

April 1, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on the Medicare Program: E-Prescribing and the Prescription Drug Program Proposed Rule (42 CFR 423).

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 116,000 doctors of internal medicine and medical students, is pleased to submit comments on proposed rule 42 CFR 423 --- "Medicare Program: E-prescribing and the Prescription Drug Program." ACP is well aware of the outstanding potential of e-prescribing to benefit the health of Medicare beneficiaries, and ultimately all Americans, in terms of reduced medication errors, improved quality of care, enhanced administrative efficiencies and lower costs. We are requesting your attention to the following issues to help ensure effective implementation of e-prescribing within the Medicare program.

1. The proposed prescription and eligibility/benefit electronic communication "foundation" standards.

The ACP supports your proposed implementation as "foundation" standards the NCPDP SCRIPT standard for prescription communications, the ASC X12N 270/271 Transaction standard for eligibility transactions between providers/institutions and health plans or just between health plans, and the NCPDP Telecommunication Standard for conducting eligibility transactions between dispensers and Part D sponsors. Each of these standards is already in widespread use in the industry both as individual standards and in combination and are recognized by the primary stakeholders within the e-prescribing field.

2. The inclusion of formulary representation and medication history standards in the final rule.

The proposed rule states the Centers for Medicare and Medicaid Services' (CMS') intention 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. While we support the defined decision criteria, we strongly recommend the additional criterion of evidence that the standard successfully interacts with the other foundation standards. It is our opinion that such evidence is lacking and that pilot testing is necessary to ensure the usefulness and correctness of the standard.

3. The need to facilitate the rapid development of RxNorm and SPL structured terminology.

The College encourages CMS to expedite the development, pilot testing and implementation of the RxNorm terminology and SPL document specification. This common dictionary and structure will allow for the e-prescribing system to adequately capture subscriber intent when bridging systems using disparate drug databases. In addition, it would allow for the addition of multiple clinical decision support features into the system that have the potential to reduce medical errors and improve quality of care.

4. The proposed rule would require most hospitals and other large clinical settings to change their current prescription transmission standard.

HL 7 is the prescription transmission standard currently used by a predominance of hospitals and other large care delivery organizations. These facilities often require the complex/detailed prescription messages available with HL7, and not currently available through the NCPDP Script standard. These facilities would have to develop and support, at some substantial expense, NCPDP Script standard for prescriptions ordered under the Medicare Part D program under the current proposed rule. The College recommends that CMS address this issue and explore the possibility of changes to the proposed rule that would allow both HL7 and NCPDP Script specifications for prescription transactions. For example, the proposed rule could be modified to support the use of an intermediary that may be a different enterprise than the prescriber in translating HL7 pharmacy order messages to the required NCPDP format. The Cleveland Clinic Foundation has already demonstrated the feasibility of this approach.

ACP also requests that CMS address the more general issue of harmonizing e-prescribing communications between the hospital and outpatient settings. For example, a medication list provided by an outpatient setting should be able to inform the admission inpatient orders; and the inpatient order list should inform the outpatient medication list at the time of discharge.

5. The use of the HIPAA electronic transmission definition to define providers covered by the proposed rule will add inefficiencies and a significant financial burden to most providers employing electronic health record (EHR) systems.

Currently, most providers using an EHR system electronically fax prescriptions to patients' pharmacists. These providers would fall under the proposed e-prescribing rule based upon the HIPAA electronic transmission definition, which includes medical information faxed from a computer. This is despite the fact that these EHR systems are not typically integrated with a true e-prescribing system. Thus, many practitioners who use an EHR system will be forced to implement one or more of the following to be in compliance with the proposed rule:

- Find an e-prescribing system consistent with the proposed rule to integrate into their current EHR system. Currently, the market only has a very limited number of e-prescribing systems capable of such integration. In addition, this adoption would add a significant financial burden to the practices.
- Revert to routinely providing patient's with paper prescriptions to take to the dispenser which adds both unnecessary costs and inefficiencies to the system.
- Create a new phone-based fax system to transmit prescriptions which adds both unnecessary costs and inefficiencies to the system. This means of faxing would be exempt from the proposed e-prescribing rule.

The College recommends that the electronic transmission definition used to define who is covered under the e-prescribing rule exclude computer-based fax transmissions.

6. The restrictive interpretation of language in the Medicare Modernization Act (MMA) that permits preemption of State laws for e-prescribing only within Medicare Part D.

The College supports the broadest interpretation of the State law preemption language included in the Medicare Modernization Act. The wide variation in State laws regarding electronic transmission of prescriptions imposes unnecessary complexity, substantial added costs and serves as a major barrier to the implementation and development of a truly functional national e-prescribing system.

ACP also requests some clarification regarding the interpretation of the State preemption language in the proposed rule. Will the current rule require physicians in those States that have laws in conflict with the adopted federal standard to follow two different protocols; one for prescription transmissions for Part D eligible and enrolled patients using the federal standard, and a second for prescription transmissions for all other patients that follow the State standard? If this is true, it basically eliminates one of the primary goals of e-prescribing, which is to increase practice efficiency.

7. The failure of the proposed rule to address how controlled drugs will be handled under the proposed Medicare e-prescribing system.

There is considerable variation among states regarding procedures physicians must follow when prescribing controlled substances. These variations interact with required Federal procedures. The situation is further complicated by the Federal Drug Administration (FDA's) current unwillingness to accept electronic signatures in prescriptions of controlled substances. ACP requests that CMS address the e-prescribing of controlled substances within the Medicare Part D program.

8. The issue of unique identifiers for dispensers, providers and patients.

ACP strongly supports the recommendation of the National Committee on Vital and Health Statistics (NCVHS), and the Department of Health and Human Services' (HHS') proposed intention of requiring the National Provider Identifier (NPI) for all dispensers

and providers participating in the electronic prescription program under Medicare Part D. The College also urges HHS to accelerate the enumeration of all providers and dispensers to support transition to the NPI for e-prescribing by the onset of the Part D program on January 1, 2006.

The proposed rule does not address the issue of a unique patient identifier. ACP believes that there are patient safety benefits in the use of a unique patient identifier in terms of ensuring accurate matching of prescription and patient data that far outweighs any reasonable privacy or government intrusion concerns. The College recommends that HHS use its resources to place this issue “on the table” for further discussion.

9. The issue of how the e-prescribing system will address “dispense as written” and “brand name medically necessary” instructions.

ACP requests that HHS define their plans for addressing “dispense as written” and “brand name medically necessary” prescription instructions within the federal e-prescribing program.

10. The enactment, monitoring and enforcement of regulations under the Medicare Part D e-prescribing system that ensure that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs.

Both language in the MMA (1860D-4(e)(3)(D)) and the legislation’s conference report reflect Congress’ intent of ensuring that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs under the Medicare Part D e-prescribing system. ACP is concerned that the proposed rule does not address this issue.

The College recommends that HHS enact regulations, and the means to monitor and enforce them, that prohibit the transmission of commercial messages within the Medicare Part D e-prescribing system that will unduly bias physician’s drug selection. In addition, the College recommends that HHS provide similar protection to ensure that health care prescribers have neutral and unbiased access to information on all covered drugs available in a plan’s formulary.

11. The need for incentives to promote provider adoption of electronic prescribing.

ACP believes that e-prescribing, along with electronic health records, has the potential to significantly improve patient safety and quality of care. Unfortunately, recent testimony presented before the NCVHS estimates that only between 5-18 percent of prescribers are currently conducting e-prescribing. A primary barrier to physician adoption is the cost of buying and implementing these systems, making related changes in the flow of office practices and training staff. ACP recommends the following incentives --- particularly in the smaller physician practices that treat a large number of our Medicare beneficiaries ---

to support the significant 10 percent annual expansion of e-prescribing over the next 5 years projected in the proposed rule:

- The availability of financial incentives (e.g. grants, loans, tax incentives) and payment increases contingent on the use of this technology to promote the initial implementation and maintained use of e-prescribing technology. These financial incentives are particularly important in small, rural and underserved clinical settings.
- The expedited revision of the Stark laws and the development of Medicare Anti-kickback law safe harbors (with strong state preemptions) to allow health plans and others, who stand to most benefit financially from adoption, to provide necessary hardware/software, technical assistance and financial incentives to providers.

In addition, there is need for increased discussion and the collection of data on how implementation of e-prescribing may affect physician personal liability risk and related insurance coverage. HHS's has suggested that implementation may decrease medical liability premiums due to its effect of decreasing medication errors. On the other hand, some clinicians have expressed concern about the potential of increased liability risk due to the making of medication judgments based on information (which may or may not be accurate) provided through the e-prescribing system. Furthermore, situations in which physicians choose, based on clinical judgment, to over-ride adverse reaction alerts or other clinical support information ultimately provided by the e-prescribing system also have the potential to increase liability risk. This issue clearly requires further exploration and the collection of relevant data.

12. The following issues were not discussed in the proposed rule and need to be addressed in future pilot studies related to the federal e-prescribing system:

- The need for all new standards added to the foundation standards (and other standards ultimately included into the system) to have adequate documentation of successful interaction to ensure the usefulness and correctness of the standard package.
- The need for means of communicating patient choice of pharmacy and change of pharmacy instructions. Optimally, the e-prescribing software should provide more than one pharmacy choice for the patient. In addition, patients who choose to change pharmacies should easily be able to have their prescriptions transferred from one pharmacy to another.
- The need for a "no fill" message to be sent to the prescribing provider.
- The need for performance and notification/acknowledgement of transmissions standards among all parties in the e-prescribing relationship.
- The assessment of the error rate in electronically transmitted prescriptions with the goal of achieving an error rate at least as low as that currently found in the banking industry --- which approaches zero.
- The evaluation of the e-prescribing process to target specific obstacles to adoption in multiple clinic; urban and rural; and small and large practice

settings. These evaluations should address financial, staffing and practice flow components of the process.

The ACP appreciates this opportunity to comment on the proposed e-prescribing standards. Please do not hesitate to contact Neil Kirschner on the ACP staff at 202 261-4535 and nkirschner@acponline.org if you have any questions regarding the submitted comments.

Sincerely,

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