

Electronic Prescribing Workgroup

Resources

August 19 2011

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SENATE RESOLUTION NO. 81

BY SENATOR MILLS

A RESOLUTION

To create the Legislative Workgroup on Electronic Prescribing to study and make recommendations concerning electronic prescribing.

WHEREAS, Louisiana is working to adopt electronic medical records systems; and

WHEREAS, a survey of physicians recently conducted by the American Medical Association found significant concerns among physicians about health insurer prior authorization requirements for both procedures and prescription medications, as well as the timely adjudication of such matters; and

WHEREAS, prior authorization programs have the potential to delay or limit access to needed treatments; and

WHEREAS, emerging electronic medical record systems may increasingly offer physicians the convenience of knowing whether a medication is covered by a health plan, and whether there are utilization management limitations associated with a medication, but health plans continue to require the submission of a prior authorization request via a paper system; and

WHEREAS, physicians often do not know the criteria for approval by a health plan of a requested treatment; and

WHEREAS, the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA), provides federal incentives for Medicare and Medicaid providers and hospitals to implement, adopt and upgrade health information technology, including electronic prescribing and electronic health record systems; and

WHEREAS, states are responsible for administering the incentive payments, and have already begun embarking on their own health IT initiatives; and

WHEREAS, the United States Department of Health and Human Services recently released guidance encouraging states to pursue the implementation of health information technology as a key to driving down health care costs; and

WHEREAS, the goals of electronic prescribing and health information technology systems are to strengthen the physician patient relationship, improve patient care by allowing physicians to coordinate care across all specialties/fields, facilitate improved quality management of chronic disease thereby reducing health system costs, and allow physicians to monitor medication adherence.

THEREFORE, BE IT RESOLVED that the Senate of the Legislature of Louisiana does hereby establish and create the Legislative Workgroup on Electronic Prescribing to study and make recommendations to the legislature concerning electronic prescribing which at a minimum would accomplish the following:

- (1) Seek to limit marketing in electronic health record systems.
- (2) Seek to encourage the provision of evidence based information at the point of care for the prescriber and patient.
- (3) Standardize prior authorization to maximize administrative simplification and efficiency and adopt a universal prior authorization form to be made available for electronic use.
- (4) Provide for a patient's freedom of choice with respect to the selection of a pharmacy.
- (5) Provide for user authentication, audit, and physical security.

BE IT FURTHER RESOLVED that the Legislative Workgroup on Electronic Prescribing is hereby established and shall be composed of the following members

- (1) One representative appointed by the Louisiana State Board of Pharmacy who will serve as co-chair.
- (2) One representative of the Louisiana State Board of Medical Examiners who will serve as co-chair.
- (3) One representative of the Department of Health and Hospitals.
- (4) One representative of the Department of Insurance.
- (5) One representative appointed by the Louisiana State Medical Society.
- (6) One representative appointed by the Louisiana Academy of Family Physicians.
- (7) One representative appointed by the Louisiana Independent Pharmacies Association.

(8) One representative appointed by the Pharmaceutical Researchers and Manufacturers of America.

(9) One representative appointed by the Louisiana Association of Health Plans.

(10) One representative appointed by the Louisiana Healthcare Quality Forum.

(11) One representative appointed by the Louisiana Hospital Association.

(12) One representative of the Louisiana Workman's Compensation Commission.

(13) One representative of the Louisiana Association of Self Insured Employers.

(14) One representative of eQHealth Solutions.

(15) One representative of the National Association of Chain Drug Stores.

(16) One representative of the Louisiana Orthopedic Association.

(17) One representative of the Louisiana State Board of Nursing.

(18) One representative of the Louisiana Association of Nurse Practitioners

(19) One representative of Medicine Louisiana, Inc.

(20) One representative of the Louisiana Chapter of the American Academy of Pediatrics.

(21) One representative of the Louisiana State Board of Optometry Examiners.

BE IT FURTHER RESOLVED that the workgroup shall study and provide recommendations on the following aspects of electronic prescribing systems:

(1) Best practices to maintain a neutral platform for the secure electronic transmission of health data including, but not limited to medication history, formulary status, and other patient information health professionals typically access when prescribing medication and other interventions.

(2) Best practices to assure attempts to influence, through economic incentives or otherwise, the prescribing decisions of the practitioner at the point of care can be kept to a minimum and focused on patient safety and outcomes that maximize patient and provider freedom of choice.

(3) Best practices to assure messages in electronic prescribing systems are substantially supported by scientific evidence, accurate, up to date, and fact based, including a fair and balanced presentation of risks and benefits, and support for better clinical decision making, such as alerts to adverse events and access to formulary information.

(4) Best practices to establish a process to provide electronic prior authorization request and approval transactions between providers and group purchasers.

BE IT FURTHER RESOLVED that the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners shall coordinate, facilitate and support the functions and duties of the Legislative Workgroup on Electronic Prescribing.

BE IT FURTHER RESOLVED that the Legislative Workgroup on Electronic Prescribing shall submit a report to Senate Committee on Health and Welfare, the Louisiana Board of Pharmacy, and the Louisiana State Board of Medical Examiners on or before January 1, 2012.

BE IT FURTHER RESOLVED that the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners shall coordinate, facilitate, and support the functions and duties of the study group.

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the Louisiana Board of Pharmacy, the Louisiana State Board of Medical Examiners, the Louisiana Department of Health and Hospitals, the Louisiana Department of Insurance, the Louisiana State Medical Society, the Louisiana Academy of Family Physicians, the Louisiana Independent Pharmacies Association, Pharmaceutical Researchers and Manufacturers of America, the Louisiana Association of Health Plans, the Louisiana Healthcare Quality Forum, the Louisiana Hospital Association, the Louisiana Workman's Compensation Commission, Louisiana Association of Self Insured Employers, eQHealth Solutions, the National Association of Chain Drug Stores, the Louisiana Orthopedic Association, Louisiana State Board of Nursing, the Louisiana Association of Nurse Practitioners, Medicine Louisiana, Inc., the Louisiana Chapter of the American Academy, and the Louisiana State Board of Optometry Examiners.

PRESIDENT OF THE SENATE



THE NATIONAL PROGRESS REPORT

ON E-PRESCRIBING AND INTEROPERABLE HEALTHCARE

YEAR **2010**



surescripts®

neutrality

transparency

physician and patient choice

open standards

collaboration

privacy

THE EVOLUTION OF E-PRESCRIBING

- 190,000—or 36%—of office-based physicians e-prescribe.
- Surescripts announces network expansion to allow clinicians to exchange all types of clinical messages with their peers.
- The U.S. Drug Enforcement Administration allows the option of issuing prescriptions for controlled medications electronically.
- Patient Protection and Affordable Care Act passes.

- CMS issues Medicare Part D e-prescribing incentive regulations.
- DEA proposes rule to allow e-prescribing for controlled substances.
- Medicare Improvements for Patients and Providers Act (MIPPA) passes; includes e-prescribing incentives.
- RxHub and SureScripts merge to form SureScripts-RxHub.

- CMS pilot-tests proposed Medicare Part D e-prescribing standards.
- First annual Safe-Rx Awards recognize top e-prescribing states.
- Institute of Medicine releases pivotal “Preventing Medication Errors” report.

- Approximately 2,500—or 0.4%—of office-based prescribers use e-prescribing.
- Office of the National Coordinator for Health Information Technology (ONC) is established.
- SureScripts launches e-prescribing community adoption programs.

- RxHub begins network operations.

2011

2010

2009

2008

2007

2006

2005

2004

2003

2002

2001

- American Recovery and Reinvestment Act provides \$19 billion toward adoption of health information technology.
- CMS releases proposed regulations defining meaningful use of EMRs. E-prescribing is a key component.
- Medicare launches MIPPA e-prescribing incentive program.
- Rhode Island announces 100 percent of its pharmacies are enabled for e-prescribing.
- SureScripts-RxHub is relaunched as Surescripts.

- Center for Improving Medication Management launched.
- E-Prescribing becomes legal in all 50 states and D.C.
- National E-Prescribing Safety Initiative launched.
- SureScripts, RxHub, Informed Decisions and the AMA launch ICERx.org to assist victims of natural disasters.

- First proposed “foundation standards” released for Medicare Part D e-prescribing.
- HHS issues Stark exemptions and fraud and abuse safe harbors.
- SureScripts and RxHub help launch www.katrinahealth.org to support victims of Hurricane Katrina.

- Institute of Medicine endorses National Health Information Infrastructure.
- Medicare Modernization Act provides incentives for e-prescribing adoption.
- SureScripts begins network operations.

- RxHub founded.
- SureScripts founded.

INTRODUCTION



A LETTER FROM THE PRESIDENT AND CEO

I am very pleased to introduce *The National Progress Report on E-Prescribing and Interoperable Healthcare for 2010*. The fourth edition of this annual report documents the status of electronic prescribing's adoption and use throughout the U.S. and features a broader analysis of the nation's drive towards more interoperable healthcare.

With over 34 percent of the nation's prescribers actively managing prescriptions electronically and 25 percent of prescriptions transmitted by this method at the end of 2010, e-prescribing is now well on its way to becoming mainstream practice. Replacing phone-, fax- and paper-based prescribing with secure electronic exchange is improving medication management, increasing patient convenience and reducing costs for all healthcare participants. What's more, the factors behind e-prescribing's success serve as a model for broader adoption and use of health IT.

The unprecedented collaboration between the public and private sectors—Whether working together on standards or on the appropriate mix of incentives for providers, the growth of e-prescribing has proven the critical importance and effectiveness of collaboration between federal and state governments and the entire healthcare industry.

The many tangible benefits for all e-prescribing participants—Benefits include fewer medical errors due to poor handwriting; greater awareness of potential adverse drug interactions; more effective communication of a patient's insurance coverage and generic alternatives; increased adherence; more accurate, efficient and lower-cost means for physicians, pharmacies and payers to communicate and process prescriptions; and a more convenient means for patients to obtain the prescription drugs they need.

Surescripts' commitment to collaborating with all healthcare participants to realize a neutral nationwide e-prescribing network—In addition to neutrality and collaboration, Surescripts' long-standing principles of transparency, open standards, protection of physician choice of therapy and patient choice of pharmacy, and privacy protection have created an ecosystem that enables the rapid growth of e-prescribing.

The vision and support of the nation's community pharmacies and leading PBMs—Ten years ago, leaders from these organizations saw the opportunity and took action together to dramatically improve one of the largest segments of the nation's healthcare system.

And now Surescripts is pleased to extend this model to allow providers to exchange clinical information with their peers. In doing so, we are responding to a clear need in the market for a nationwide network for clinical interoperability, one that supports HITECH Meaningful Use requirements and serves emerging models of collaborative care. We are committed to applying the same principles and lessons learned from e-prescribing to further inform and improve health care outcomes, patient safety, and the overall doctor-patient relationship.

I encourage you to explore our 2010 report to learn more about how e-prescribing and interoperable healthcare are growing and driving the digital transformation of the nation's healthcare system.

Regards,

A handwritten signature in blue ink, appearing to read 'HT', written over a light blue grid pattern.

Harry Totonis
President and CEO, Surescripts



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INTRODUCTION

The need for the secure and timely electronic exchange of clinical health information has been identified as fundamental for supporting ongoing improvements in the quality and efficiency of healthcare.

The combination of an aging population and higher demands for healthcare through recent reform efforts is accelerating the demand and adoption of health-related technology. Government incentive programs consider the use of such technology to be critical toward promoting a more efficient and more collaborative environment for patient care.

Measuring the adoption and use of health information technology will be essential to determine if such technology is living up to its promise. As the most established form of electronic clinical message exchange, electronic prescribing (e-prescribing) can serve as a valuable bellwether for assessing

the overall use of health-related technology. As evidenced through e-prescribing's high rates of growth, the electronic exchange of healthcare information is on a path to becoming mainstream.

As the organization that manages the nation's e-prescription network, Surescripts has been in an ideal position to observe and report on the growth of e-prescribing through its annual *National Progress Report on E-Prescribing*. This year's report tracks the adoption and use of e-prescribing between 2008 and 2010.

For 2010, the *Report* offers analysis of statistical trends and underlying factors that extend beyond e-prescribing. Future editions of the *Report* will feature qualitative and quantitative analysis on a broader set of factors driving the overall interoperability of the nation's healthcare system.

EXECUTIVE SUMMARY

E-Prescribing Adoption and Use

Significant growth was seen between 2008 and 2010 in the adoption and use of the three critical steps that enable the e-prescribing process: prescription benefit, medication history and prescription routing.

Part 1: Electronic Prescribing Use

- **Prescription Benefit:** Electronic responses to requests for prescription benefit information grew 125% from 188 million in 2009 to 423 million in 2010.
- **Medication History:** Prescription histories delivered to prescribers grew 184% from 81 million in 2009 to 230 million in 2010.
- **Prescription Routing:** Prescriptions routed electronically grew 72% from 191 million in 2009 to 326 million in 2010.
- **EHR vs. Standalone E-Prescribing Software:** About 79 percent of prescribers used EMRs in 2010, up from 70 percent in 2009.

Part 2: Electronic Prescribing Adoption

- **Prescribers:** The number of prescribers routing prescriptions electronically grew from 156,000 at the end of 2009 to 234,000 by the end of 2010—representing about 34 percent of all office-based prescribers.
- **Payers:** At the end of 2010, Surescripts could provide access to prescription benefit and history information for more than 66 percent of patients in the U.S.
- **Community and Mail Order Pharmacies:** At the end of 2010, approximately 91 percent of community pharmacies in the U.S. were connected for prescription routing and six of the largest mail order pharmacies were able to receive prescriptions electronically.

Part 3:

Industry Drivers

The federal government is playing a significant role in influencing the growth of interoperable health technologies.

Drivers of Interoperable Healthcare in 2010

- **HITECH:** Incentive programs offered through the Health Information Technology for Economic and Clinical Health Act.
- **MIPPA:** Incentive programs offered through the Medicare Improvements for Patients and Providers Act.

