

**Written Comments of the American College of Physicians
on
Standards for e-Prescribing
for
United States House of Representatives
Committee on Ways and Means
Subcommittee on Health Hearing
July 22, 2004**

The American College of Physicians (ACP), representing over 116,000 internal medicine physicians and medical students, is pleased to provide written comments on Standards for e-Prescribing. Specific ACP recommendations on e-prescribing are provided beginning on page 8.

E-prescribing's impact will be constrained by the degree to which all health care system players can communicate with each other electronically. Optimal impact will only be achieved when every physician, clinic, hospital, nursing home, laboratory, health plan, and payor can seamlessly transmit medical information electronically in uniform languages and formats. Attainment of this ideal is the very definition of an interoperable health information infrastructure, a goal ACP not only supports along with the Department of Health and Human Services and several legislators, but is also actively pursuing through participation in key demonstration programs such as the Doctors Office Quality—Information Technology demonstration project (implementing Section 649 of the Medicare Modernization Act of 2003).

In furtherance of ACP's advocacy of bringing advanced communications technology to the physician's office, including e-prescribing, the College has recently published a series of three papers* related to this subject. The three papers are listed at the end of this testimony and can be found on the ACP website at:
http://www.acponline.org/hpp/menu/med_tech.htm.

Our comments will address the areas of e-prescribing's potential benefits, practical and technical barriers to wide scale e-prescribing adoption, ways to make e-prescribing appealing to physicians without adding to practices' administrative burdens, and the need to assure that e-prescribing medication decisions are not driven by proprietary interests.

1. E-Prescribing's Potential Benefits

The many benefits of using e-prescribing, in terms of reduced medication errors, improved quality of care, enhanced administrative efficiency, and lowered costs, clearly justify efforts to expand use of e-prescribing systems.

In the eHealth Initiative's April 14, 2004 report: *Electronic Prescribing: Toward Maximum Value and Rapid Adoption*, there is clear evidence that many untoward drug events are avoided by use of integrated e-prescribing/electronic health record (EHR) systems, averting the associated costs of such drug caused morbidity and mortality. The

report indicates that out of 8.8 million adverse drug events which occur each year, over 3 million of these are preventable. Medication errors also account for 1 out of 131 ambulatory care deaths. With over 3 billion prescriptions written each year, the report shows that e-prescribing, if universally adopted in the United States, could save \$27 billion annually. Some of these savings would come from prevention of adverse drug events, while the majority of savings would result from better utilization of drugs, through guidance from formulary information included in e-prescribing systems. Any short term start-up costs associated with widespread adoption of e-prescribing technology should be quickly offset by significant cost avoidance related to misadministration of medications. Other potential benefits could be lowered physician malpractice insurance premiums and higher levels of patient confidence and satisfaction.

2. Practical and Technical Barriers to Wide Scale E-Prescribing Adoption

a. Need for a Universally Accepted E-Prescribing Drug Classification and Coding Nomenclature

For e-prescribing to be adopted on a wide scale, there must first be a universal drug classification and coding nomenclature that is accepted throughout the U.S. health care system.

ACP understands that current day e-prescribing systems can range from the limitations of a stand alone personal digital assistant (PDA) with basic formulary and prescription generating software, to sophisticated systems which are fully integrated with EHR and clinical decision support software. These advanced systems are potentially able to conduct two way electronic communications with pharmacies, other physicians and providers, laboratories, health insurers, and pharmacy benefit management organizations. However, at this point in time, two way electronic transmission of patient medication information is a rarity. This is why it is vital that core uniform e-prescribing standards, as called for by the Medicare Modernization Act, be simple and as easy to implement as possible. These standards also need to be easily adaptable from the simplest to most complex of health care settings and must accommodate existing e-prescribing systems without necessitating major software changes, staff retraining, or increased costs. It is also critical that use of e-prescribing systems be transparent to both physician and patient, and enhances rather than distract from the process of patient care.

The current National Council for Prescription Drug Programs (NCPDP) script codes for medications has been accepted as the best available code set available; however, the current NCPDP script codes are not the final solution for bringing simplicity to the identification of medications. In fact, NCPDP has different proprietary codes for every unique product for each pharmaceutical manufacturer, meaning that something as simple as aspirin would have several unique codes due to dosage of each pill and number of pills per package. Another manufacturer of aspirin would have an entirely different set of codes for the same dosages and package sizes, so there is no easy way for a physician to evaluate medications using the current NCPDP script codes.

To try to overcome this unnecessary complexity, the federal government has undertaken a major effort to develop a simplified, unified system of e-prescribing, known as RxNorm. While RxNorm does allow specification of a particular drug's ingredients, dosage, and form (pill, patch, tab, etc.), this new system does not go far enough in allowing a physician to specify critical details of his/her choice of patient medication. Specifically, this includes if a drug should be provided in a compliance packaging form (e.g., certain steroids have to be taken on a strict and reducing dosage regimen), whether certain allergic ingredients such as gluten must be avoided, and what flavoring a child's prescription must have to ensure the child complies with taking the medicine.

There are other gaps in the present NCPDP and RxNorm standards that must be addressed. Standardization of the required data elements ("sig") is necessary to create an electronic prescription. These elements must include the ability to give directions for specific medications in oral or topical form and in various dosing patterns.

There is also a need to standardize specifications of allergy groups, drug interaction groups, etc., so there is consistency as one changes to different applications that use different commercial dictionaries.

Encouragement is needed for unification of varying state regulations concerning the proper format of a prescription as well as unifying standards, terms, and structures used by formulary information service providers.

The resulting standards also need to include a single set of messaging standards that is reconciled with developing HL7 conventions, and can continue to grow and develop to meet future business needs.

In short, ACP encourages the development of a nationwide system expanding upon the efforts of RxNorm to meet the above needs but also avoiding the excessive complexity of NCPDP script codes

b. Overcoming Acquisition Cost Barriers and Encouraging Physician Acceptance of Change

Adoption of e-prescribing technology can best be encouraged by providing the strong financial incentives needed to take the sting out of taking on this new technology's substantial acquisition and start-up costs. The source of these incentives should be the federal government and health plans which will ultimately be rewarded for this investment in the long run as savings are generated by e-prescribing systems. This will be particularly crucial in light of Medicare projections of eight years of physician payment cuts between 2006 and 2013, amounting to a 40 percent pay cut relative to 2005 reimbursement rates. As such, ACP applauds the initiative of health plans such as WellPoint Health Networks, which will soon offer free e-prescribing software to its 19,000 participating physicians.

As more and more physicians make the move to e-prescribing, it will be hard for the rest of the medical universe to resist coming on board, as both doctors and patients clamor for the therapeutic accuracy and quality improvement only e-prescribing can provide.

In addition, standards for e-prescribing must take into account the wide variety of clinical settings and specialties and should be flexible and scalable to reflect a practice's size and prescribing volume. Since universal e-prescribing is likely to precede achievement of a national interoperable health information infrastructure, e-prescribing standards must allow for basic stand alone electronic prescribing platforms used by smaller practices, as well as more sophisticated integrated EHR/clinical decision support/practice management/e-prescribing systems used by larger group practices and health systems. Most importantly, the physician-patient relationship must be enhanced, not impaired by this new technology.

c. Careful Pilot-Testing of E-Prescribing to Assure Smooth Operability in All Health Care Environments

E-prescribing system prototypes should be carefully pilot-tested in a wide array of clinical settings, including small independent community-based physician practices, to ensure e-prescribing works smoothly in all environments. Settings should be both urban and rural, and include the particularly difficult situation where integrated information networks are essentially non-existent and must be developed. The process of development and testing must have the active input of all affected providers and insurers, with cooperative standard setting, and voluntary participation of physicians. Once final standards are decided upon, implementing regulations should provide ample time for those choosing voluntary e-prescribing to come into compliance, avoiding the implementation problems currently experienced with the Electronic Transactions and Code Sets rule under the Health Insurance Portability and Accountability Act.

d. Compliance with Final HIPAA Security Standards and Drug Enforcement Agency (DEA) Requirements

Any e-prescribing standards developed must address many issues in the final HIPAA Security standards, due to be implemented in 2005, including what physical safeguards are necessary to guard data integrity, personal authentication, encryption, and patient confidentiality. E-prescribing standards must also address how access to DEA-controlled drugs will be restricted, since many states currently only allow such prescriptions to be written through use of a triplicate (or other special paper) prescription order.

3. Issues Critical to E-Prescribing Adoption by Physicians

ACP believes that, for e-prescribing to have widespread acceptance and adoption amongst physicians, this new technology must prove itself as speedy or efficient as filling out a paper script, and hold other advantages not possible with a paper-based system. One absolutely vital component for raising the value of e-prescribing in assuring patient safety and quality is integration with EHR and clinical decision support software. Such

an integrated system can help physicians choose the right drug and dose for a patient, based on data already contained in the EHR and patient medication history.

ACP is a leader in the development and dissemination of evidence-based electronic clinical decision support tools, with its Physician Information and Education Resource (PIER), which can be integrated with EHR/e-prescribing software. PIER offers over 300 modules focusing on the diagnosis and treatment of diseases including: a comprehensive, in-depth drug database; a convenient search engine and bookmark features; evidence indicators and standard tables; and the latest clinical information culled from the medical literature. PIER is also available in a PDA format already integrated with some e-prescribing systems presently available on handheld computers. PIER is meant to be a helpful guide to physician decisions and, as should be the case with e-prescribing advice, is never intended to mandate a physician's or patient's final choice of treatment or medications.

