THE ERISA INDUSTRY COMMITTEE

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Advocating the Benefit and Compensation Interests of America's Major Employers

April 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule Regarding Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Administrator McClellan:

The ERISA Industry Committee (ERIC) respectfully submits these comments in response to proposed regulation "Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule" (42 CFR Part 423) published in the *Federal Register* on February 4, 2005. ERIC, representing the interests of America's major employers, is pleased to offer our comments on the recent CMS proposed standards for electronic prescribing in the electronic prescription drug program under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003. This regulation details electronic prescribing standards for Medicare's new Part D, the Voluntary Prescription Drug Program.

Our primary goal in these comments is to present feedback to CMS from the standpoint of America's large employers, who will be party to the electronic prescription program through retiree health plans. A majority of ERIC's members offer a retiree health plan. We support the use of electronic prescribing for its capacity to increase accuracy, effectiveness and patient safety, as well as its potential to lower the administrative burden on healthcare providers and physicians. However, we are aware that the use of electronic prescribing warrants a cautious approach and precise uniformity of computer programs, and that all actors involved must play a role in maintaining the confidentiality of patients' medical data.

We look forward to working with you and your staff to further discuss our suggestions and recommendations. If you would like to schedule a meeting or conference call to discuss these comments, please contact Edwina Rogers, ERIC's Vice President for Health Policy at 202-789-1400.

I. Purpose of Proposed Electronic Prescribing Regulations

On February 4, 2005, CMS released a set of proposed rules and standards for the e-prescribing and prescription drug program of the Medicare Prescription Drug, Improvement and Modernization Act (MMA). This proposal would be the first set of uniform standards for the electronic prescribing program, and would ensure interoperability between all prescribing healthcare entities, prescription dispensers, and insurers encompassed under Medicare. CMS has requested public comments on this proposal in order to tailor a comprehensive and complete final set of standards.

II. Introduction

A. The ERISA Industry Committee

The ERISA Industry Committee is a nonprofit association committed to the advancement of employee retirement, health and other benefit plans of America's largest employers. ERIC's members provide comprehensive retirement, healthcare coverage, and other economic security benefits directly to some 25 million active and retired workers and their families. ERIC has strong interests in proposals affecting its members' ability to deliver those benefits, their cost and effectiveness, and the role of those benefits in the American economy.

B. Statement of Interest

The proposed rule would require Prescription Drug Plan (PDP) sponsors – as well as Medicare Advantage Organizations offering prescription drug plans and other Part D sponsors – to support and comply with final standards as soon as they come into effect. Although not all prescriptions will immediately be made electronically, Part D sponsors must be able to accommodate any that are electronic. This mandate will extend to providers that prescribe or dispense Part D drugs only when certain other standards for health information technology are in place.

Many ERIC members are PDP sponsors who would be immediately affected by final standards. ERIC maintains it necessary to incorporate the perspective of our members, America's major employers, in refining the process for any standards that will amount to new mandates.

III. Privacy and Liability

A. Issue for Discussion

While the benefits of moving to an electronic system are numerous, the potential for lapses in privacy is equally great. Much focus and attention must be placed on securing the transactions between doctors, pharmacies, and insurers. We are concerned that any

privacy rules CMS implements will be tangled in a complicated web of state laws that could make the policy meaningless. ERIC, along with other members of the Confidentiality Coalition, sent a letter on January 18, 2005, to Dr. David J. Brailer, the National Coordinator for Health Information Technology, addressing this issue.

B. ERIC Recommendation: Nationwide Standards

ERIC urges that the final regulations regarding electronic prescribing include rigorous safeguards to protect patient privacy and data security. We also urge that CMS preempt state laws when it comes to privacy standards, as currently there are problems with HIPAA and other state health privacy protections, involving some states that have significantly different and conflicting requirements. It would be to the benefit of all involved if CMS adopted uniform standards for privacy and data security, and could assure these standards were utilized nationwide, to accommodate multi-state employers. If PDP sponsors and insurers were required to meet multiple privacy standards, lack of standardization would cause unnecessary confusion and reduce the efficiency of moving to an electronic system. When uniform standards are adopted and adhered to, PDP sponsors should not be held liable for any data or security loss that takes place while complying with these uniform standards.

IV. Preemption

A. Issue for Discussion

CMS has adopted a narrow view of when federal laws preempt state laws. Preemption occurs when a state law meets the following two-part test: "[i]s contrary to the standards or restricts the ability to carry out this [regulation]" and also "[p]ertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under this [regulation]." This interpretation limits preemption to only prescriptions written for beneficiaries enrolled in Part D when the prescription is made, rather than all Medicare recipients. It also limits preemption to only drugs covered by Part D, while Medicare recipients can have drug coverage from other sources, even other parts of the Medicare program. Further, under this view of the preemption rule, a state law would have to be in full disagreement with the federal standards to warrant preemption, instead of a wider range of state laws that interfere with the policy goals of uniform federal electronic prescribing standards.