Future Drivers of Interoperable Healthcare Growth

- **PPACA:** Reform efforts under the Patient Protection and Affordable Care Act.
- **EPCS:** DEA regulatory changes that give prescribers the option of issuing prescriptions for controlled substances electronically.

Recommendations

To support the continued growth of interoperable health-care—including e-prescribing—Surescripts recommends extending the collaboration between government and industry in order to:

- **Drive utilization:** Continue to develop programs that focus on driving the utilization of e-prescribing and interoperable health technologies.
- **Bridge adoption gaps:** Address gaps in e-prescribing and EHR adoption by solo practitioners, by independently owned pharmacies and by state Medicaid programs.
- **Promote clinical collaboration:** Support emerging collaborative models of care.

INTRODUCTION

PROFILES IN INTEROPERABLE HEALTHCARE:

CREATING CONNECTIONS THAT LAST—A Q&A WITH SURESCRIPTS' BOARD OF DIRECTORS

Surescripts was founded by the nation's retail pharmacies and the largest pharmacy benefit managers to transform the delivery, safety and efficiency of healthcare. Though long-time competitors, the benefits to all healthcare consumers compelled pharmacies and PBMs to take action together—despite their differences. By creating a neutral network based on industry standards, the Surescripts network has grown to become the nation's largest health information network.

The following interview with the Surescripts board of directors highlights how this was accomplished and how the Surescripts network creates a unique opportunity for all parts of the nation's healthcare system to connect, collaborate and transform healthcare.

Surescripts' Board of Directors

John Driscoll (Co-Chairman)—Medco Health Solutions

Donald C. Huonker (Co-Chairman)—Walgreens

Steve B. Miller, M.D.—Express Scripts

Ralph Petri—Kerr Drug

Jeffery T. Smith—CVS Caremark

Doug Hoey, R.Ph.—National Community Pharmacists Association

It's no secret that your organizations have been seen as competitors by the industry. What ultimately made you decide to work together when it came to e-prescribing and Surescripts?

John Driscoll: Much of our decision to work together stemmed from a shared belief in the benefits and opportunities that exist with e-prescribing. E-prescribing is inclusive of every party interested in high-quality, accurate and affordable prescriptions.

Don Huonker: Surescripts enables all “boats to rise”—independent of business model and whether or not we may be competitors. In the end, working together lets us improve health outcomes for our patients and enables lower costs for the healthcare system.

What role does e-prescribing play and what value does it bring to the nation's efforts to reform healthcare?

John Driscoll: With e-prescribing, we have a working parable of success. It enhances the entire healthcare system by bringing to bear 21st-century technological standards for mobility and quick and secure access to information. Moreover, e-prescribing improves outcomes for all parties and reduces costs.

Don Huonker: E-prescribing enables improved health outcomes while helping to lower costs—the sweet spot of health reform. E-prescribing improves the safety and quality of the prescribing process while reducing costs by increasing efficiencies for all stakeholders in the value chain. The neutrality and transparency of Surescripts help enable this collaborative solution.

“E-PRESCRIBING IS INCLUSIVE OF EVERY PARTY INTERESTED IN HIGH-QUALITY, ACCURATE AND AFFORDABLE PRESCRIPTIONS.”

Are you surprised by the significant growth in e-prescribing, or is it in line with what you thought was possible when Surescripts began?

Steve Miller: The growth of e-prescribing has surprised me in several regards. In the first place, adoption and growth have been much slower than any of us anticipated 15 years ago. For what appears to be a compelling case (safer, more affordable and more convenient), the initial uptake was much slower than originally anticipated. However, the growth in the last two years has been astonishing. We have reached the proverbial tipping point.

What do you think are the most significant benefits that e-prescribing has brought to the market?

Ralph Petri: The most significant benefit e-prescribing has brought to the market is a high-quality electronic network that allows providers to communicate in a very secure and efficient manner. Surescripts has created a platform that will enable healthcare providers to use the network for many more healthcare transactions, which will ultimately lead to much improved health outcomes at a significant savings.

Many point to Surescripts' neutrality and collaboration as two of its key attributes. What do neutrality and collaboration mean to your organizations, and why are they important to a network like Surescripts?

Steve Miller: Surescripts has been successful because it is both collaborative and neutral. Prior to the merger of RxHub and Surescripts, you had two distinct entities competing in the same space. By collaborating and merging, the combined company became greater than the sum of the two parts. It was truly synergistic. Continued growth has occurred because the diverse ownership has required ongoing collaboration and neutrality.

“NEUTRALITY AND COLLABORATION ARE ESSENTIAL FOR SURESCRIPTS TO SUCCEED.”

Ralph Petri: Neutrality and collaboration are essential for Surescripts to succeed. Competing providers must have confidence that the network is being used to advance improved patient outcomes and not provide any specific advantage to individual providers or segments of the market.

Some skepticism appears to exist around e-prescribing for some independents. How has e-prescribing benefited independents? What still needs to be done to get everyone connected?

Doug Hoey: Years ago, when many pharmacies first signed up, there was not a critical mass of e-prescriptions coming in from physicians. However, now that we are seeing 20 percent of prescriptions coming through as e-prescriptions, the need is much clearer.

From a benefit standpoint, we are starting to see increased efficiency and safety. Increased efficiency allows pharmacists more time to spend with patients—i.e., more time to provide clinical services that they often don't have time for.

The physician incentives have clearly worked to attract more physicians to e-prescribing. This, in turn, has helped spur demand among independent pharmacies. The vast majority of independent pharmacies are now e-prescribing and I believe we are at the last mile.

How important are the principles of neutrality and collaboration when it comes to facilitating the broader exchange of health information (e.g., labs, referrals, summaries)?

Jeff Smith: Healthcare is undergoing a fundamental shift. Managing costs is not enough—all stakeholders must drive outcomes. This, in turn, is driving healthcare toward a more integrated, more collaborative model of care in which

providers need access to the right information at the right time. Without neutrality, nobody can support this new business model.

Doug Hoey: Those are the cornerstones of Surescripts and they are absolutely essential to facilitating broader health information exchange. It is important to keep in mind that the Surescripts network is voluntary. Organizations choose to collaborate on the network. If an organization ever felt it was being disadvantaged, it would no longer use the network. If organizations stop using the network, then there is no collaboration. Without collaboration, you lose the integration of healthcare that leads to lower costs and better patient outcomes.

E-prescribing has grown more than sixfold in the last two years. What lessons can the nation apply to achieve similar rates of growth in clinical message exchange?

Jeff Smith: The first lesson is that everyone must benefit from the system. With e-prescribing, physicians, pharmacies, payers and patients all benefit from improved safety and efficiency.

“BY ENABLING COLLABORATION BETWEEN HEALTHCARE PROVIDERS, WE ARE OPTIMIZING THE SYSTEM..”

The second lesson is that e-prescribing has proven that collaboration works. Take standards as an example. Pharmacies, PBMs and prescriber technology vendors demonstrated—through their work with NCPDP—how to develop standards in an inclusive way that would be acceptable to all. Driving ease of use is another example: e-prescribing really started to take off when it became easier for prescribers to implement. Improved ease of use was enabled by stakeholders collaborating on certification and otherwise working together to improve the prescriber experience.

Surescripts and MinuteClinic have already taken these lessons and successfully applied them to clinical message exchange. As one of the earliest implementations of the CCR standard, MinuteClinic nurse practitioners are able to exchange clinical messages with their patients' physicians. By enabling collaboration between healthcare providers, we are optimizing the system and creating better outcomes for patients.

REVIEW: E-PRESCRIBING UTILIZATION AND ADOPTION GROWTH

Electronic prescribing, or ‘e-prescribing,’ supports a shift to a paperless and more informed way for prescribers, payers and pharmacists to make clinical decisions and improve work flows related to medication management.¹

Significant growth was seen between 2008 and 2010 in the adoption and use of the three critical services that enable the e-prescribing process: prescription benefit, medication history and prescription routing.

PART 1: ELECTRONIC PRESCRIBING USE

PRESCRIPTION BENEFIT

Surescripts works with the nation’s payers and PBMs to offer prescribers access to their patients’ prescription benefit—formulary and eligibility—information in real time during a patient encounter.

Electronically accessing a patient’s prescription benefit information allows prescribers to choose medications that are on formulary and are covered by a patient’s drug benefit.

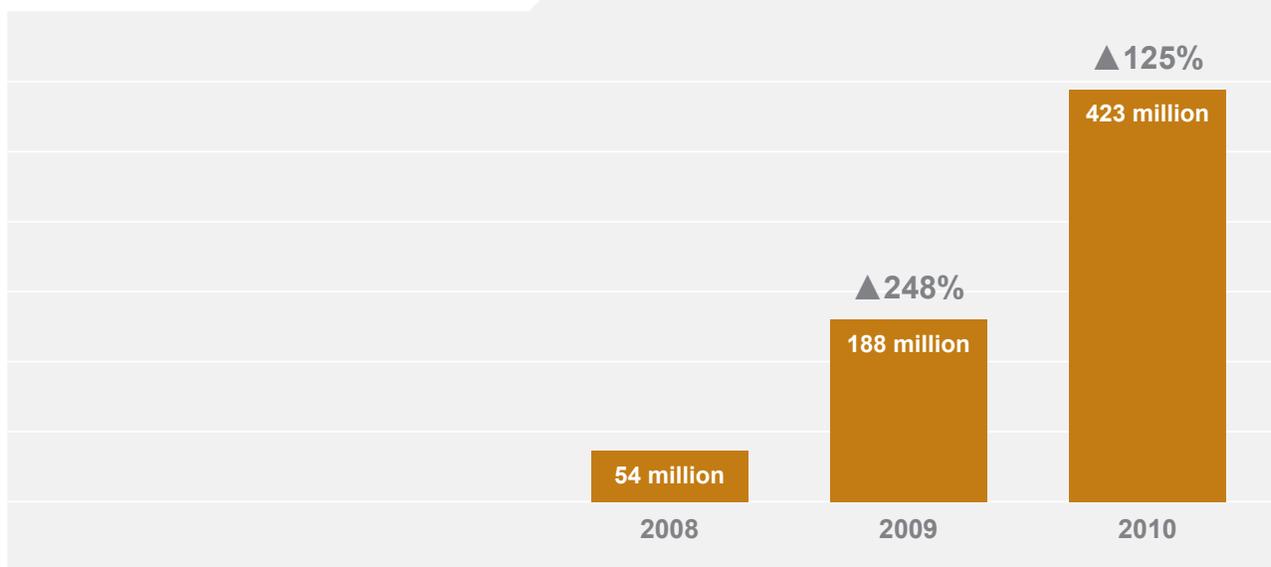
Prescribers access prescription benefit information using software provided by a vendor that is certified by Surescripts for this service.²

1 IN 3 PATIENT VISITS NOW INCLUDES THE OPPORTUNITY TO LOWER PRESCRIPTION COSTS

KEY STATISTICS

- Electronic responses to requests for prescription benefit information grew 125 percent in 2010.
- On average, the response rate to prescription benefit requests (the rate at which information for the patient can be returned to the prescriber) was approximately 69% in 2010, up from 62% in 2009.
- Approximately 36 percent of patient visits involved one of these responses in 2010, up from 19 percent in 2009.³

Prescription Benefit Responses



Contributing Factors	2008	2009	2010
Active Prescribers (pg. 15)	74,000	156,000	234,000
Number of E-Prescribing Applications Certified for this Service (pg. 14)	43	78	137

Page 8 Footnote:

1 To view a demonstration of how e-prescribing works, please visit <http://www.surescripts.com/about-e-prescribing/how-e-prescribing-works.aspx>.

Page 9 Footnotes:

2 For more information about Surescripts certification, go to <http://surescripts.com/connect-to-surescripts/certification-overview.aspx>.

3 According to the August 2009 National Ambulatory Medical Care Summary, an estimated 956 million visits were made to office-based physicians in 2008 (data released 2010), an average of about 309 visits for every 100 persons—using 2010 U.S. population figure of approximately 309 million.

PART 1: ELECTRONIC PRESCRIBING USE

MEDICATION HISTORY AVAILABLE FOR MORE THAN TWICE AS MANY OFFICE VISITS IN 2010

MEDICATION HISTORY

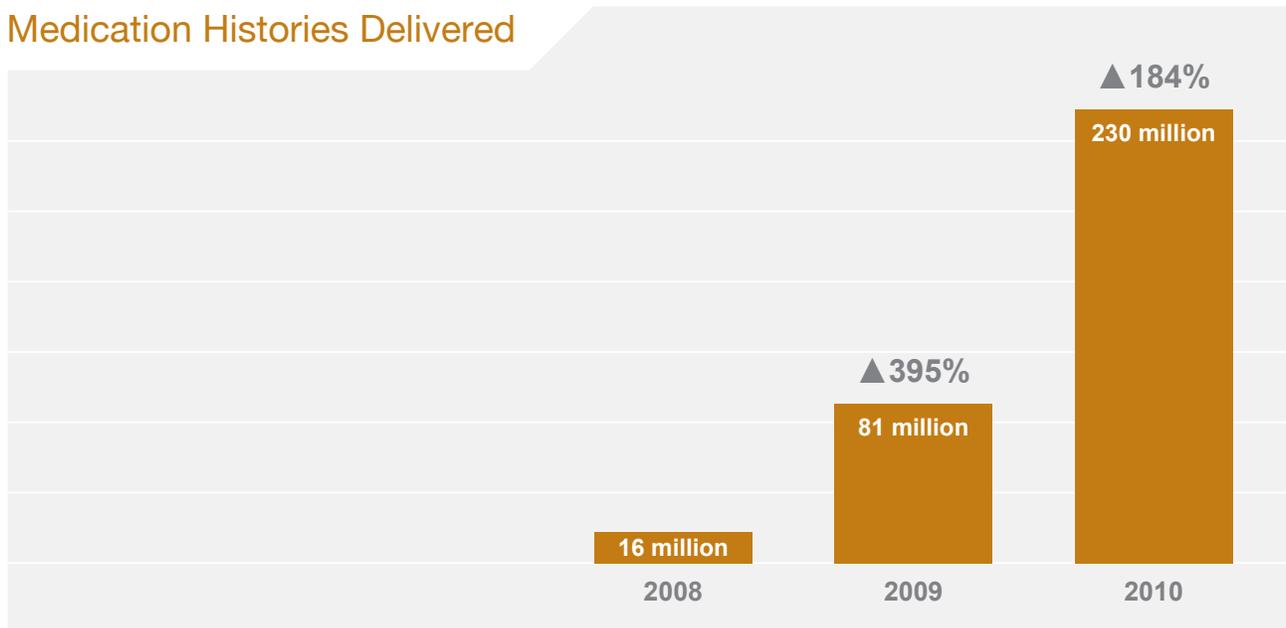
With a patient's consent,⁴ medication history allows a prescriber to review a more complete record of patient medication by electronically requesting and receiving history information from payers and community pharmacies.

Surescripts works with payers and community pharmacies to make this information available to prescribers nationwide. Prescribers access medication history information through software provided by a vendor that is certified by Surescripts for this service.

KEY STATISTICS

- The number of medication histories delivered to prescribers electronically grew 184 percent.
- Approximately 24 percent of patient visits involved an electronically delivered medication history in 2010, up from 9 percent in 2009.
- In addition, medication history was electronically accessed by clinicians working in acute-care environments to support transitions in care.
- In 2010, over 14.6 million medication histories were delivered to clinicians in this environment.

Medication Histories Delivered



Contributing Factors	2008	2009	2010
Active Prescribers (pg. 15)	74,000	156,000	234,000
Number of E-Prescribing Applications Certified for this Service (pg. 14)	42	76	133

PROFILES IN INTEROPERABLE HEALTHCARE

MEDICATION HISTORY IN THE ACUTE SETTING



Dr. Tom McGill, Vice President, Quality and Safety
Butler Health System, Butler, PA

“You can’t practice good medicine if you don’t have an accurate, up-to-date medication list for the patient. This service has added significant value for us in terms of vastly expanding the physician’s knowledge base.”

Introduction

As aggregated records of patient medication history can now be delivered to acute-care settings, hospitals and other institutions are now finding new ways to streamline the medication reconciliation process.

Description

With more than 40,000 patients per year coming into their ER, Butler Health System was looking for solutions to help streamline the medication-reconciliation process. Medication reconciliation—in the absence of networked health technology—involves generating an active medication list for each incoming patient by using a combination of an interview process and phone- or fax-based follow-ups. Completeness and accuracy in the process are paramount, but the time needed to achieve it can be significant. While a Joint Commission standard, real-world performance of medication reconciliation can have significant flaws.

As a forward-looking institution, Butler piloted electronically sourced medication history as part of a larger program to build efficiencies, adopt patient-centered best practices and achieve higher standards of care through the implementation of health technology. This pilot provided an opportunity for Butler to assess the return on investment of this electronic service by comparing the use of technology against standard practice.

Study Design

In a randomized sample of 160 ER visits, Butler compared 71 visits that used electronically accessed patient medication history—accessed through the hospital’s

Health Monitoring Systems MediCenter application, with a connection to the Surescripts network—with 89 visits that used the standard medication reconciliation process.

Key measurement factors included the number of medications reported, the time needed to acquire a thorough medication history and the extent to which clinically significant medications were discovered.

Results

Through its analysis, Butler determined that use of electronically sourced medication history information achieved an average delivery of approximately 95 percent of current patient medications versus just 70 percent when relying on a patient interview alone. The pilot study also demonstrated that it would take an average of 19 additional minutes of staff time to achieve the 95 percent threshold using standard phone- and fax-based follow-ups.

In addition, when the study control group was reexamined using the acute-care medication history service, a number of clinically significant medications were discovered—including cardiac drugs and antibiotics—that had not been discovered using the interview-based process alone.

Next Steps

Having demonstrated the clinical utility and cost-effectiveness of electronically delivered patient medication history, Butler Health System now uses this service as part of its standard patient intake process within the ER. Future plans include expansion of the service hospital-wide.

PART 1: ELECTRONIC PRESCRIBING USE

1 IN 4 PRESCRIPTIONS IS NOW AN E-PRESCRIPTION

PRESCRIPTION ROUTING

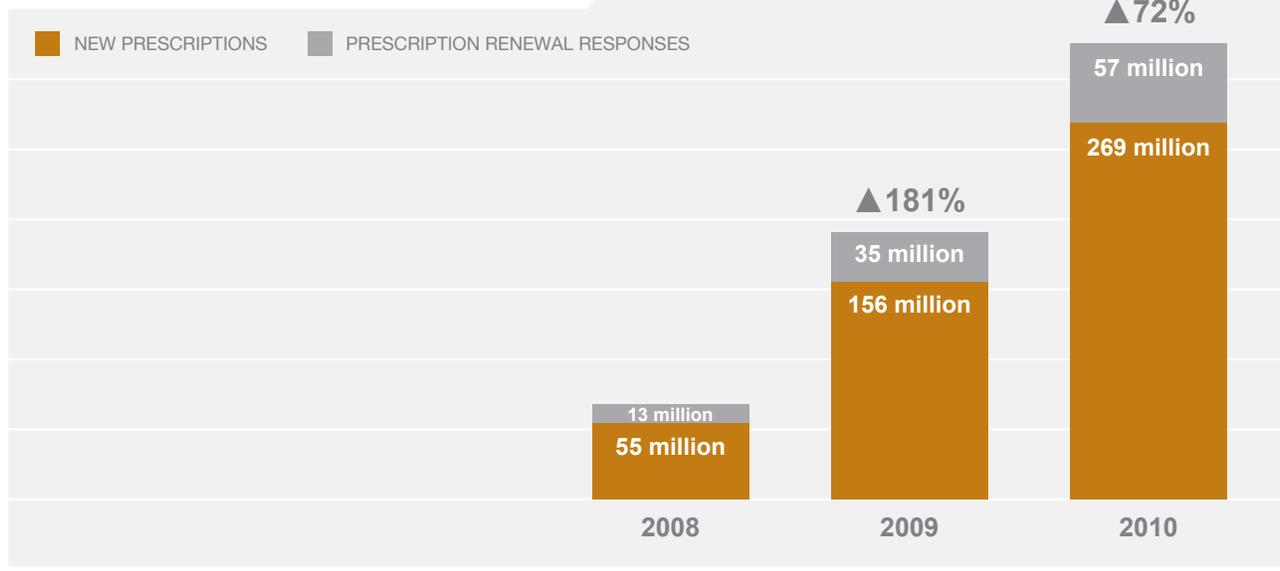
Prescription routing allows new prescriptions to be sent electronically to the computer system at the pharmacy of the patient's choice, as opposed to sending it by fax, calling it in or writing it on paper. Renewal authorization requests can be sent electronically from a pharmacy's computer to a practice's e-prescribing software, where they can be reviewed and responded to.

Prescribers exchange prescription information with pharmacies electronically and bi-directionally using software provided by a vendor that is certified by Surescripts for this service.

KEY STATISTICS

- At the end of 2010, approximately one in four prescriptions was delivered electronically, up from one in 18 prescriptions at the end of 2008.
- About 20 percent of eligible prescriptions were sent electronically in 2010 versus 12 percent in 2009.⁵
- By December 2010, approximately 25 percent of eligible prescriptions were being sent electronically.⁶
- Over 326 million prescriptions were routed electronically in 2010 versus 190 million in 2009—a 72 percent increase.⁷
- Of this, over 8 million electronic prescriptions were routed to mail order pharmacies.

Prescription Routing Transactions



Contributing Factors	2008	2009	2010
Active Prescribers (pg. 15)	74,000	156,000	234,000
Number of E-Prescribing Applications Certified for this Service (pg. 14)	80	134	196
Connected Community Pharmacies (pg. 19)	76%	85%	91%

PROFILES IN INTEROPERABLE HEALTHCARE

QUALITY: THE KEY TO MORE CONFIDENT, FREQUENT AND MEANINGFUL USE



David Yakimischak, Chief Quality Officer
Surescripts

“We believe that quality must be actively managed and not left to chance.”

Through its industry-wide quality program, Surescripts is committed to improving the end-to-end quality of e-prescribing—from the time a prescription is first considered by the prescriber to the time the medication is dispensed and at all points in between. Our efforts to measure, analyze and continually improve quality help us to minimize potential issues while helping to more fully realize the benefits of e-prescribing. We do this in two ways: first, through the management of our own operations, and second, through our end-to-end work with participants on the Surescripts network. This proactive approach requires a combination of skills from pharmacists, clinicians, technologists and Six Sigma Black Belt experts.

While the focus to date has been on e-prescribing, the Surescripts quality management program is being extended to improve other forms of health information exchange. Moving health information electronically is not enough—it must be accurately and reliably communicated. We believe that quality must be actively managed and not left to chance.

Driving Quality Improvements in 2010

In 2010, we took significant steps toward achieving 100 percent reliability of the end-to-end e-prescribing process:

- By conducting clinical quality reviews on millions of electronic prescription messages, Surescripts has been able to measure and analyze the safety, accuracy and completeness of the electronic prescriptions that have flowed through the network.⁸ This has enabled Surescripts to publish industry guidelines that define what an electronic prescription should or should not contain in order to convey to the pharmacist and the patient the clinician's therapeutic intent in an accurate, understandable, complete, unambiguous and efficient manner. These guidelines are available at <http://www.surescripts.com/eprescribingquality/page/guidelines.aspx>.
- Surescripts created quality measurement scorecards for vendors, practices and pharmacies. We shared these scorecards with our network participants and sought their commitment to enhancing their operations as part of the end-to-end focus on quality improvements.
- Surescripts completed the ISO quality standards 17025 and 65 required by the Office of the National Coordinator for Health Information Technology to become an ONC-authorized certification and testing body for e-prescribing in support of the HITECH meaningful use requirements. These independent quality standards confirm that Surescripts is following the highest standards for quality processes.

Quality's Broader Role in Interoperable Healthcare

In 2011, Surescripts will conduct more in-depth measurement and analysis of e-prescribing quality while broadening its perspective to include all types of health information.

Within e-prescribing, Surescripts will go beyond conformance with guidelines to measure how often prescriptions require pharmacy intervention. An intervention is typically defined as a phone call made from the pharmacy back to the prescriber to clarify or confirm the prescriber's intent. Such measurement and analysis will afford the industry a deeper understanding of how much more efficient e-prescriptions are compared to paper prescriptions and what opportunities exist to continually improve that efficiency.

Surescripts will also look to develop new methods for measuring and analyzing the quality of prescription benefit and medication history messages, along with other types of clinical messages. As part of this effort, we will work with physicians, pharmacies, PBMs, payers and the technology vendors that serve all these network participants to gain a more detailed understanding of how quality improvements in work flow, safety and efficiency not only can reduce the risk of potential issues but also provide more value for these participants and the patients they serve. By looking to improve all aspects of quality, Surescripts aims to drive more confident, frequent and meaningful use of health information.

For more information and to get more involved, visit www.surescripts.com/about-us/quality-program.aspx.

Page 12 Footnotes:

5 This calculation is based on the 326 million new prescriptions and renewal responses electronically transmitted in 2010 and the 1.66 billion new prescriptions and renewals eligible for electronic routing in 2010 in the U.S., according to NACDS. (Note: These 1.66 billion prescriptions do not include controlled substances, as Surescripts did not observe any instance of a controlled substance being delivered electronically to pharmacies in a manner compliant with DEA regulations. This figure also excludes preauthorized refills on existing prescriptions, as they do not require communication between a physician and a pharmacist.)

6 Note: The potential addition of prescriptions for controlled substances to the total number of prescriptions that are eligible for electronic routing in 2011 will affect the overall calculations for the percentage of prescriptions that are delivered electronically for the 2011 calendar year. It is estimated that 19 percent of total prescriptions written are for controlled substances, not counting preauthorized refills.

7 Requests for prescription renewals are not represented in this section, as prescription renewal requests do not lead directly to the issuing of prescription orders.

Page 13 Footnote:

8 When conducting clinical quality reviews of prescriptions, no personal health information is accessed.

PART 1: ELECTRONIC PRESCRIBING USE

EHR VS. STANDALONE E-PRESCRIBING SOFTWARE

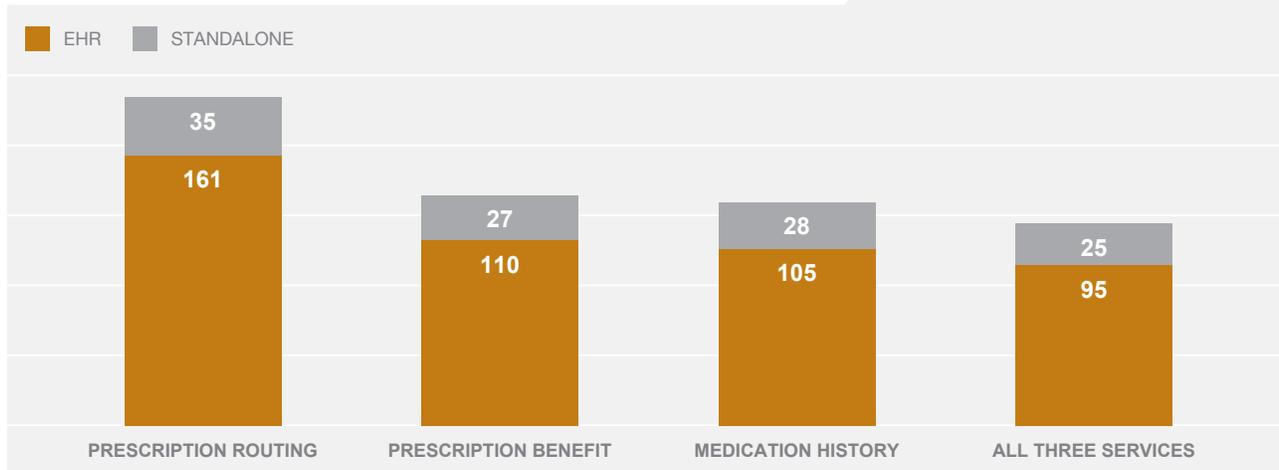
EHRs OUTNUMBER STANDALONE E-PRESCRIBING APPLICATIONS BY 4 TO 1

Prescribers e-prescribe using either electronic health record (EHR) software or standalone e-prescribing software. Standalone e-prescribing software performs only the e-prescribing function. By comparison, e-prescribing is integrated as a component within EHR software as one of many functions such as documentation and charge capture.

KEY STATISTICS

- About 91 percent of prescribers who used EHRs in 2010 to e-prescribe used one that was deployed for all three e-prescribing services, versus 78 percent in 2009.
- 83 percent of deployed e-prescribing software applications are included within EHRs and 17 percent are standalone.
- 53 percent of certified and deployed EHR software was deployed for all three ambulatory e-prescribing services at the end of 2010—Benefit, Routing, History—compared with 68 percent of standalone software.⁹
- Some standalone e-prescribing software vendors license use of their products to companies that provide EHRs. At the end of 2010, 148 EHRs used imbedded standalone e-prescribing software that was certified for connectivity to the Surescripts network.

Vendor Software Certified and Deployed for E-Prescribing



Percentage of Active Prescribers Using EHR vs. Standalone E-Prescribing Software



PART 2: ELECTRONIC PRESCRIBING ADOPTION

PRESCRIBERS

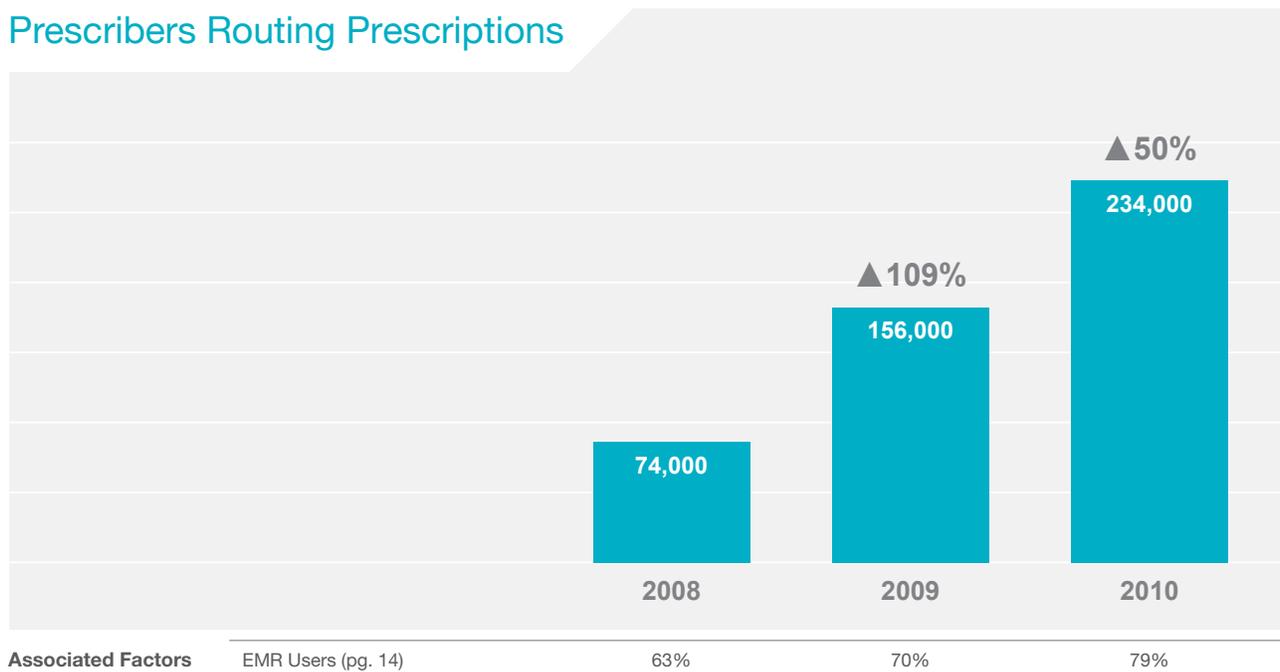
Prescribers using electronic prescribing in the United States include physicians, nurse practitioners and physician assistants. Prescribers use either stand-alone e-prescribing software or an electronic health record (EHR) to e-prescribe. All prescribers described in this section of the *Report* used Prescription Routing services. A portion of these prescribers also used Prescription Benefit and Medication History services.

36% OF OFFICE-BASED DOCTORS USE E-PRESCRIBING

KEY STATISTICS

- Approximately 234,000 prescribers routed prescriptions electronically by the end of 2010, up from 156,000 at the end of 2009. This represents about 34 percent of all office-based prescribers.¹⁰
- Of this 234,000, approximately 81 percent were doctors.
- Surescripts estimates that approximately 36 percent of office-based physicians are e-prescribing nationwide.

Prescribers Routing Prescriptions



Page 14 Footnote:

⁹ Certification for all three e-prescribing services is comprehensive of certification for Prescription Benefit, Medication History and Prescription Routing services. Routing services include connectivity to retail and mail order pharmacy and the ability to manage prescription renewals electronically.

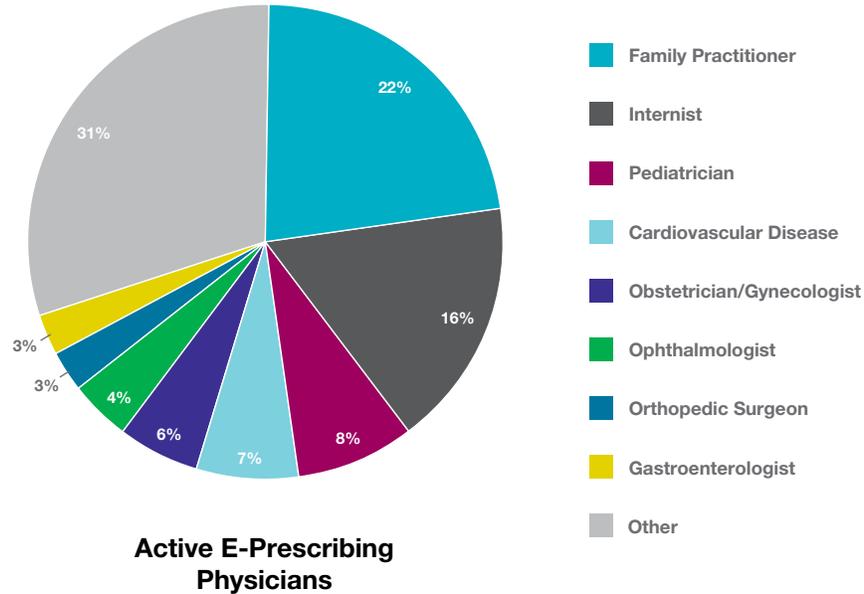
Page 15 Footnote:

¹⁰ Based on total count of 679,000 office-based prescribers, per SK&A data. Surescripts counts of active e-prescribers represent those that have used ambulatory prescription routing services within the last 30 days of 2010. A small proportion of these prescribers have been registered by hospitals and other organizations that do both ambulatory and acute care.

PART 2: ELECTRONIC PRESCRIBING ADOPTION

E-PRESCRIBING PHYSICIANS BY SPECIALTY

Surescripts estimates that physicians e-prescribing through the Surescripts network are representative of the following specialties.¹¹



CARDIOLOGISTS, FAMILY PRACTITIONERS LEAD E-PRESCRIBING ADOPTION

Percentage of Specialists Actively E-Prescribing

Specialty	% E-Prescribing
Cardiovascular Disease	49%
Family Physician	47%
Internist	45%
Ophthalmologist	40%
Gastroenterologist	38%
Pediatrician	36%
Obstetrician/Gynecologist	34%
Orthopedic Surgeon	24%
Other ¹²	19%

PROFILES IN INTEROPERABLE HEALTHCARE

HEALTH INFORMATION TECHNOLOGY AND THE FAMILY PRACTITIONER



A conversation with Dr. Steven Waldren, Director, Center for Health-IT American Academy of Family Physicians (AAFP)

“Accountable care models and medical homes will only work effectively if the communication between these parties can be conducted in a seamless, interoperable manner.”

The AAFP has long maintained a focus on influencing the adoption and use of health information technology. Here, Dr. Steven Waldren, director of AAFP’s Center for Health Information Technology, shares his perspective on how HIT is shaping the process of clinical care.

Why has the AAFP placed such a focus on health information technology (HIT)?

I believe our focus is a natural extension from the business of being a family practitioner. We find that family doctors are often entrepreneurial, innovative and engaged in the business of medicine. The nature of our membership has allowed us to develop our role as advocates for HIT to the extent that we have.

What do you see as the biggest technology challenge facing the family practitioner right now?

Family doctors are transitioning between established models of medicine and evolving models that are placing increasing focus on collaboration and quality. Health information technology plays an important role in supporting this shift.

We know that our members have been strong adopters of health technologies, with about 60 percent reporting use of electronic health record systems. But these implementations may not ready these practices for future needs. Implementations have typically been done with an eye towards automating documentation, securing remote access and supporting processes necessary to secure reimbursement with current payer-driven models.

Now—with emerging models of accountable care and medical homes, we are seeing a significant shift to more quality-driven care. In this respect we are finding that a minority of our membership—only about 20–30 percent—have implemented the tools to be ready for this change. Examples of what’s needed include population management tools, quality-based reporting and so on.

How else is the shift toward accountable care driving the need for health information technology?

Well—you need to look at all participants in a patient’s care and their relationships. Today patients see their family practitioner and any number of specialists. Nurses, physician assistants and pharmacists are also involved in this care. Using today’s models of communication, the relationships between all these parties can be fragmented. Accountable care models and medical homes will work effectively only if the communication between these parties can be conducted in a seamless, interoperable manner.

And how are practitioners reacting to government efforts to boost use of HIT?

The incentive programs have given HIT a real boost, that’s for sure. But recognize that doctors are looking for ways of using their systems to both care for their patients and ensure that they are making the proper documentation to get reimbursed under these programs. I consistently hear from doctors during our AAFP forums that their systems do not always support the type of information capture and support necessary.

For instance, they are required to review history, capture their information to document the care that was delivered and then capture information to support population based reporting. And all during a seven-minute patient visit.

So what is an “ideal” state moving forward?

The promise of HIT is the ability to use delivered, structured, codified clinical data in a way that offers meaningful clinical decision support to physicians.

In fact, the scope is larger than that. Given the busy nature of today’s practices, this support can help spread responsibilities to the most appropriate healthcare providers. For instance, tools may identify a need for a mammogram—which then triggers tasks for a referral specialist to manage. Then that referral, along with the patient’s information, can be sent electronically to the specialist of the patient’s choice.

What’s more, all of this data can generate quality measurement information that can be delivered to health systems to demonstrate the value of the care received and to establish benchmarks in care.

And how is e-prescribing related to all this?

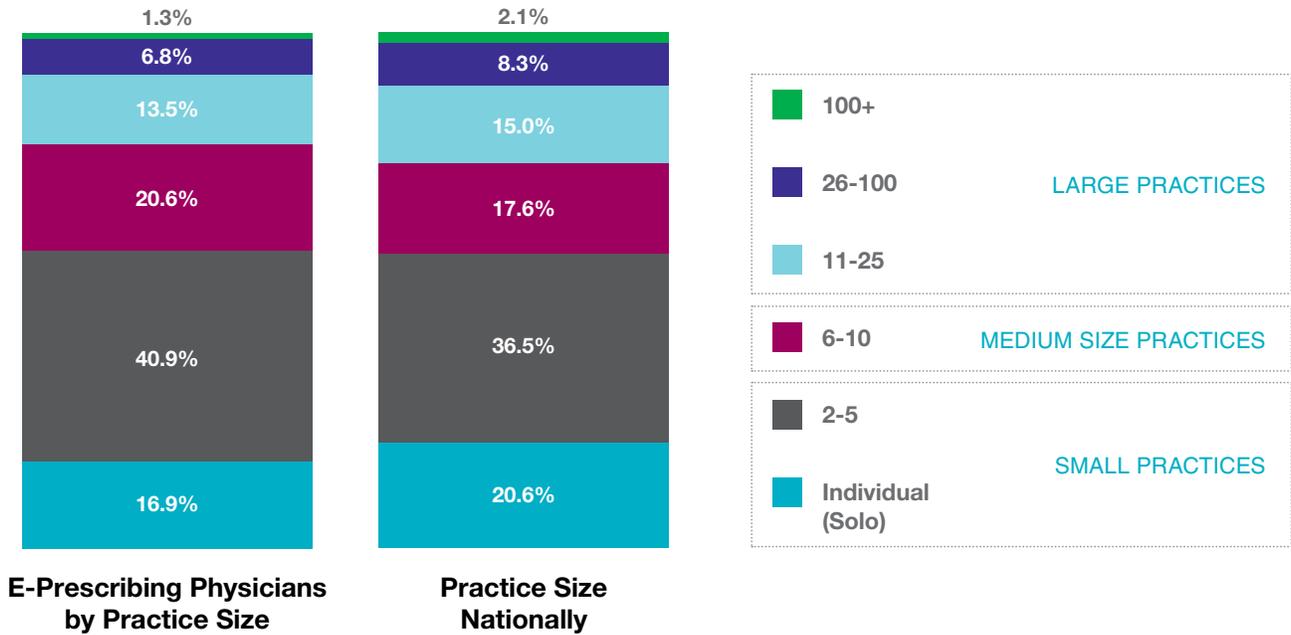
E-prescribing has not just built efficiency within the prescribing system, it has demonstrated the value of clinical messaging. But overall e-prescribing has been a real success story and I think it’s because it’s been built on a very strong business model. Practices can see the value that replacing paper and fax with electronic communication has brought. Once this value is seen by the practices that start to use it, other physicians can be brought along.

Now with the need for broader types of clinical messaging we have the opportunity to learn from the e-prescribing model and leverage it toward new types of networking that can exchange a broader range of clinical information electronically.

PART 2: ELECTRONIC PRESCRIBING ADOPTION

E-PRESCRIBING PHYSICIANS BY PRACTICE SIZE

Surescripts estimates that physicians e-prescribing through the Surescripts network are representative of the following practice sizes.¹³



PRACTICES WITH 2 TO 10 PHYSICIANS LEAD E-PRESCRIBING ADOPTION

E-Prescribing Adoption by Practice Size

Practice Size	% Active E-Prescribers	% EHR Users
100+	21.9%	99.3%
26-100	30.7%	93.3%
11-25	33.6%	84.5%
6-10	43.5%	79.9%
2-5	41.7%	73.8%
Individual (Solo)	30.6%	63.5%

PHARMACIES—COMMUNITY AND MAIL ORDER

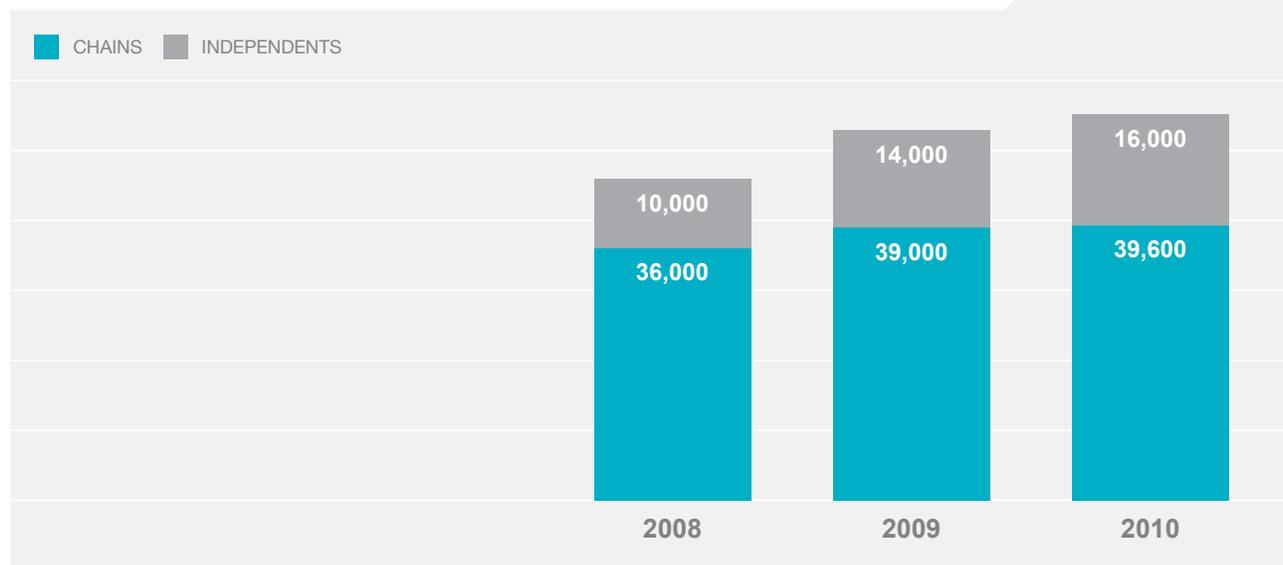
There are approximately 62,000 community pharmacies in the United States, representing both chain and independently owned pharmacies.¹⁴ Of these, about 65 percent are chain pharmacies and 35 percent are independently owned (including those that are part of buying groups). In addition, PBMs and some chain pharmacies operate mail order pharmacies. Surescripts works with these pharmacies to provide prescription routing connectivity with prescribers—the ability to send new prescriptions electronically to the computer system at the pharmacy of the patient’s choice and the ability for pharmacies to send prescription renewal requests to the practices’ e-prescribing software for their review and electronic response.

91% OF THE NATION’S
 COMMUNITY PHARMACIES
 NOW ACCEPT
 E-PRESCRIPTIONS

KEY STATISTICS

- At the end of 2010, approximately 91 percent of community pharmacies in the U.S. were connected for prescription routing and six of the largest mail order pharmacies were able to receive prescriptions electronically.^{15,16}
- More than 98 percent of chain pharmacies and 73 percent of independent pharmacies were connected to the Surescripts network for prescription routing in 2010.

Community Pharmacies Connected for Prescription Routing



Supporting Data

Community Pharmacies Connected:	76%	85%	91%
Independent Pharmacies Connected:	46%	62%	73%

¹⁴ Based on NCPDP data analysis.

¹⁵ Note: In addition to retail and mail order pharmacies, Surescripts also connects some pharmacies associated with federal and state governments and with medical device manufacturers. For a list of e-prescribing pharmacies, go to www.surescripts.com/connected-pharmacies.html.

¹⁶ CVS Caremark, Express Scripts (WellPoint, NextRx), Medco Health Services, Prescription Solutions, Prime Therapeutics (Prime Mail) and Walgreens Mail Services.

PART 2: ELECTRONIC PRESCRIBING ADOPTION

E-PRESCRIBERS IN 19 STATES CAN NOW ACCESS PRESCRIPTION INFORMATION FOR MORE THAN 70% OF PATIENTS

PAYERS

The nation's public and private payers and their associated pharmacy benefit managers (PBMs) provide prescription benefit and medication history information to help inform prescribers when they select medication therapy. Surescripts gives prescribers access to this information through its electronic connections to PBMs, which represent connections to thousands of health plans.

For a list of payers and PBMs that are connected to Surescripts, please visit <http://www.surescripts.com/about-us/connected-payers.aspx>.

KEY STATISTICS

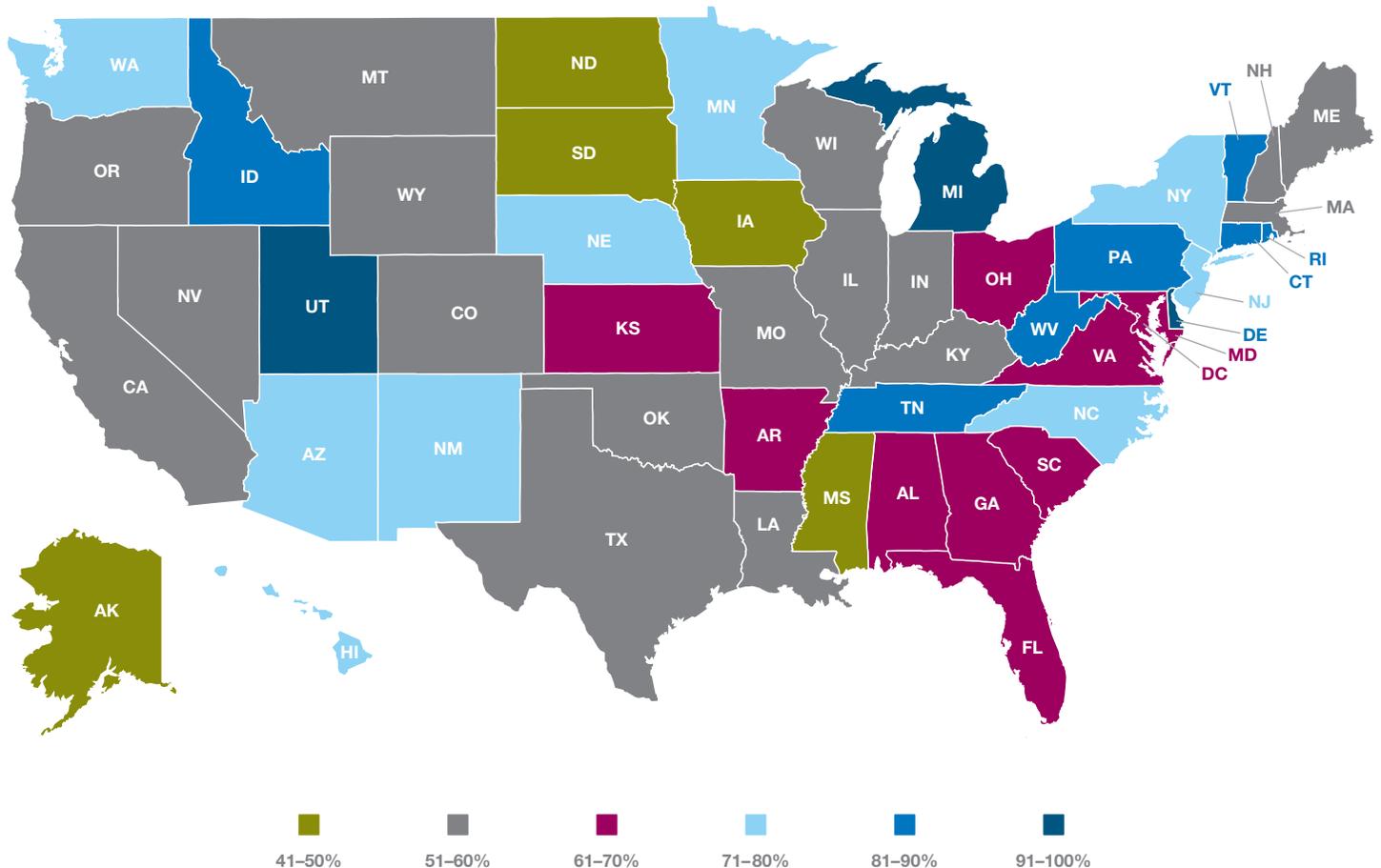
- At the end of 2010, Surescripts was able to provide access to prescription benefit and medication history information (on behalf of payers and pharmacies) for more than 66 percent of patients in the U.S.^{17,18}
- By the end of 2010, participation by payers in e-prescribing allowed prescribers to locate and access more than 250 million member records from participating health plans.¹⁹
- In 2010, Surescripts provided access to more than 30,000 formulary files, including formulary status, coverage, co-pay and alternative medication lists maintained by participating health plans.

¹⁷ Calculated by taking the number of records, less 19 percent for patients who have more than one source of prescription benefit coverage, and dividing it by the U.S. population figure of 309 million. Figures include the District of Columbia, Puerto Rico and U.S. territories. U.S. population figures are from *Annual Estimates of the Resident Population for the United States and Puerto Rico*, Population Division, U.S. Census Bureau Release, July 1, 2010.

¹⁸ Surescripts suggests that payers can provide a medication history for an estimated 95 percent of the patients for whom it can provide prescription benefit information. This is because some pharmacy benefits, when offered as a carve-out, are not associated with a claims-based medication history.

¹⁹ This figure is inclusive of records from all 50 U.S. states and the District of Columbia.

PERCENTAGE OF PATIENTS FOR WHOM PAYERS CAN PROVIDE PRESCRIPTION BENEFIT AND MEDICATION HISTORY INFORMATION



PART 3: INDUSTRY DRIVERS

DRIVERS OF INTEROPERABLE HEALTHCARE IN 2010

HITECH AND THE GROWTH OF E-PRESCRIBING

Federal incentives had significant influence on the number of prescribers who use e-prescribing.

HITECH incentives were one of the most significant drivers of growth in 2010—especially for e-prescribing. 2011 will be a year with increased focus on utilization measurement.

The Health Information Technology for Economic and Clinical Health (HITECH) Act is a key component of the American Recovery and Reinvestment Act of 2009 (ARRA). The main goal of the HITECH Act is to encourage the adoption and meaningful use of electronic health records (EHRs) through incentive payments to physicians and hospitals.

Under the Act, eligible prescribers can receive incentive payments by meeting qualitative and quantitative standards for the meaningful use of a certified EHR, starting in 2011. As specified by the HITECH Act, e-prescribing is a key component of meaningful use requirements, including a mandatory requirement that EHR systems must be capable of electronic prescription routing to pharmacies, and that 40 percent of eligible prescriptions be sent in this manner during a reporting period.

Per federal rules released in July 2010, meaningful use is structured in three phases:

- 1) Capturing and sharing of data—current phase, Phase I (2011)
- 2) Advanced-care processes with decision support—Phase II (2013)
- 3) Improved outcomes and population management—Phase III (2014–2015)

The Act also makes provisions for incentive payments to support the acquisition and use of certified EHR technology for prescribers who treat high volumes of Medicaid patients. It also makes federal matching funds available for some state Medicaid plans for programs that encourage the adoption and use of EHR technology.

According to survey data released by the Office of the National Coordinator for Health Information Technology in January 2011, 81 percent of the nation's hospitals and 41 percent of office-based physicians intend to take advantage of federal incentive payments to increase their adoption and meaningful use of certified EHR technology.

Though ARRA incentives are expected to cover only a fraction of the costs involved in providing this technology, expected gains in efficiency and the potential for fewer adverse drug events promise to provide additional financial incentives for participants to make up the difference. For instance, a 2010 McKinsey report²⁰ suggests that the broad use of EHRs could lead to a combined savings of more than \$30 billion for hospitals alone.

THE MIPPA E-PRESCRIBING INCENTIVE PROGRAM

Despite HITECH's greater visibility, the MIPPA incentive programs remained a key driver of e-prescribing growth in 2010—particularly for non-EHR practices.

The Medicare Improvements for Patients and Providers Act (MIPPA)—introduced in 2009—offered a 2 percent bonus payment in 2010 for qualified e-prescribers that prepared and sent prescriptions to pharmacies electronically using a qualified e-prescribing system. Such systems could be imbedded in a practice's EHR, or used as a standalone application.

Such reimbursement levels are offered through 2013, with the maximum of 2 percent available in 2009 and 2010. Reimbursement will fall to 1.5 percent in 2011, 1 percent in 2012 and 0.5 percent in 2013. MIPPA also creates a penalty for prescribers who do not start using e-prescribing by 2012. Specifically, those prescribers will suffer a penalty on their Medicare reimbursements rates starting at 1 percent.

Given MIPPA's inclusion of both EHR-based and stand-alone e-prescribing technology as "qualified systems" under program requirements, MIPPA provides a way for practices to see the benefits of e-prescribing and benefit from incentive monies without a significant capital outlay.

The looming penalties in 2012 will be of concern to non-adopting practices and will influence acquisition of prescribing technology through 2011. That being said, practices should be reassured by the fact that requirements for compliance are relatively low. For instance, practices are only required to send 10 prescriptions electronically during Medicare visits in the first six months of 2011 to avoid MIPPA financial penalties for non-compliance in 2012, and only 25 during all of 2011 to avoid MIPPA financial penalties in 2013. Sending 25 prescriptions electronically in 2011 also qualifies practices for MIPPA financial incentives for the year.

FOCUS: INTEROPERABLE HEALTHCARE AND THE IMPACT OF UPCOMING MEANINGFUL USE REQUIREMENTS

Requirements for e-prescribing under meaningful use will drive utilization through 2015. Watch for the impact of initial reporting deadlines by October 1, of 2011.

Under current Stage 1 meaningful use requirements, 40 percent of eligible prescriptions must be routed electronically to pharmacies. Participating physicians must demonstrate that they have met this standard to receive incentive dollars—making the measurement of e-prescribing use an important factor of program involvement.

In order to maximize potential incentive payments, physicians must file to receive benefits in 2011 or 2012. Since “demonstrated use” must progress for at least 90 days in a calendar year to be eligible, the 2011 deadline is September 30.

Proposed Phase 2 and Phase 3 meaningful use requirements will place increasing responsibilities on physicians to manage prescriptions electronically and to take advantage of available prescription benefit and medication history information that is able to be delivered to them electronically.²¹ Requirements include:

- Routing of at least 50 percent of eligible electronic prescriptions to pharmacies in Stage 2 and 80 percent in Stage 3
- Use of electronically delivered prescription benefit information (patient formulary and benefits eligibility) to inform prescribing decisions
- Access to patient medication history information
- Electronic sharing of clinical information

For those who wish to take advantage of HITECH incentive dollars, the window to adopt electronic health record technology with full e-prescribing capabilities is closing. Physicians begin to lose opportunities to receive these financial incentives in 2013. Starting in 2015, penalties for non-adoption will begin.

FOCUS: EHR CERTIFICATION

The infrastructure is now in place to allow physicians to identify/confirm eligibility of particular EHR systems under HITECH.

Any EHR technology adopted under HITECH must complete a certification process designed to ensure that a particular system has the capabilities to allow participating physicians to meet meaningful use requirements. These include the ability to manage prescription information electronically.

In 2010, five organizations were designated by the Office of the National Coordinator for Healthcare Information Technology to certify these technologies. The federal government is keeping an updated list of products that have been certified, with over 200 listed at the end of 2010.

This listing may be found at <http://onc-chpl.force.com/ehrcert>. Products are certified as complete EHRs or modular systems, and linked to specific certification criteria. A specific ONC certification number is granted to each certified system which is essential to document in order to receive incentive payments.

In early 2011, Surescripts joined the list of organizations that have been granted ONC ATCB status. Surescripts is able to certify that e-prescribing functionality meets the requirements of the HITECH incentive program.

PART 3: INDUSTRY DRIVERS

FUTURE DRIVERS OF INTEROPERABLE HEALTHCARE GROWTH

IMPACT OF HEALTHCARE REFORM

Beyond incentive dollars, PPAC provisions are driving use of health information technology.

Under the rubric of healthcare reform, the Patient Protection and Affordable Care (PPAC) Act carries certain key provisions that helped drive the adoption of healthcare technology in 2010 and will continue to drive adoption and use during the next three to five years. These factors include:

(i) Potential growth in the number of insured patients: (ii) Adjusted expense ratios for insurers:

The PPAC Act suggests that 30 million additional lives will be covered over time. With increased demand for services, and pressure to shift reimbursement models from a volume basis to a value basis, Health IT demand from practices, hospitals and health systems will strengthen. This is particularly relevant with systems that enable stronger provider communication and access to timely, relevant clinical data and coverage information. The need for advanced electronic tools to manage claims-related data will be felt by payers too as their volume of claims increases. Lastly, an increased volume of office visits is expected to have a proportional effect on prescribing volume, with more prescriptions than ever before making their way to community and mail order pharmacies.

In October 2010, the National Association of Insurance Commissioners announced that certain IT expenses can be included as medical expenses when calculating an insurer's medical loss ratio under the PPAC. Under the Act, as of January 1, 2011, insurers will be required to spend 85 percent of large-group premiums and 80 percent of small-group and individual plan premiums (with certain adjustments) on healthcare, or to improve healthcare quality or return the difference to the customer as a rebate.

Expenditures made to facilitate communications between healthcare providers and their patients can fall under the 80–85 percent expense ratio—thereby encouraging investment in health information technology that can manage these communications electronically and thus increase the potential for quality improvements and efficiencies through streamlined workflow and the timely delivery of more robust clinical information.

ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

Prescribers have long dealt with dual workflows due to the need to maintain paper- and fax-based prescribing for controlled substances. Now DEA regulations offer the opportunity to manage these prescriptions electronically.

Starting June 1, 2010, the U.S. Drug Enforcement Administration (DEA) allowed prescribers the option of issuing prescriptions for controlled medications electronically, subject to requirements specified in the DEA's Interim Final Rule (IFR), published in the March 31, 2010 issue of the *Federal Register*.

By establishing a framework by which prescribers can manage controlled substances electronically, the DEA provides a path for prescribers to manage all their prescriptions within an electronic workflow, rather than forcing them to maintain parallel processes—paper- and fax-based methods for controlled substances and electronic processes for all other medications.

In order to electronically prescribe controlled substances (EPCS), prescribers must adhere to the following key DEA regulations:

- 1) They must use an e-prescribing application that is certified for this purpose.
- 2) They must complete an identity proofing process.
- 3) They must use a two-factor authentication process each time one of these prescriptions is issued.

Two-Factor Authentication Defined

In addition to the use of an existing security feature within an e-prescribing application, prescribers must use a separate and distinct security feature to prescribe controlled substances. This could be a “hard token” such as a radio frequency identification device, a password from an independent password generator and so on.

With this it is expected that educational efforts must be undertaken to ensure that prescribers are comfortable with the workflow adjustments and hardware acquisition that are necessary to prescribe these medications electronically.

Surescripts has expressed its commitment to readying its network operations to supporting EPCS.

Surescripts' own research has suggested that prescribers have a strong desire to prescribe controlled substances electronically, with the consideration that new workflow processes needed to comply with DEA regulations will have an impact on adoption. Results from a fall 2010 prescriber survey conducted by Surescripts show that:

- Approximately three-quarters of prescribers are highly aware that the DEA now permits EPCS
- An equal proportion (74 percent) has a high degree of interest in EPCS
- The majority of prescribers—56 percent—want to prescribe controlled substances electronically as soon as possible once the service becomes available to them

Unfortunately, when presented with details regarding the DEA's ID-proofing requirements, prescribers with a high degree of interest in EPCS dropped from 74 percent to 56 percent.

These findings were consistent across practice sizes and most specialties. A higher degree of interest was shown by those in specialties who issue a higher proportion of prescriptions for controlled medications, such as psychiatry.

This suggests that a degree of care must be taken to put DEA requirements into proper context and to provide a clear workplan for the adoption and use of additional technologies required to be in compliance. This includes offering a variety of options for two-factor authentication to ensure that prescribers can select one that is best for their office workflows.

PART 3: RECOMMENDATIONS

SUPPORTING THE CONTINUED GROWTH OF INTEROPERABLE HEALTHCARE

Each year, Surescripts provides a series of recommendations within the *Report* to address issues that we believe need to be rectified to help make e-prescribing and interoperable healthcare standard practice. Our 2010 recommendations are summarized below.

Drive utilization. Continue to develop programs that focus on driving the utilization of e-prescribing and interoperable healthcare technologies.

Bridge adoption gaps. Government and industry must collaborate to address gaps in adoption by solo practitioners, independently owned pharmacies and state Medicaid programs.

Promote clinical collaboration. Support emerging models of collaborative care.

1. FOCUS ON UTILIZATION

Status: Continued Identified Need—Carryover from 2009 National Progress Report

2010 Assessment

Recent studies show that the use of e-prescribing within EHR systems continues to be sub-optimal. According to the Center for the Study of Health System Change,²² of the 44 percent of physicians who report using EHRs (in part or in full), only 42 percent reported using an e-prescribing prescribing system.

Of these:

- 23% do not use it routinely
- 65% use it to check for adverse drug events (ADEs)
- 54% use it to transmit prescriptions to pharmacies electronically
- 34% use formulary features
- 23% use all features regularly

Recommended Actions

If e-prescribers are to achieve acceptable standards of utilization—with the most immediate need being the achievement of Phase 1 meaningful use requirements (at least 40 percent of eligible prescriptions are managed electronically)—public and private interests must provide the education and tools needed to do so.

Recommended actions include:

- Benchmarking data to assist prescribers in assessing system performance in relation to others in their area and against meaningful use requirements
- Definitive best practices with respect to user interfaces, data delivery and interpretation with associated certification
- Increased role of Regional Extension Centers to support such education

PART 3: RECOMMENDATIONS

SUPPORTING THE CONTINUED GROWTH OF INTEROPERABLE HEALTHCARE

2. CLOSE GAPS IN ADOPTION

Status: Continued Identified Need—Carryover from 2009 National Progress Report

2010 Assessment

Solo Practitioners: Although HITECH incentive programs are providing an impetus for solo practitioners to adopt electronic health record technology, the ability to recover the cost of implementing such technology is often hampered by lack of specialized IT staff who can support its implementation, and the time and training resources needed to support ongoing use.

Independently Owned Pharmacies: Compared with chain pharmacies, independents have adopted e-prescribing at a slower pace. The gap between independent/chain growth in e-prescribing connectivity has closed in the past year, but not to the extent that it can be considered equal.

Given the strong relationships that independent pharmacies often have with prescribers in their communities, their connectivity is important to promote more consistent prescribing workflows in the practice setting.

State Medicaid Programs: At the end of 2009, nine state Medicaid programs were able to provide eligibility and formulary information to prescribers electronically, with another seven in process. By the end of 2010, this figure had risen to 15 and five, respectively. While this demonstrates good progress, 30 state Medicaid programs have not yet made efforts to establish this connection.

Recommended Actions

Solo practitioners should be a special focus for educational and technical support programs led by payers, health systems and Regional Extension Centers to ensure that implementing and using such technologies happen in a way that minimizes workflow impact, especially during the first few months after its introduction.

State, private and local programs already working to encourage the adoption of health technologies must remember the independent pharmacy, as programs in North Carolina and New York have already done. Independent pharmacies in these states have adopted e-prescribing at a rate that is 15 percent and 10 percent higher—respectively—than the national average.

Any Medicaid program that has not yet undertaken planning to electronically provide prescription benefit information to prescribers in their respective states should take steps to do so. This will involve both state and federal legislative support and potentially incentives to encourage participation.

3. SUPPORT EMERGING MODELS OF COLLABORATIVE CARE

Status: New for Report

2010 Assessment

The concept of patient-centered medical homes (PCMHs) and accountable care organizations (ACOs) promises better use of resources to enhance patient outcomes over time through a shift from quantity-based to quality-based medical care. Under these models, inpatient and outpatient care is coordinated among all physicians treating a patient. Compensation is based on the overall progression of patient responsiveness to assigned therapies versus a panel of patients with similar conditions.

As care broadens in this respect, reliance on health information technology to facilitate this communication becomes more and more important. The Centers for Medicare and Medicaid Services itself stated that the use of electronic health records with information-exchange capabilities (such as clinical decision support and access to the patient's medical records, lab results and medication history) was key to success as an ACO. This is understandable given that estimates suggest that the average Medicare patient sees seven physicians over a two-year period.²³

Recommended Actions

Quality-driven collaborative care requires both the software technologies to store and interpret clinical information and the networking support to ensure smooth, effective communications among all participants in patient care.

This suggests both an expectation that regionally based networks developed by integrated delivery networks and health information exchanges will grow, and a limitation that will be faced by these same networks to develop effective networking communication with all needed participants in patient care.

Such technologies must ensure interoperability to leverage existing private and regional networks provided by health information exchanges, integrated delivery networks and electronic health record providers, and to provide access points for those who have no access.

PART 3: ABOUT SURESCRIPTS

The Surescripts network supports the most comprehensive ecosystem of healthcare organizations nationwide. Pharmacies, payers, pharmacy benefit managers (PBMs), physicians, hospitals, health information exchanges and health technology firms rely on Surescripts to more easily and securely share health information.

Guided by the principles of neutrality, transparency, physician and patient choice, open standards, collaboration and privacy, Surescripts operates the nation's largest health information network. By providing that information for routine, recurring and emergency care, Surescripts is committed to saving lives, improving efficiency and reducing the cost of healthcare for all.

For more information, go to www.surescripts.com and follow us at twitter.com/surescripts.

WHY WE ISSUE THIS REPORT

With more than 34 percent of the nation's prescribers, 91 percent of the nation's community pharmacies and the nation's leading PBMs, payers and mail-order pharmacies managing prescriptions electronically through the Surescripts network, Surescripts can track important trends in the adoption and use of prescribing technologies. As of 2010, e-prescribing has become our nation's most commonly electronically exchanged form of clinical information.

With this unique vantage point, and driven by our corporate commitment to neutrality and transparency, Surescripts has issued the annual *National Progress*

Reports on E-Prescribing since 2008. Through this comprehensive report, we hope to show that the growth of e-prescribing adoption—and more important, its sustained use—can offer the industry an important bellwether for the adoption and use of health information technology as a whole.

And with the addition of network capabilities that support interoperable clinical communication between healthcare providers, Surescripts will expand this report moving forward to examine a broader range of data covering networked healthcare.