ACP fully recognizes that adoption of e-prescribing technology will not be without its growing pains. The vast number of different e-prescribing systems and languages presently in use make interoperable communication among health system components a still distant goal at this time. One ACP member in Maine noted that, although his 25 member group practice had the capability of sending prescriptions electronically to local pharmacies and pharmacy benefit management organizations, virtually no capability exists at the receiving end to accept e-prescriptions and e-signatures. Instead, about 75% of prescriptions must be electronically faxed to the receiving organizations, while the remaining 25% must be printed out as a paper prescription which patients must carry to their pharmacies. The practice estimates printing out prescriptions administratively adds about \$1 to the cost of each prescription.

ACP member physicians who previously tried e-prescribing systems also report difficulty with accuracy of formulary information. Many times the formulary information is not kept current with the rapid changes made at the health plan level and physicians' offices remain burdened with phone calls from pharmacies asking for changes because health plan formulary changes have not yet made it through to the e-prescribing software. Other ACP members say they still believe writing out a prescription by hand is faster than doing it on a computer, so winning converts to the advantages of this new technology will be a major challenge for the medical industry in the years ahead.

ACP believes the following key areas must be addressed to ensure e-prescribing is widely accepted and used by physicians, and does not create new, counter-productive administrative burdens.

a. Immediate Electronic Access to All Medication and Patient-Specific Information

To gain the support of the physician community, the e-prescribing system must provide all information a physician requires for reaching a fully informed, optimal clinical decision for the patient, as well as accommodating patient insurance coverage and cost considerations. This means having complete and current formulary information which

shows all available medications for a particular condition, including therapeutic substitutions and generic alternatives. Prices for all medications and whether or not a patient's insurance plan provides coverage must also be available online, so that a physician can choose the lowest cost alternative for each patient. This information must be kept up to date and in full agreement with the latest formulary information used by pharmacies and health plans.

The e-prescribing system must also provide a patient medication profile that includes prescriptions from all pharmacy sources and all physicians in a single unified view. The system would provide a list of every individual prescription filled for a given patient by any pharmacy and any physician within a specified time frame from most recent to least recent and also indicate which prescriptions have been discontinued. In addition the e-prescribing system must be dynamically updated and bi-directionally linked to the physician office medical management system and the most current health plan formularies to eliminate the need for double entry of information such as insurance and demographic information.

b. Non-Interference in Physician Medication Choices

It is critical that the e-prescribing system not include elements that would permit payors and pharmacy benefits managers to pressure physicians to prescribe a different therapy or medication than what the physician concludes is best for a particular patient based upon scientific evidence and knowledge of the patient's medical history.

c. Real Time Online Medication Prior Authorization Adjudication

One absolutely crucial element of an effective e-prescribing system is inclusion of a real time, online prior authorization adjudication process for physicians with insurers, health plans, and pharmacy benefit management organizations. Physicians will be discouraged from using e-prescribing systems if, every time there is a dispute over coverage/payment for a prescribed drug, they are forced to make a lengthy phone call to get approval, or fill out additional paperwork to override an initial denial. Such tactics intentionally frustrate physicians, forcing them to use the payors' lower cost choices, rather than make the best therapeutic choice for their patients. If the federal government truly wants e-prescribing to have broad acceptance and usage in the physician community, rapid online decisions for prior approval medications must be a cornerstone of all future e-prescribing systems.

4. Need to Assure that E-Prescribing Medication Decisions Are Not Driven by Proprietary Interests

To create a universally beneficial e-prescribing system, the drug classification and coding systems, as well as prescribing databases must be free of commercial bias. ACP is concerned that the current multiple drug classification, vocabulary, and database systems in use are often proprietary, designed to optimize profits of manufacturers, pharmacy benefit managers, and health plans rather than provide the medically best and cost-effective drug a patient needs. One major loophole in the Medicare Modernization Act of

2003 is that even though the U.S. Pharmacopoeia is charged with developing a single drug classification system, payors are not required to use it. Payors can consolidate or expand drug classification categories as they see fit, which will allow formulary comparisons and physician prescribing patterns to be inappropriately influenced. Clearly, all parties involved with the manufacture, sale, distribution, and prescription of prescription drugs should work with a consistent classification system free of commercial bias to permit fair, objective comparison of drug costs and benefits.