B. ERIC Recommendation: Broader Preemption Provision

ERIC urges CMS to adopt a broader interpretation of the preemption provision, so that the federal law will preempt any state laws that contradict the federal standards explicitly or implicitly. This view of federal preemption has precedent and would be more effective in ensuring that the uniform federal standards for electronic prescribing are adhered to and not compromised by a patchwork of contradictory state laws. This wider interpretation of the preemption provision would make the e-prescribing standards far easier to administer for care providers, dispensers, and insurance entities, especially those

who operate in multiple states. There are several types of state laws that clearly would be prohibitive to the electronic prescribing standards, including statutes requiring that prescriptions be given by doctors directly to dispensers, laws that require patient permission to release information about certain conditions, and state prescription format laws.

V. Stark (Anti-Kickback) Laws and Regulations

A. Issue for Discussion (BACKGROUND (A) 3)

The Stark laws severely restrict transfers of any type of assets to healthcare providers. These laws were designed to maintain the integrity of doctors and hospitals from the reach of bribery, conflicts of interest or deal-making. The Stark laws have been interpreted to prohibit reimbursement of hospitals, healthcare providers, and dispensers of drugs for expenses involving technologies such as the purchase of hardware, software, and related training. Unfortunately, even if purchases are made for the specific purpose of advancing or simply complying with emerging health information technology standards, electronic prescribing would be covered under the law.

B. ERIC Recommendation: Creation of Stark Law Exception

ERIC applauds the efforts of CMS to amend the anti-kickback statute in order to facilitate the training of healthcare professionals and to allow hospitals to distribute hardware and software to their doctors. While the issue is not resolved in these proposed rules, we urge CMS to support the necessary legislative change needed to create a Stark law exception for electronic prescribing as quickly as possible. Encouraging wide use of electronic prescribing must continue to be a top priority in the implementation of the MMA, and would do much to promote cost-effectiveness, save time and advance patient safety.

VI. Messaging Standards

A. Issue for Discussion (BACKGROUND (G))

The MMA stipulates that messages may be sent through the e-prescribing system to providers for the purpose of improving patient safety, but not for advertising purposes. The limitations for messaging, however, are nebulous and without any specifications. The final standards must include detailed stipulations on messaging.

B. ERIC Recommendation: Limit Messaging

We urge CMS to adopt standards that allow messaging only to help protect patients. Rigorous safeguards should be in place to prevent any interference with physicians' decisions, excepting only scientific advice concerning drug conflicts, etc. Messaging input should be properly prioritized as well as limited by its timing in the prescription process; drug suggestions should not be sent to physicians by any outside sources before they make an initial recommendation. ERIC supports firm limitations on messaging

between parties via electronic prescribing systems, and supports it in order to advance patient safety only.

VII. Pilot Testing

A. Issue for Discussion (BACKGROUND (F))

CMS has proposed to forego any pilot testing due to what it describes as "adequate industry experience" with electronic prescribing. This has the effect of speeding up adoption of final uniform standards, but also may decrease the program's initial efficiency due to lack of a limited trouble-shooting phase. While pilot testing would delay the implementation of new systems and standards, it also may help CMS to see and avoid potential problems that may arise when e-prescribing becomes more widely practiced.

B. ERIC Recommendation: Adoption of Pilot Testing

ERIC supports the use of pilot testing as a cost-saving and safety-enhancing practice. The decision of CMS to implement standards without first running a short pilot program may result in more electronic errors, less effective prescribing safeguards, or increased system vulnerability and instability. We urge CMS to reconsider this decision. We maintain that it would be preferable to delay the program for a short time than to start the program and risk unnecessary problems that could jeopardize the program later.

VIII. Lack of Uniform Standard for Cancellation of Refill Orders

A. Issue for Discussion (**§ 423.160 Standards for electronic prescribing.** *(b) Standards.* (1))

While most of the important electronic transactions are listed to be uniform among program users, there is no specific listing of a transaction for the alteration of the status of a requested refill. For example, if a drug refill is requested and a doctor wishes to cancel this request, there does not appear to be a uniform transaction to accomplish this task. Other transactions also include response transactions to verify that a command was received from the prescribing entity.

B. ERIC Recommendation: Create Additional Uniform Transactions

ERIC recommends that prescribing healthcare bodies be able to cancel a refill order just as they are able to cancel an original prescription order, that there be a response transaction to verify that the order was accepted, and that CMS design a uniform means of doing so. This could save money for all members involved in the PDP, as prescription refills (like first-time orders) are sometimes erroneous or later deemed unnecessary. However, it would also be a matter of safety, since prescriptions that are sent to dispensers sometimes need to be altered or cancelled.

IX. Conclusion

In conclusion, ERIC appreciates the opportunity to provide suggestions to the proposed standards, and realizes that CMS must take into account the interests and commentary of multiple stakeholders. We urge you to revise the standards as suggested here, and to mold the electronic prescription process into one that is mutually beneficial to large employers, their employees, physicians and healthcare providers, and other crucial parties to the program. ERIC firmly believes that CMS can, in cooperation with those that will be sponsoring PDPs, create comprehensive uniform standards that will implement the necessary changes in privacy rules and anti-kickback legislation, and will include all the required functions and necessary safeguards to ensure a properly working system.

As requested by CMS, ERIC is submitting these comments (without any duplicates by mail or by hand) electronically to www.cms.hhs.gov/regulations/ with the text attached in the preferred Microsoft Word format.

Sincerely,

[signed]

Mark J. Ugoretz
President
The ERISA Industry Committee