THE SURESCRIPTS' ELECTRONIC PRESCRIBING NETWORK

Surescripts connects prescribers in all 50 states—through their choice of certified e-prescribing software—to the nation's leading payers, chain pharmacies and independent pharmacies.

Any e-prescribing software provider—including those offering standalone e-prescribing solutions and those that integrate e-prescribing capabilities into electronic health record systems—may connect their customers to Surescripts' secure nationwide e-prescription network, as long as they

have completed Surescripts' certification process. This process validates that the certified software is able to send and receive electronic messages in accordance with industry standards.

Surescripts certifies software used by prescribers, pharmacies and payers/PBMs for access to three main services: Prescription Benefit, Medication History and Prescription Routing.

PRESCRIPTION BENEFIT SERVICES

Prescription Benefit—Ambulatory	Allows prescribers to request information on patient eligibility and formulary at the time of prescribing.
Eligibility Services—Pharmacy	Allows pharmacies to check patient eligibility, in real time, at the point of sale.
Eligibility Services—Medicaid	Allows Medicaid MMIS vendors to request pharmacy eligibility, in real time, from Surescripts before adjudicating a claim.

MEDICATION HISTORY SERVICES

Medication History—Ambulatory	With a patient's permission, this service allows prescribers to securely access aggregated medication history data from community pharmacies and patient medication claims history from payers and PBMs.
Medication History—Acute	Allows prescribers and authorized staff in acute-care settings to query and receive aggregated details for up to a year's worth of patient medication history from payer and pharmacy records representing over 240 million patients.
Medication History—Personal Health Records (PHRs)	Allows patients who use select PHR technologies to receive their medication history information from retail pharmacies.

PRESCRIPTION ROUTING SERVICE

Surescripts' Prescription Routing service allows prescribers to prepare and send a prescription directly to the computer at 91 percent of the nation's retail pharmacies, and six of the nation's largest mail order pharmacies. In turn, pharmacies can use this service to send requests for prescription renewals directly to the computer at a practice so that prescribers can review and respond to them directly.

PART 3: ABOUT SURESCRIPTS

THE SURESCRIPTS NETWORK FOR CLINICAL INTEROPERABILITY

In October 2010, Surescripts announced that it was expanding its network operations to establish the Surescripts Network for Clinical Interoperability™—a common and neutral point of connection to facilitate the secure exchange of clinical information between all types of healthcare providers.

This new network leverages Surescripts’ significant experience and business approach to electronic clinical message exchange to allow healthcare providers to exchange a wide array of clinical information—peer to peer—regardless of network affiliation or use of technology.

With its neutral approach to connectivity Surescripts NCI acts as a “network of networks”—permitting health systems, health information exchanges and electronic health record providers to connect their affiliated clinicians to their peers both locally and nationwide. This single point of access avoids the need to establish complex individual network connections and allows clinicians to maintain their relationship and user experience with their existing network solutions.

Connectivity to the Surescripts Network for Clinical Interoperability can be achieved through a suite of connectivity tools designed for flexible implementation and integration.

The Surescripts Network for Clinical Interoperability supports transmission of a full range of clinical information:

- Discharge summaries
- Referrals
- Medication histories
- Continuity of care documents
- Structured and unstructured notes
- Lab results
- Immunization records

Using a variety of protocols:

Including Surescripts’ network standards, Direct and NHIN Exchange Projects, HL7, and other meaningful use standards as they develop

Supported by Surescripts’ established network services:

- Network Infrastructure
- Certification & Compliance
- Directory Management
- Customer Support & Education
- Security & Authentication
- Implementation

SURESCRIPTS' CLINICAL INTEROPERABILITY TOOLSET

<p>1) Surescripts Net2Net Connect</p>	<p>This tool allows network and technology providers to build a direct connection to Surescripts' national network.</p>
<p>2) Surescripts Message Stream</p>	<p>Offers all certified network connectivity services of Net2Net Connect and adds a rich set of management and storage tools applicable for internal and/or external communication.</p>
<p>3) Surescripts Clinical Messaging Portal</p>	<p>A simple, secure, browser-based portal for clinical interoperability that provides basic, reliable communication between providers through secure portal technology. Designed for those who do not have access to existing network-connected technology or for network providers who wish to provide an interim connectivity solution for their clients.</p>

SURESCRIPTS—VALUE-ADDED NETWORK SERVICES

In order to ensure the success of our health information network, Surescripts provides many services free of charge, including:

- **Certification**—Surescripts implements and consistently applies open standards for certification and implementation of technology systems.
- **Compliance**—Surescripts conducts audits of technology vendors and connected entities to ensure compliance with standards and commitments for connectivity.
- **Standards Development**—Surescripts works with NCPDP, CCHIT, HITSP and other standards bodies to develop, evolve and certify against industry technical standards.
- **Education and Collaboration**—Surescripts engages with national, state and regional entities, both public and private, to develop educational programs, adoption and utilization programs, quality initiatives, and dialogue to support ongoing growth in the adoption and meaningful use of e-prescribing and health IT.
- **Support**—Surescripts provides technical assistance and resources to support physicians, pharmacies, payers and vendors through its account team and its Electronic Prescribing Resource Center.
- **Monthly Participant Calls and Biannual Participant Workshops**—Surescripts hosts regular events with network participants to inform them of developments and best practices around e-prescribing.
- **Pilot Programs**—Surescripts participates in and supports CMS, AHRQ and other public/private pilot programs.

ACKNOWLEDGMENTS

Surescripts would like to thank Circle Square Inc., the National Association of Chain Drug Stores' Economics Department and SK&A for their expertise and significant contributions to *The National Progress Report on E-Prescribing and Interoperable Healthcare*.

For more information about Surescripts, visit www.surescripts.com and follow us at twitter.com/surescripts.





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Topical Review

Electronic Prescribing of Controlled Substances (EPCS)

June 20, 2011

Controlled substances can now be legally prescribed electronically, once specific criteria¹ are met. States across the country are working to adapt regulations to accommodate this rule, vendors are changing their products, and new groups are stepping forward to help create the needed infrastructure. Electronic prescribing of controlled substances is coming, but is not ready for clinician use just yet. This tool offers advice for getting the medical office or pharmacy ready, current best practices for managing controlled substances, and the projected changes in best practices based on the present legislation.

Getting Ready for Electronic Prescribing of Controlled Substances: Medical Office

1. Evaluate the relative impact of EPCS for your office by surveying the number of controlled substance prescriptions currently handled in a day, week, or month.
 - a. If more than 30% of prescriptions are controlled substances, consider implementing most, if not all, of the following suggestions.
 - b. If 10% to 30% of prescriptions are controlled substances, consider implementing the top 3 of the following suggestions most appropriate to your practice.
 - c. If less than 10% of prescriptions are controlled substances, consider implementing one or 2 of the following suggestions most appropriate to your practice.
2. Choose an e-prescribing application that is certified for EPCS by a DEA²-approved authority. Each prescriber of controlled substances will need 2-factor authentication credentials.
 - a. With your software vendors, identify the timeline on which this certification or audit is expected to be completed. This determines the date you can begin using EPCS.
3. Reshape workflows that leverage time freed up for office staff to balance the additional prescriber time needed for EPCS. Work with your vendor to answer:
 - i. How should refills be handled?
 - ii. Who has the ability to approve CS³ prescriptions and send them to the pharmacy?
 - iii. How does the system prevent or limit fraud or misuse by staff?
 - iv. How should prescribers and staff educate patients on changes that e-prescribing brings?
4. Acclimate patients to calling the pharmacy for renewal requests of non-controlled substances. When EPCS is available, the transition to calling the pharmacy for controlled substances will be seamless.
5. Create a document defining the conditions for a patient requesting a renewal for a controlled substance that should prompt a referral and discussion to the prescriber. After EPCS is ready, share this document with the top twenty pharmacies to which these prescriptions are sent.

¹ As defined in 21 CFR Parts 1300, 1304, 1306, and 1311

² DEA = Drug Enforcement Administration

³ CS = Controlled Substances

6. Script a patient education process for the staff to review with patients. This script should include the best way to request a renewal after patients receive a prescription for controlled substances.
7. Add e-prescribing training to the orientation of new employees that have prescription responsibilities.

Note: *If a transmission of EPCS fails, current regulations for a paper prescription of CS should be followed.*

Getting Ready for Electronic Prescribing of Controlled Substances: Pharmacy

1. Use electronic communication tools to provide more detailed communications to medical offices when resolving or anticipating questions regarding non-controlled substances.
2. Create a document defining the conditions that warrant a referral of a patient to their provider for further evaluation. After EPCS is ready, share this with your top twenty medical offices. Keep a copy on hand for ad hoc requests.
3. Script a patient education process for pharmacy staff to review with patients on the best way to request a renewal.
4. Instruct patients to call for refills and renewals for all prescriptions.
 - a. Choose or upgrade the pharmacy software to include an e-prescribing module that is certified for EPCS by a DEA-approved authority. Each pharmacist may need 2-factor authentication credentials, but this has not yet been finalized.
5. Work with your vendor to educate staff regarding processes that change as a result of e-Prescribing controlled substances.
6. Work with prescribers to establish an understanding of usual time frames needed to process renewal requests, any additional information prescribers may need along with the request, and conditions that would prompt a patient to make an appointment with their provider for a renewal.
7. Incorporate controlled substance legal requirements into the standard medication counseling. Provide patients with reasonable expectations regarding the process for requesting renewals and define the scenarios where the patient must see their primary care provider.

References and Further Information

Full legal text of the interim final rule for electronic prescribing of controlled substances:

http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf

Q&A for EPCS: http://www.deadiversion.usdoj.gov/ecom/e_rx/faq/faq.htm

Rationale for pharmacists in the medical home model:

http://www.cshp.org/uploads/file/Newsroom/2010/why_pharmacists_belong_in_med_home_5_2010.pdf

Episode #14: Complexities of e-Prescribing: Physician and Pharmacist Viewpoints:

<http://www.himss.org/ASP/physicianCommunityPodcast.asp>

Renewal Requests

Bottom Line: Work shifts from office staff to the prescriber

Current Best Practice:	Expected change after EPCS:
<ul style="list-style-type: none"> • Patients call the prescriber’s office to request renewals; <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> • Pharmacies fax a renewal request to the prescriber’s office; <p style="text-align: center;"><i>THEN</i></p> <ul style="list-style-type: none"> • Secretary/Nurse prepares the prescription for prescriber review and authorization. In electronic systems, the prescription is printed instead of sent electronically. 	<ul style="list-style-type: none"> • Patient calls the pharmacy to request renewal. • Pharmacy sends electronic renewal request to the prescriber’s office. • Secretary/Nurse prepares the prescription for prescriber review and authorization. The response is sent electronically. <ul style="list-style-type: none"> ○ If the electronic transaction fails, the prescription is printed, signed, and managed as a paper prescription.

Rationale: The record of previous dispensing allows pharmacists to submit an accurate electronic request for a renewal, decreasing the burden of phone calls on medical office staff. The pharmacist is often in a better position to determine the medication the patient is requesting since the record of previous dispensing limits the possible medications the patient could be requesting. Communication fields in pharmacy software allow for robust notes to accompany the request and facilitate a reply by the prescriber, including whether the patient needs to be seen by their primary care provider before a prescription can be issued.

New Prescriptions

Bottom Line: No big changes in workflow

Current Best Practice	Expected change after EPCS
<ul style="list-style-type: none"> • The prescriber generates the prescription using an e-prescribing application or writes a paper prescription • The prescription is printed for a wet signature <ul style="list-style-type: none"> ○ State legislations vary with respect to fax and phone processes 	<ul style="list-style-type: none"> • The prescriber generates the prescription using an e-prescribing application • Then “Signs” the prescription electronically using 2-factor authentication • Then transmits the prescription electronically to the patient’s pharmacy of choice.

Rationale: No expected workflow changes as the prescriber is the primary actor in the current best practice and is expected to remain so after EPCS.

EPCS Documentation

Bottom Line: Automatic documentation is balanced against more documentation

Current Best Practice	Expected change after EPCS
<ul style="list-style-type: none"> • Prescriptions for controlled substances are documented in the chart as to: <ul style="list-style-type: none"> ○ Drug ○ Quantity ○ Directions ○ Start and stop dates • Some documentation of prescriptions for the chronic patient may be delegated • Ideally, documentation is in the chart that the patient is aware that deviations from the normal pattern of use will result in appropriate penalties. 	<ul style="list-style-type: none"> • If the prescriber already has an EMR⁴, the documentation of controlled substances does not change much. • There will likely be a new step in the clinic’s workflow: a check to see if the patient already has a prescription (from another pharmacy and/or from another physician) for a given CS prescription. <ul style="list-style-type: none"> ○ These kinds of databases are already available in some states (e.g., Ohio); their existence and the form they take will vary from state to state.
<p>Electronic documentation in both pharmacy and prescriber’s office makes information surrounding the CS prescription more available. Though not easily done in today’s paper based systems, workflows for checking adherence, timeliness of past fills, pharmacies used, and past prescribers may quickly develop, as much to mitigate the prescriber’s and pharmacy’s liability as to improve safety and accuracy of care. The advent of EPCS makes these functions much more realistic and accessible.</p>	

⁴ EMR = Electronic Medical Record

EPCS Patient and Staff Education

Bottom Line: Work shifts from the prescriber's office to pharmacies

Current Best Practice	Expected change after EPCS
<ul style="list-style-type: none"> • Patients usually learn about controlled substance requirements in two ways: <ol style="list-style-type: none"> a. From the pharmacist, when a prescription cannot be filled. b. From practitioners and their staff, when a controlled substance prescription is needed, often prompted by a patient's request for renewal. • Staff may or may not have formal training on the legal requirements of controlled substance prescriptions. The same is true for learning workflows and procedures within the office or pharmacy to educate and instruct patients on the expectations and requirements surrounding controlled substances. 	<ul style="list-style-type: none"> • Counseling and education regarding controlled substance requirements will likely take on a much larger role in the pharmacy while simultaneously decreasing at the provider's office. • Additional formal staff education is needed in places where office staff participates in the electronic prescriptive process. • Accommodations in workflows may be necessary to allow for additional patient instruction time. • Offices may need to restructure workflows to leverage staff freed up from some demands (many renewal requests and CS education tasks will be shunted to the pharmacy) to provide support for prescribers that now have additional demands placed on them (2-factor authentication is required for both new prescriptions and renewal requests)

Rationale: Patients are increasingly being instructed by the practitioner's office to request renewals through the pharmacy. The increased complexity of sending controlled substances electronically requires that prescribers have a prominent role in the final disposition of all controlled substance prescriptions sent electronically, increasing demands for their time while that of their office staff decreases. Pharmacists are in a key position as both requestors of renewal prescriptions and dispensers of the final product to educate the patient regarding the regulations, expectations, and best practices surrounding controlled substances.

