. RxNorm, was used and as long as attention was given to the leakage of key prescription information as described above.

Page 6265

NCPD Script

I support the use of the NCPD script but not as the sole prescription message standard. Hospitals all use HL7 for prescribing information. There is large potential for error in the transfer of patients between settings of care. Providers in hospitals write prescriptions for discharge using their inpatient systems much. Much out patient care is also given by hospital systems. Further, the medications given in the hospital would ideally be incorporated into the

medication history being proposed. Indeed, RxHub currently has a very useful HL7 version of that medication history.

We would propose that HL7 be an allowed electronic message standard for large institutions with the proviso that the coding systems would be aligned with those in the NPRM. HL7 already has a much more sophisticated medication message including structured information about the instructions for dispensing (mentioned on page 6262). Furthermore, NCPD has no ability (yet) to deal with complex home IV and other prescriptions that will tend to be intermixed with oral and other medications in some patients.

HL7 and NCPD are already working toward greater harmonization.

CMS should permit the use of HL7 as an alternative standard for prescriptions written in hospitals and other large organizations and require the two SDO's to harmonize to the degree that they can inter-operate. Then intermediaries could accurately translate from one to the other.

This is the best time to push that harmonization to completion- because it is in the interest of both SDO's and health care in general.

Page 6267

We are supportive of the overall direction, but the current usage of e prescribing by providers is very close to zero (in doctor's offices – per testimony at NCVHS about 1 year ago). On the other hand, it is true that the communication between pharmacists and PBMs through NCPD standards is very high. But am puzzled by the claim that this is "nothing new" (per page 6267- 3rd column) to the physician's offices – targeted by this NPRM. Just hope we are not skipping an important check

Page 6270

It may be that some modest number of (5% or larger) are writing prescriptions, via direct input to computer office practice setting—especially in large institutions and the VA. But a very small percent of these are transmitting them via the proposed standards to commercial pharmacies for a variety of reasons. The testing process should be cognizant of the relative newness of this process.

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[1] Phillips DP, Christenfeld N, and Glynn LM. Increase in US Medication-Error deaths between 1983 and 1993. The Lancet, 351:643-44, 1998.

[2] Morbidity and Mortality Weekly Report url: http://www.cdc.gov/mmwr/