



January 14, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Standards for E-Prescribing under Medicare Part D, 42 CFR Part 423 (Nov. 16, 2007) (File Code- CMS-0016-P).

Dear Administrator Weems:

The American College of Physicians (ACP), the nation's largest medical specialty organization representing 124,000 physicians and medical students, appreciates this opportunity to provide comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule on the *Proposed Standards for E-Prescribing under Medicare Part D*, 42 CFR Part 423 (Nov. 16, 2007) (File Code- CMS-0016-P). ACP is well aware of the outstanding potential of e-prescribing to benefit the health of Medicare beneficiaries, and ultimately all Americans, and strongly supports CMS' efforts to facilitate adoption of this technology throughout the healthcare system. The College generally supports the recommendations in this proposed rule and believes that they are positive steps towards the goal of full e-prescribing adoption.

Initial Standards

The College supports the adoption of CMS standard proposals for e-prescribing functions that are mature, "market-ready" and can be successfully implemented at the practice level on a daily basis. The College strongly believes that any required e-prescribing functions be backed by research evidence reflecting its operability not only within the laboratory setting, but also in the "real world" practice setting. Based upon this philosophy,

- The College supports the proposed **Standard for Formulary and Benefits**. However, we urge caution when estimating potential opportunities for savings. Formulary choices are often dictated by special pricing arrangements to health plans - so use of on-formulary drugs might improve health plans' bottom line - but not overall spending.

- The College supports the proposed **Standard for Medication History**. The ability to exchange medication history information is necessary to facilitate complete and accurate medication reconciliation, but it is not sufficient. Without additional changes to current workflows, doctors will still not have access to the complete medication history for their patients.
- The College agrees that the proposed **Standard for Structured and Codified SIG** is not sufficiently developed for use at this time. We urge CMS to fund further development of this standard.
- The College agrees that it is not appropriate to implement the proposed **Standard for Fill Status Notification** at this time. The workflow difficulties are complex and unknown. Similarly, there needs to be an analysis of the anticipated obligations of the physician regarding this information and their implications regarding increased medical liability. The College believes that the future potential benefits of this function are high. We urge CMS to fund studies of the potential impacts of fill status notifications on care delivery.
- The College agrees that the proposed **Standard for Clinical Drug Terminology: RxNorm** is not ready for use at this time. We urge CMS to fund further development of this standard.
- The College urges CMS to push aggressively for completion of the **Standard for Prior Authorization**. More than any other component of e-prescribing, automated, real-time prior authorization holds the promise of actual, measurable savings of costs and time to prescribers. A CMS mandate requiring payer support for prior authorization through e-prescribing will significantly and positively impact the perceived attractiveness of e-prescribing adoption by prescribers.

Adoption of the National Provider Identifier (NPI)

The College is in general support of the proposal to adopt the National Provider Identifier (NPI) as the national uniform identifier for use in the proposed e-prescribing standards. We are not aware of significant difficulties with use of NPI for HIPAA-compliant transactions. If there are adequate data to reflect high reliability/accuracy of NPI for transactions that require high fidelity identification of individual providers, then this identifier should be used. .

Proposed Compliance Date

The College questions whether the proposed compliance date of one year after the publication of the uniform standards is realistic. We question whether it would provide Electronic Health Record (EHR)/E-prescribing vendors sufficient time to comply. In addition, we question whether physician practices who are currently volunteering to use e-prescribing can effect the necessary changes during this time period. We recommend that some on-going assessment of proposed standard implementation be established, and a means of extending the compliance period be developed if implementation during the 1-year time period appears unreasonable.

Regulatory Impact Analysis

Medical Practices

The College believes that the impact analysis on medical practices for implementing these proposed standards is an underestimate. Whether or not HIT vendors institute additional charges for required updates to effect compliance, the cost of implementation on providers will be huge. Software costs typically are only 20% of the direct cost for HIT projects. Indirect costs (re-designing clinical workflows and educating the clinicians, support staff, and administrators who make it all work) are greater than the direct costs. So, even if the software upgrades were free, the total cost of the changes to the organization would be substantial. There are also additional costs for practices using e-prescribing that have to create and maintain duplicative workflow because they are not already using EHRs. Doctors have avoided e-prescribing because of this issue, and not specifically because of the cost of devices or software support.

As mentioned previously, the mandating of real-time prior authorization through e-prescribing would provide practices with significant cost and time savings, and also provide a clear incentive for the adoption of this technology.

Benefits Estimates

Formulary and Benefit Standard – Generic Drug Usage

The College urges caution when projecting saving from more effective use of payer formularies. While the projected savings to Medicare from increased use of generics might be appropriate, the potential for savings for the overall healthcare system from the use of payer formularies is suspect. Formulary choices are often dictated by special pricing arrangements to health plans - so use of on-formulary drugs might improve a health plan bottom line - but not overall spending.

Medication History Standard – Reduction of Adverse Drug Events (ADEs)

The College is not aware of any real-world effectiveness studies demonstrating overall improvements in ADEs due to e-prescribing. Achieving such improvements is likely to be dependent on the quality of the implementation (compared with the quality of the existing system) and especially on the effectiveness of the care systems in which e-prescribing is embedded. It is likely that in some e-prescribing implementations ADEs will increase. The numbers and studies cited within this proposed rule reflecting decreased ADEs from e-prescribing include events unrelated to errors in prescriptions that could be reduced through e-prescribing. For example, the implementation of a standard for the interchange of medication history data does not ensure that prescribers will have access to a full and accurate medication history for a patient at the time of prescribing. In addition, decision support systems can not be expected to deliver accurate recommendations if there are gaps and errors in the medication history.

The College contends that the development and adoption of uniform standards alone will not be enough to facilitate the widespread use of e-prescribing throughout the healthcare system. The efforts to facilitate widespread adoption must address a number of additional significant

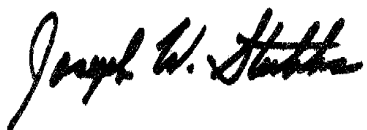
barriers. These barriers, which affect all practices, but have the greatest effect on small and medium size practices and rural practices, include:

- a. The significant software, hardware, implementation and maintenance costs to the practice.
- b. The substantial practice workflow changes that are required to effectively implement e-prescribing into the practice.
- c. The limited evidence for a “business case” to implement e-prescribing technology at the practice level. Most benefits and costs savings are received by the patient, the pharmacy benefit manager, the pharmacy and the payer.
- d. The significant technical difficulties being encountered in implementing current e-prescribing products in the market place being reported by our members and in the literature.
- e. The lack of a system to certify and ensure that the e-prescribing products available in the market place are functionally effective.

The American College of Physicians urges CMS and has previously urged Congress to focus their efforts to address all these barriers with the goals of facilitating e-prescribing adoption and increasing the quality and efficiency of care throughout our healthcare system.

Please do not hesitate to contact Thom Kuhn on our staff at tkuhn@acponline.org or 202-261-4550 if you have any questions regarding these comments.

Respectfully,

A handwritten signature in black ink that reads "Joseph W. Stubbs". The signature is written in a cursive, flowing style.

Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee.