

e-Prescribing Controlled Substances Coalition

November 27, 2007

The Honorable George W. Bush
The President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We applaud and support the leadership that you and your Administration have demonstrated in encouraging the adoption of health information technology that will facilitate the delivery of quality health care while wringing the excess costs out of the health care delivery system.

The e-Prescribing Controlled Substances Coalition is a coalition of diverse stakeholders focused on promoting health care information technology, and electronic prescribing in particular. The Coalition is asking your assistance in remedying the current inability to prescribe controlled substances electronically. This significant gap in the prescribing process is denying patients and the health care system the full benefits that electronic prescribing offers. Just as importantly, this gap is depriving law enforcement of a tool that could facilitate drug diversion control far better than today's labor-intensive, inefficient, and costly paper process.

Controlled substances comprise approximately 12.5 percent of all prescriptions, and permitting them to be e-prescribed will accelerate the adoption of electronic prescribing technology. Many prescribing clinicians are deterred from adopting e-prescribing if they can only e-prescribe for non-controlled substances. Further, Coalition members believe that current e-prescribing systems offer significantly more protection from illicit prescribing, doctor shopping and drug diversion than the current system of paper and oral prescriptions. We continue to believe that the current e-prescribing process can address the concerns expressed by the Drug Enforcement Administration (DEA) in numerous public meetings over the last several years. Greater detail on the safety and security of e-prescribing is provided in the Summary Questions, at Attachment 1, and the White Paper, at Attachment 2.

While controlled substances could be prescribed electronically today, this is not allowed under current DEA regulations. Members of the Coalition, the U.S. Department of Health and Human Services, and the Centers for Medicare and Medicaid Services have been working with the DEA for as long as five years to try to achieve the common goal

of permitting prescribing clinicians to e-prescribe controlled and non-controlled substances through a single e-prescribing system. Despite the evidence of e-prescribing's safety and security provided by the public and private stakeholders, the DEA has yet to develop a workable regulation that would permit the e-prescribing of controlled substances.

The undersigned members of the Coalition request that your office assist us in encouraging DEA to promulgate immediately a workable, technology neutral e-prescribing regulation that builds on today's safe and secure e-prescribing infrastructure. This would not only reduce diversion of controlled substances, but would also encourage clinician adoption of e-prescribing and, ultimately, all facets of health information technology.

The country can no longer afford to have a two-tiered prescribing system. It is time for the e-prescribing and law enforcement communities to work together to harness all of the attendant benefits that health information technology can provide to the nation's health care system and the consumers it serves.

Sincerely,

e-Prescribing Controlled Substances Coalition

cc: The Honorable Michael O. Leavitt
Acting DEA Administrator Michele Marie Leonhart

Attachments: List of Coalition members – pages 3 and 4
Coalition contact information – page 5

e-Prescribing Controlled Substances Coalition Members

Achieve Healthcare Information Technologies, LP
Aetna
American Benefits Council
American Health Care Association
America's Health Insurance Plans
American Medical Group Association
American Medical Informatics Association (AMIA)
American Nurses Association
Anthem Prescription Management
Arcadian Health
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
BlueCross BlueShield Association
ChartConnect, Inc.
CIGNA
Comcast
CVS Caremark
ePrescribe Florida
eRx Network, LLC
Express Scripts, Inc.
First Health Group Corporation
Giant of Maryland
Giant Foods
Healthcare Information and Management Systems Society
Healthcare Leadership Council
Humana, Inc.
Information Technology Industry Council
Kmart
Medco Health Solutions
MediMedia Information Technologies
MedPlus, Inc., a Quest Diagnostics Company
National Association of Chain Drug Stores
National Association of Health Underwriters
National Association of Manufacturers
National Council for Prescription Drug Programs, Inc.
Pharmaceutical Care Management Association
Prescription Solutions
Prime Therapeutics, LLC
Rite Aid Corporation
RxHub, LLC
RxNT

Sage Software
Sears
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SureScripts
The Kroger Company
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Attachment 1

e-Prescribing for Controlled Substances

ISSUE: Federal laws and regulations prohibiting controlled drug substances from being electronically prescribed are an impediment to the widespread adoption of electronic prescribing.

What is e-prescribing?

Electronic prescribing is a system that enables prescribing clinicians to securely deliver prescriptions via computer immediately from the point of care directly to a patient's pharmacy of choice. In addition to this prescription delivery function, e-prescribing improves patient safety through warnings to the prescribing clinician about adverse drug interactions and allergies, and previous medication history. It also addresses patient drug-regimen compliance issues by providing information on insurance eligibility status, prescription fill status notification and prescription renewal capability.

Is e-prescribing secure?

E-prescribing is far safer and more secure than paper prescriptions. Paper prescription pads are often stolen or counterfeited, signatures can be easily forged, and drug quantities can be manually altered before the prescription is delivered to the pharmacy.

E-prescribing is *not* simply sending a message to a pharmacy over the Internet. E-prescriptions are transmitted over secure, private networks, which employ industry-wide privacy and security standards to ensure the safety of patient data and its secure transmission. E-prescribing systems adhere to HIPAA privacy and security regulations with safeguards that include strong user authentication, firewalls, intrusion detection systems, security assessment, violation scanning and audit tools, periodic system risk assessments, data encryption and backup/disaster recovery capabilities. E-prescribing networks assure robustness of processes and performance through third-party oversight and accreditation (e.g., EHNAC).

Why are controlled substances not e-prescribed?

E-prescribing is not allowed for controlled substances at the present time under federal law and Drug Enforcement Administration (DEA) regulations. The DEA's reasons for not permitting e-prescribing of controlled substances are:

- Only written prescriptions can reliably authenticate prescribers.

But e-prescribing does that as well. Prescribers must be credentialed, approved and also must use secure log-ons to access the secure e-prescribing network. At the pharmacy, prescriptions are received only through trusted partners or agents. Electronic audit functions document, including time-date stamps and who touched the prescription, at each point in the process.

- The written prescription is “hard” evidence of the prescriber’s order and the actual dispensing of the controlled substance.

E--prescribing does that as well. Electronic prescriptions will provide pharmacists with a higher level of confidence in the authenticity of prescriptions, which can only be received from trusted partners and agents. E-prescribing systems can help identify improper prescriptions and patterns of irregular use.

- “Hardcopy” prescriptions and so-called “wet” (ink) signatures provide a level of non-repudiation and physical evidence necessary for criminal legal proceedings

Yet e-prescribing system records can offer equally valid legal evidence of ownership and the e-prescribing infrastructure can provide a mechanism for third-party auditing and establish accountability for the prescriber.

What about drug diversion and illegal prescribing of controlled substances by “rogue” Internet pharmacies?

Identifying and prosecuting diversion of controlled substances currently requires the time-consuming and expensive process of sifting through thousands of paper prescriptions in disparate locations. The electronic audit trail of e-prescribing allows for faster identification and investigation of possible abuse.

Another avenue for abuse of controlled substances is patient “doctor shopping” and re-use of prescriptions. Since e-prescribing passes directly from the doctor to the pharmacy, there is no opportunity for abuse or diversion by the patient.

The e-prescribing infrastructure is a closed system. In order to receive e-prescriptions, pharmacies must be registered and certified to access the secure networks transmitting the prescriptions. Therefore, “rogue” Internet pharmacies would not be able to bypass these stringent safeguards.

What are the next steps?

The time has come to permit e-prescribing of controlled substances. The Drug Enforcement Administration and the Department of Justice need to promulgate regulations immediately for e-prescribing of controlled substances. These rules need to –

- be technology neutral;
- build on today's safe and secure e-prescribing infrastructure;
- take into account the unique needs of prescribing in institutional settings, such as nursing homes, correctional facilities, and assisted living facilities; and
- allow for future changes and growth in technology, privacy and security safeguards, and industry expansion.

Attachment 2

e-Prescribing Controlled Substances Coalition

Controlled Substances and e-Prescribing: Saving Lives, Reducing Costs, and Helping Law Enforcement

Introduction

Federal laws and regulations prohibiting controlled drug substances from being electronically prescribed are an impediment to the widespread adoption of electronic prescribing. The purpose of this white paper is to describe the e-prescribing process and how e-prescribing can be used to safely and securely transmit prescriptions for controlled substances. It also describes how the current inability to e-prescribe controlled substances is hindering e-prescribing adoption, and how e-prescribing can help law enforcement with drug diversion control.

E-prescribing is the use of healthcare technology to improve prescription accuracy, increase patient safety and reduce costs, as well as enable secure, real-time, bi-directional, electronic connectivity between clinicians and pharmacies. This is achieved by providing prescribers with a secure means of electronically accessing health plan formulary, patient eligibility and medication history at the point of care and securely transmitting the prescription electronically into the pharmacy's computer system, which also is bi-directional, meaning that messages can flow back from the pharmacy to the prescriber.

E-prescribing also gives the provider access to real-time patient clinical decision support information at the point of care. This includes:

- Patient pharmacy benefit eligibility & coverage
- Formulary information
- Medication history information
- Drug-drug interactions and allergies

E-prescribing is *not* transmitting raw patient information over the open Internet. Prescriptions and other information are transmitted through secure, private networks. Prescribers and pharmacies must be credentialed and approved before they can participate in the e-prescribing process. They also must securely log on before they can e-prescribe or receive a prescription. Infrastructure technology partners, vendors and

others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks.

The e-prescribing business model is very robust, with double digit growth in e-prescribing volume and in eligibility requests over the past five years. Industry analysts believe this will continue in the near future. The model also is self sustaining, with costs shared among the participants:

- Clinicians (usually physicians) pay for the e-prescribing or electronic health record systems.
- PBMs/health plans pay for the patient-level decision support information (eligibility, formulary, medication history) to be delivered to the prescribing clinician at the point of care.
- Pharmacies pay for their e-prescribing systems and also pay transaction fees when they receive electronic prescriptions and prescription renewal authorizations.

Underlying the business model is a secure and robust infrastructure, which is in operation today and transmits prescriptions to the patient's pharmacy of choice. Infrastructure providers include RxHub, SureScripts, Emdeon, Relay Health and eRx Network.

The model also results in enhanced patient convenience, preservation of patient choice, reduced costs for payers and patients, improved patient safety, increased efficiency for clinicians and pharmacies, improved medication compliance for patients, and better quality of patient care.

E-Prescribing Saves Lives, Improves Quality, and Reduces the Costs of Care

A paperless prescribing system is preferable to today's paper world because it adds new dimensions of safety and efficiency to current practice. Errors can occur at many points in the paper-based medication prescribing and delivery system; many of these potential points of error are due to failures in process and communication. These include:

- Miscommunication due to illegible handwriting
- Unclear abbreviations and dose designations
- Unclear telephone or verbal orders
- Ambiguous orders and fax-related problems
- Complex benefits plans
- Complex prescription regimens and dosages
- Wide range of drug choices for treating a medical problem
- High incidence of Adverse Drug Events (ADEs) and error rates

In 2006, the Institute of Medicine (IOM) recommended that all prescriptions be written and received electronically by the year 2010. Recognizing the problems of today's paper system detailed in the IOM report, and recognizing the benefits of e-prescribing and the opportunities to reduce the costs of care, many are calling for the increased use of e-

prescribing in Medicare Part D. For example, a coalition of nearly two-dozen key stakeholders, including the Pharmaceutical Care Management Association, recently called on Capitol Hill leaders to require mandatory use of e-prescribing for prescriptions for Medicare beneficiaries. That need was echoed in similar requests from the Blue Cross/Blue Shield Association of America and the e-Health Initiative.

Many State governments and public/private partnerships have taken the initiative to launch or support programs that encourage the adoption of e-prescribing technology as an effort to reduce costs and improve the efficiency, safety, and quality of patient care in their respective states. State initiatives include e-Prescribe Florida, and efforts in Minnesota, Mississippi, New Hampshire, and Tennessee.

E-prescribing also provides better patient compliance with their therapeutic regimens. Medication noncompliance is a huge problem for the American health care system. Medication noncompliance is the failure to take drugs as prescribed, which can include not taking a medication on time, taking a different dose, or not taking the medication at all. In general, prescribing clinicians are unable to determine if their handwritten prescriptions are filled or not. Identification of unfilled, handwritten prescriptions is a very labor intensive process, requiring manual review by a number of pharmacists and others.