Summary

The coming revolution in electronic health information technology is one that will benefit all, simultaneously raising health care quality, lowering costs, and expediting the process of care. Accruing evidence shows that e-prescribing has the greatest potential to improve patient care substantially and quickly, which is why it must be a top priority as the nation moves from a fragmented, multi-system, primarily paper-based approach to a unified electronically-based system for handling patient medications. As such, ACP lends its hearty support to this worthy endeavor and is willing to actively participate in e-prescribing and national health information infrastructure pioneering efforts.

ACP e-Prescribing Recommendations

Following is a set of ACP recommendations aimed at encouraging expanded adoption of e-prescribing throughout the U.S. health care system:

- 1. There should be a single universal vocabulary and classification system for prescription drug information that must be developed and maintained in a manner that is free of commercial bias so that prescription drugs can be accurately used and compared.**
- 2. The health care industry should support the widespread adoption and further enhancement of RxNorm to provide a consistent, easily used, drug vocabulary that includes:**
 - a. a specification system of drug active ingredients, dosage, and route of administration expanded to include inactive ingredients**
 - b. standardization of required data elements (“sig”), drug dictionaries and state regulations concerning the proper format of a prescription**
 - c. a single set of messaging standards that is reconciled with developing HL7 conventions that can continue to grow and develop to meet future business needs.**
- 3. Due to substantial evidence showing e-prescribing systems have a major and immediate impact on averting adverse drug events and associated costs, first priority in developing a national health information infrastructure should be placed on developing uniform standards for e-prescribing, and providing sufficient federal support and financial incentives to ensure all providers adopt and utilize e-prescribing systems.**
- 4. Development of e-prescribing standards and software should be a voluntary, cooperative process between the federal government and health care industry, with the goal of ensuring buy-in of all affected parties to expedite implementation once universally accepted standards are achieved. Standards developed should be easily adaptable to existing e-prescribing systems, with minimal disruption and cost while also having the flexibility to meet future business needs.**
- 5. To have maximum impact on quality of care, e-prescribing systems must be designed so they can be easily integrated with electronic health records and clinical decision support software.**
- 6. To ensure that e-prescribing systems can work at the national level, they should first be pilot tested in a wide array of health care settings and environments to identify and correct any technical problems that would undermine widespread implementation.**

7. In designing and pilot testing e-prescribing systems, to win provider support, it is vital that objective data be collected that clearly demonstrates such systems not only avert medication errors, but also save providers time and money over pre-existing systems.

8. Even after pilot testing has proven successful, national adoption of e-prescribing systems should not be rushed, giving voluntary providers sufficient time to acquire the necessary software and hardware and communications networks, as well as time to become familiar with and confident in using the new systems. Implementation timelines should allow ample time to make all necessary adjustments and allow sufficient time for training and system testing before going live.

9. The physician's responsibility to make patient care decisions and prescribe medications, based on his or her clinical expertise and experience, must be preserved. Electronic health record (EHR), e-prescribing, and other e-health technology must be designed to facilitate access to unbiased and evidence-based decision support tools.

10. EHR and e-prescribing systems must dynamically/bi-directionally link to the physician office medical management system, reducing the need for double entry of information such as insurance and demographic information.

11. Insurance companies must place clear formulary codes on insurance cards and e-prescribing systems so that formulary checking can be seamless and accurate and up to date with the most recent formulary requirements.

12. E-prescribing systems:

- a. Must provide a patient medication profile that includes prescriptions from all pharmacy sources in a single unified view. The system would provide a list of every individual prescription filled for a given patient by any pharmacy or physician within a specified time frame from most recent to least recent and indicate which prescriptions have been discontinued.**
- b. must be dynamically updated with the most current health plan formularies.**
- c. must conform to the final HIPAA Security standards, due to be implemented in 2005, and address issues such as what physical safeguards are necessary to guard data integrity, personal authentication, encryption, and patient confidentiality, as well as addressing the impact of e-prescribing on access to DEA-controlled drugs, which can only be provided through a triplicate (or other special paper) prescription order in many states.**

- d. must not be used as a means for payers and pharmacy benefits managers to pressure physicians to prescribe a different therapy or medication than what the physician concludes is best for a particular patient based upon scientific evidence and knowledge of the patient's medical history.**
- e. must have a real time online prior authorization adjudication process for all physicians' prescriptions.**

ACP References

* Three ACP Papers Referenced on Page 1 of Testimony:

(Available on ACP website at: http://www.acponline.org/hpp/menu/med_tech.htm)

1. *Enhancing the Quality of Patient Care Through Interoperable Exchange of Electronic Healthcare Information* (April 2004).
2. *The Paperless Medical Office: Digital Technology's Potential for the Internist* (March 2004).
3. *The Changing Face of Ambulatory Care—Reimbursing Physicians for Computer-Based Care* (March 2003).