Noncompliance is dangerous and expensive for the prescribing clinician, patient, and health plan. Non-compliance with prescription medication causes an estimated 125,000 deaths annually and costs at least \$75.6 billion each year.¹ Other impacts include such adverse outcomes as avoidable hospitalization, development of complications, disease progression, and premature disability.² The research and policy communities agree that these attributed adverse effects of medication noncompliance and related costs are substantially underreported. With e-prescribing, prescribers will know to which pharmacy a prescription has been sent and whether the patient has picked it up. This will offer opportunities for prescribing clinicians and pharmacists to better track and communicate about patient compliance.

In addition to the patient safety benefits, e-prescribing also offers cost savings resulting from the ability to identify the patient's formulary and benefit structure before the prescription is written. This helps the prescriber identify therapeutically appropriate alternatives that the patient's insurance will cover. The result is more affordable care for patients and payers through increased generic use and formulary compliance. For

¹ Reminders Not Effective for Medication Compliance, Study Says. Research report from the Ohio State University. Retrieved 12/01/2006 at <http://research.news.osu.edu/archive/noncomply.htm>.

² Dunbar-Jacob J, Mortimer-Stephens MK. (2001). Treatment adherence in chronic disease. *J Clin Epidemiol* 54(suppl 1):s57-s60. Ellis S, Shumaker S, Sieber W, Rand C. (2000). Adherence to pharmacological interventions: Current trends and future directions. *Control Clin Trials*: 21(Suppl):218-225. Jackevicius CA, Mamdani M, Tu JV. (2002). Adherence with statin therapy in elderly patients with and without acute coronary syndromes. *JAMA* 288:462-467.

example, participants in the Southeast Michigan e-Prescribing Initiative (SEMI)³ saw significant increases in generic use and formulary compliance through e-prescribing. With the use of e-prescribing for its workers and their families, General Motors has seen increases in its rates of generic drug prescribing and compliance with preferred drug lists, both of which save money. For each one-percent shift to generic drugs from a brand name, GM saves nearly \$20 million. The Henry Ford Health System –another SEMI participant--conservatively estimates it is saving \$4 million a year with e-prescribing, mostly from switching its patients from brand-name drugs to less costly generic alternatives.⁴

Finally, e-prescribing creates time and workflow efficiencies in pharmacies and clinicians' offices, such as through more efficient prescribing processes, more accurate medication orders and less manual intervention and rework for each prescription. E-prescribing also automates the prescription renewal authorization process, which is extremely time-consuming and labor intensive for both pharmacies and prescribers in today's paper world.

E-Prescribing is Safe and Secure

E-prescribing is far safer and more secure than today's paper world, in which prescription pads are stolen, home computers easily can print out counterfeit prescriptions, signatures can be easily forged, and drug quantities can be altered manually by patients before prescriptions are delivered to the pharmacy

The e-prescribing industry works diligently to ensure the privacy and safety of patient data, and the secure transmission of that data among the various points in the e-prescribing chain. The industry is constantly making changes to ensure that the infrastructure complies with the state of the art, as well as all federal and state standards, laws and regulations.

The industry also actively participates in professional organizations that develop and approve e-prescribing transaction, privacy and security standards, such as NCPDP, HL7 and ANSI. In addition, the e-prescribing industry participates in organizations relating to the security and interoperability of health information technology. For example, RxHub

³ SEMI is a broad coalition involving General Motors, Ford Motor Company, Chrysler LLC, the United Auto Workers (UAW), Blue Cross Blue Shield of Michigan, Health Alliance Plan, Henry Ford Medical Group, Medco Health Solutions, Inc. and CVS Caremark Corporation. SEMI has generated nearly 6.2 million prescriptions using e-prescribing technology since its launch in February 2005. Today there are nearly 2,500 physician participants writing more than 282,000 e-prescriptions each month. Recently released findings show that e-prescribing substantially improved patient safety by alerting physicians of risks related to drug interactions and other potential medication problems and resulted in a significant number of prescription changes that prevented possible adverse events. Based on the program's success thus far, the SEMI coalition partners will extend the e-prescribing initiative into 2008, continuing to enroll physicians through March. (Source: SEMI press release 10/29/07)

⁴ Kosmetatos, Sophia. (2007, October 29). Online Rx program helping cut errors. *Detroit News*.

and SureScripts, are among the e-prescribing infrastructure companies that are certified members of the Electronic Healthcare Network Accreditation Commission (EHNAC), which is a nationally recognized accreditation body with focus on HIPAA privacy/security and improvement of quality and efficiency of healthcare. RxHub and SureScripts networks also are certified for interoperability testing through the Certification Commission for Health Information Technology.

- ***Reliable Authentication of Prescribers.*** Electronic prescriptions will provide pharmacists with a higher level of confidence in the authenticity of prescriptions. Prescriptions will be received only through trusted partners or agents, who have been credentialed and approved to access the secure networks. Prescribers and pharmacies also must securely log on before they can e-prescribe or receive a prescription. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks.
- ***Access to Data.*** E-prescribing systems, network infrastructure and related business practices must comply with all applicable state and federal laws. These ensure authentication before users can access the system, making sure that users really are who they say they are, and providing another layer of protection for patient data. Security procedures are in place to restrict access only to users and other entities in the e-prescribing chain who are contractually obligated to take measures to ensure data privacy in accordance with HIPAA requirements, state laws, and agreed-on business rules. HIPAA mandates that there must be a Business Associate Agreement (BAA) formally binding all covered entities and those they allow to access protected health information on their behalf to the Privacy and Security provisions of HIPAA. This includes e-prescribing vendors, pharmacies, data networks and data providers. Access to patient data is “role based,” meaning that only certain people can access the system on a predetermined “need to know” basis. For example, office managers who need certain demographic data in order to schedule appointments do not have access to write prescriptions. Finally, these processes create additional safeguards for privacy and security that far exceed the minimal and fragmented practices in today’s paper world.
- ***Security.*** E-prescribing networks must comply with all the security provisions of HIPAA. This includes encryption for all exchanges that involve personally identifiable information from the point of prescribing to the point of dispensing. Server operating systems are “hardened,” containing only essential system software. Firewalls enforce a strict access policy for contracted participants and log all traffic on the network. Network intrusion detection systems are in place, and systems are continually monitored and upgraded to prevent breaches. Internal assessments are done periodically using scanning tools to ensure network and system security and annual security risk assessments are conducted using

specialists trained in this field. Data are encrypted before going off-site for backup/disaster recovery purposes.

E-Prescribing and Controlled Substances

Accelerating Adoption of e-Prescribing and EMRs. E-prescribing could be used for controlled substances, but is not allowed at the present time under federal law and regulations promulgated by the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ). Although the proportion of prescriptions for controlled substances is modest--the DEA has estimated that such prescriptions account for up to a fifth of total prescription volume-- the ability to prescribe them electronically will accelerate e-prescribing adoption. That is because a large number of prescribing clinicians are waiting to purchase a system that will prescribe the complete range of drugs their patients need.

E-prescribing of controlled substances will also increase the development and adoption of electronic medical records (EMRs), as the medication history developed through the electronic prescribing process is a major building block for EMRs and for which a complete medication history (including all prescribed drugs) will be essential. Federal policymakers and a growing number of Congressional and state legislators are calling for e-prescribing for controlled substances to enable public and private payers, consumers and others to fully take advantage of the safety benefits, quality of care improvements and increased cost savings accruing from e-prescribing.

Similarly, the current inability to e-prescribe controlled substances is hindering e-prescribing adoption in nursing facilities and other institutional settings, including assisted living facilities, correctional facilities, hospices, and group homes. All patients the range of institutional settings would benefit from the ability to prescribe controlled substance medication orders electronically. In order for prescribing to work in institutional settings, however, some changes would be needed to DEA regulations. For example, the DEA's definition of "LTC Facility" must be expanded to specifically include assisted living facilities and other sites of care, such as hospices. This will be important because current DEA regulations only name "nursing homes, retirement care, mental care or other facilities or institutions which provide extended care to resident patients."

Enhancing patient safety and quality of care. E-prescribing could easily be used to prescribe controlled substances, as the infrastructure exists to handle such transactions and prescription claims currently capture controlled substances. This also could enhance patient safety and quality of care, because the controlled substance information could then be added to a patient's medication history. This will give prescribers a complete picture of all the drugs a patient is taking. The e-prescribing decision support will identify drug-drug interactions, allergies, and other problems from all the medications a patient is taking. Not having this information creates unnecessary holes in the prescribing and clinical decision support processes that could have adverse consequences for patients.

E-prescribing and Drug Diversion and Diversion control

Stopping Abuse and Helping Law Enforcement. Federal and State officials are struggling to keep pace with identifying and prosecuting the diversion of controlled substances. This is further slowed and complicated in today's paper world by the time-consuming and expensive process required for law enforcement staff to painstakingly sift through thousands of paper prescriptions in disparate locations, many months after the fact.

E-prescribing offers a potential solution today to these challenges by helping identify drug abuse and diversion of controlled substances, as well as being a tool for assisting law enforcement create documentation for prosecution of drug diversion. When the paper prescription (printed or written) is removed from the patient's hands, a key capability to deter patient abuse is established. Through its ability to provide at the point of care a patient's medication history and prescriber relationships that the patient has established, e-prescribing achieves a critical care and safety component that additionally greatly reduces the opportunity for patient abuse. In addition, e-prescribing addresses loss of forensic evidence. With appropriate authentication and security/audit controls, proof of prescribing should be maintained. E-prescribing also offers real-time controlled substance reporting and monitoring capabilities that allow the DEA, as well as state and local law enforcement agencies, the ability to identify potential abuse immediately rather than days or weeks after dispensing.

Putting an end to "doctor shopping." E-prescribing also could help to quickly identify patients who doctor shop and garner multiple prescriptions for controlled substances. E-prescribing additionally creates an immediate electronic audit trail that is documented and time-stamped through each point in the process, from the prescribing clinicians' office to the pharmacy. These electronic audit trails show who touched the prescription and when. If the prescription is created and sent electronically, these built-in audit trails also could be used to identify drug shopping, even if the patient pays cash. These records, when subpoenaed, could assist law enforcement in prosecuting diversion control cases, much as is done in today's reactive process.

Guarding against rogue Internet pharmacies. Pharmacies and e-prescriber systems must be registered and certified to access the secure networks and e-prescribing infrastructure provided by RxHub, SureScripts and others. Further, contracts are in place among the participating parties to ensure that prescribers and pharmacies are credentialed and authorized to use the infrastructure. Rogue Internet pharmacies would never pass these stringent safeguards.

It should be noted that there is no silver bullet and that e-prescribing cannot address every instance of drug diversion. E-prescribing, however, will help eliminate illicit prescribers and facilitate the identification of illicit prescribers and prescription channels, which will help mitigate the problem over time.

Conclusion

E-prescribing is safe and secure. It is an effective tool that is saving lives, improving the quality of healthcare and reducing the costs of care. The inability to e-prescribe controlled substances is preventing patients, prescribers and payers from taking advantage of these benefits. Moreover, the inability to e-prescribe controlled substances is depriving law enforcement of a tool that could help stop illicit prescribing and doctor shopping and assist with diversion control.

The time has come to permit e-prescribing of controlled substances. The DEA and DOJ need to promulgate regulations immediately for e-prescribing of controlled substances. These rules need to be technology neutral; build on today's safe and secure e-prescribing infrastructure; and allow for future changes and growth in technology, privacy and security safeguards, and industry expansion.

The rules also should take into account e-prescribing for controlled substances in institutional settings where an electronic prescription/order must be sent from the prescriber to the pharmacy and facility/institution. The definition of facility should be expanded not only to include nursing homes, but also assisted living facilities, correctional facilities, hospices, group homes, etc. The unique, three-way communication in these settings will need to be addressed in DEA regulations and applicable standards.

Forthcoming rules also need to preserve some of the features of today's regulations with respect to long-term care and institutional settings, such as allowing facility nurses to act as the agent of the prescriber. This should be the case for controlled substance electronic prescribing as well.

In conclusion, the country can no longer afford to have a two-tiered process for prescribing controlled substances. E-prescribing for controlled substances is needed now, and can be made possible through expedited rulemaking. It is time for the e-prescribing and law enforcement communities to work together to harness all of the attendant benefits that health information technology can provide to the nation's health care system and the consumers it serves.