Annotations and Comments

Until the Rules' publication, there was no legal authority for an electronically transmitted controlled substance prescription. This resulted in:

- A complete separation of activities in which controlled substance prescriptions are written on paper while non-controlled substance prescriptions are transmitted electronically.
- OR*
- A process by which the prescriptions are entered electronically in order to gain the safety checks associated with CPOE⁵, but a corresponding paper copy is printed and signed for delivery to the pharmacy in order to handle the regulatory aspect of a legal prescription.
 - EPCS aligns the medication order check process more consistently, improves patient satisfaction by reducing different methods by which their medications are dispensed, and affords high traceability of prescriptions through the security requirements defined by DEA.

⁵ CPOE = Computerized Physician Order Entry

Interim Final Rule with Request for Comment Questions and Answers for Prescribing Practitioners [as of 03/31/2010]

The questions and answers below are intended to summarize and provide information for prescribing practitioners regarding the Drug Enforcement Administration (DEA) Interim Final Rule with Request for Comment “**Electronic Prescriptions for Controlled Substances**” (75 FR 16236, March 31, 2010) [Docket No. DEA-218, RIN 1117-AA61]. The information in this section is not intended to convey specific information about every aspect of the rule, nor is it a substitute for the regulations themselves.

- **Introduction**
- **General**
- **Individual Practitioners: Getting Started**
- **Institutional Practitioners: Getting Started**
- **Accessing the Electronic Prescription Application or Electronic Health Record Application to Sign Controlled Substances Prescriptions**
- **Creating and Signing Prescriptions**
- **Other Issues**
- **Transmitting Prescriptions to the Pharmacy and Printing Prescriptions**
- **Reporting Security Incidents**

Introduction

Q. What is DEA’s rule “Electronic Prescriptions for Controlled Substances?”

A. DEA’s rule, “Electronic Prescriptions for Controlled Substances” revises DEA’s regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule was published in the Federal Register Wednesday, March 31, 2010 and becomes effective on June 1, 2010.

Q. Is the use of electronic prescriptions for controlled substances mandatory?

A. No, the new regulations do not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor do they require pharmacies to accept electronic prescriptions for controlled substances for dispensing. Whether a practitioner or pharmacy uses electronic prescriptions for controlled substances is voluntary from DEA’s perspective. Prescribing practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled

substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances. Electronic prescriptions for controlled substances are only permissible if the electronic prescription and the pharmacy application meet DEA's requirements. In addition, electronic prescriptions for controlled substances may be subject to state laws and regulations. If state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision.

Q. Did DEA consider public comment in the development of this rule?

A. DEA considered almost 200 separate comments received from the public to the "Electronic Prescriptions for Controlled Substances" Notice of Proposed Rulemaking (73 FR 36722, June 27, 2008) in the development of this rule.

Q. Did DEA work with other Federal agencies in the development of this rule?

A. DEA worked closely with a number of components within the Department of Health and Human Services. DEA's discussions with the Office of the National Coordinator for Health Information Technology (ONC), Centers for Medicare and Medicaid Services (CMS), and Agency for Healthcare Research and Quality (AHRQ) were instrumental in the development of this rule. DEA also worked closely with the National Institute of Standards and Technology and the General Services Administration.

General

Q. When can a practitioner start issuing electronic prescriptions for controlled substances?

A. A practitioner will be able to issue electronic controlled substance prescriptions only when the electronic prescription or electronic health record (EHR) application the practitioner is using complies with the requirements in the interim final rule.

Q. How will a practitioner be able to determine that an application complies with DEA's rule?

A. The application provider must either hire a qualified third party to audit the application or have the application reviewed and certified by an approved certification body. The auditor or certification body will issue a report that states whether the application complies with DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. (A limited set of prescriptions require information that may need revision of the basic prescription

standard before they can be reliably accommodated, such as hospital prescriptions issued to staff members with an identifying suffix.) The application provider must provide a copy of the report to practitioners who use or are considering use of the electronic prescription application to allow them to determine whether the application is compliant with DEA's requirements.

Q. Until a practitioner has received an audit/certification report from the application provider indicating that the application meets DEA's requirements, how can the electronic prescription application or electronic health record application be used to write controlled substances prescriptions?

A. Nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription or EHR application that does not comply with the interim final rule to prepare and print a controlled substance prescription, so that EHR and other electronic prescribing functionality may be used. Until the application is compliant with the final rule, however, the practitioner will have to print the prescription for manual signature. Such prescriptions are paper prescriptions and subject to the existing requirements for paper prescriptions.

Individual Practitioners: Getting Started

Note: The questions and responses below assume that the practitioner is an individual practitioner (e.g., physician, dentist, veterinarian, nurse practitioner) and is a DEA registrant lawfully permitted to prescribe controlled substances. The practitioner may be a member of a group practice. They further assume that the practitioner has received an audit or certification report from the application provider of the practitioner's software used to create prescriptions for controlled substances that indicates the application meets DEA's requirements.)

Q. Is identity proofing of individual prescribing practitioners required. If so, who will conduct it?

A. Yes, identity proofing is critical to the security of electronic prescribing of controlled substances. Authentication credentials used to sign controlled substance prescriptions may be issued only to individuals whose identity has been confirmed. Individual practitioners will be required to apply to certain Federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificate. The CSP or CA will be required to conduct identity proofing that meets **National Institute of Standards and Technology Special Publication 800-63-1 Assurance Level 3**. Both in person and remote identity proofing will be acceptable.

Q. If a practitioner wants to undergo identity proofing to prescribe controlled substances, how is this accomplished?

A. DEA expects application providers will work with CSPs or CAs to direct practitioners to one or more sources of two-factor authentication credentials that will be interoperable with their applications. Prescribing practitioners may wish to contact their application provider to determine which CSP or CA the provider recommends the practitioner use. The specifics of each application will determine what kind of two-factor credential will be needed.

Q. Is remote identity proofing permissible?

A. Yes, the rule permits both in-person and remote identity proofing. DEA believes that the ability to conduct remote identity proofing allowed for in National Institute of Standards and Technology Special Publication 800-63-1 Level 3 will ensure that practitioners in rural areas will be able to obtain an authentication credential without the need for travel.

Q. Once a practitioner has undergone identity proofing, will the practitioner receive something?

A. The CSP or CA that conducted the identity proofing of the practitioner may issue a new hard token or register and provide credentials for an existing token. Regardless of whether a new token is provided and activated, an existing token is registered, or a biometric is used for the signing of controlled substance prescriptions, communications between the CSP or CA and practitioner applicant must occur through two channels (e.g., mail, telephone, e-mail).

Q. Why is DEA requiring the use of two-factor authentication credentials?

A. Two-factor authentication (two of the following – something you know, something you have, something you are) protects the practitioner from misuse of his/her credential by insiders as well as protecting him/her from external threats because the practitioner can retain control of a biometric or hard token. Authentication based only on knowledge factors is easily subverted because they can be observed, guessed, or hacked and used without the practitioner's knowledge.

Q. What two-factor credentials will be acceptable?

A. Under the interim final rule, DEA is allowing the use of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information). The hard token, if used, must be a cryptographic device or a one-time password device that meets Federal Information Processing Standard 140-2 Security Level 1.

Q. What is a hard token?

A. A hard token is a cryptographic key stored on a hardware device (e.g., a PDA, cell phone, smart card, USB drive, one-time password device) rather than on a general purpose computer. A hard token is a tangible, physical object possessed by an individual practitioner.

Q. Is it permissible for an individual practitioner to have the office manager or other staff maintain custody of the individual practitioner's hard token?

A. No, the practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token or knowledge factor may provide a basis for revocation or suspension of the practitioner's DEA registration.

Q. If an individual practitioner wants to use a biometric as one factor of the two-factor authentication credential, does DEA have any special requirements?

A. DEA is establishing several standards for the use of biometrics and for the testing of the software used to read the biometrics. DEA wishes to emphasize that these standards do not specify the types of biometrics that may be acceptable. Any biometric that meets the criteria DEA has specified may be used as the biometric factor in a two-factor authentication credential used to indicate that prescriptions are ready to be signed and sign controlled substance prescriptions. The use of biometrics as one factor in the two-factor authentication protocol is strictly voluntary, as is all electronic prescribing of controlled substances.

Q. Does an individual practitioner need separate authentication credentials if the practitioner has more than one DEA registration?

A. No, a single authentication credential can be used. The practitioner or the practitioner's agent must, however, select the appropriate DEA registration number when the prescription is created.

Q. If an individual practitioner uses more than one application to create and sign controlled substance prescriptions, will the practitioner need to undergo identity proofing for each and obtain separate credentials for each?

A. Whether the individual practitioner needs to undergo identity proofing and obtain separate credentials for separate applications will depend on the requirements of the applications. It is likely that if a practitioner has privileges at one or more hospitals, the hospitals will require separate credentials to use their applications.

Q. Once a practitioner possesses the two-factor credential, is the practitioner ready to sign controlled substance prescriptions?

A. No, there is another step that must be taken. Any application that meets DEA's requirements will require the practice to set access controls so that only individuals legally authorized to sign controlled substance prescriptions are allowed to do so. The application will determine whether access control is set by name or by role. If the logical access controls are role-based, one or more roles will have to be limited to individuals authorized to prescribe controlled substances. This role may be labeled "DEA registrant" or physician, dentist, nurse practitioner, etc.

Q. How are access controls set?

A. Setting access controls requires two people. One person must determine which individuals are authorized to sign controlled substance prescriptions and enter those names or assign those names to a role that is allowed to sign controlled substance prescriptions. A DEA registrant must then use his/her two-factor credential to execute the access control list. The access control list will need to be updated when registrants join or leave a practice.

Q. Who has to determine whether a prescribing practitioner's DEA registration is current and in good standing?

A. A person at the practice who is setting access control has to check to be sure that each practitioner being granted authorization to sign controlled substances prescriptions has a DEA registration, state authorization to practice and, where applicable, state authorization to dispense controlled substances that are still current and in good standing. DEA expects this will be done simply by checking the latest certificates.

Institutional Practitioners: Getting Started

(Note: The questions and responses below assume that the practitioner is an institutional practitioner (e.g., a hospital or clinic) and is a DEA registrant lawfully permitted to prescribe controlled substances. They further assume that the practitioner has received an audit or certification report from the application provider of the practitioner's software used to create prescriptions for controlled substances that indicates the application meets DEA's requirements.)

Q. Is identity proofing required for any individual practitioner whom the institutional practitioner is granting access to issue prescriptions using the institution's electronic prescribing application? If so, who will conduct it?

A. Yes, as identity proofing is critical to the security of electronic prescribing of controlled substances. Authentication credentials used

to sign controlled substance prescriptions are issued only to individuals whose identity has been confirmed. DEA is allowing institutional practitioners, who are DEA registrants, to conduct the identity proofing for any individual practitioner whom the institutional practitioner is granting access to issue prescriptions using the institution's electronic prescribing application. Because institutional practitioners have credentialing offices, those offices may conduct in-person identity proofing as part of the credentialing process. DEA is not requiring institutional practitioners to meet the requirements of National Institute of Standards and Technology Special Publication 800-63-1 for identity proofing. Before the institutional practitioner issues the authentication credential, a person designated by the institutional practitioner must check the individual practitioner's government-issued photographic identification against the person presenting it. The institutional practitioner must also check State licensure and DEA registrations, where applicable.

Q. Is an institutional practitioner required to conduct identity proofing in this manner?

A. No, institutional practitioners are allowed, but not required, to conduct identity proofing. If an institutional practitioner decides to have each practitioner obtain identity proofing and the two-factor authentication credential on his own, as other individual practitioners do, that is permissible under the rule.

Q. For an institutional practitioner, is remote identity proofing permissible?

A. The rule only allows institutional practitioners to conduct in-person identity proofing. Remote identity proofing is not permissible for institutional practitioners.

Q. For an institutional practitioner, how is the two-factor authentication credential issued?

A. Under the rule, the institutional practitioner may issue the two-factor authentication credentials or obtain them from a third party which will have to be a CSP or CA that meets the criteria DEA has specified. In the latter case, the institutional practitioner could have each practitioner apply for the two-factor credential himself, which would entail undergoing identity proofing by the CSP or CA. Alternatively, the institutional practitioner can serve as a trusted agent for the third party. Trusted agents conduct part of the identity proofing on behalf of the CSP or CA and submit the information for each person along with a signed agreement that specifies the trusted agent's responsibilities.

Q. Why is DEA requiring the use of two-factor authentication credentials?

A. Two-factor authentication (two of the following – something you know, something you have, something you are) protects the practitioner

from misuse of his/her credential by insiders as well as protecting him/her from external threats because the practitioner can retain control of a biometric or hard token. Authentication based only on knowledge factors is easily subverted because they can be observed, guessed, or hacked and used without the practitioner's knowledge.

Q. What two-factor credentials will be acceptable?

A. Under the interim final rule, DEA is allowing the use of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information). The hard token, if used, must be a cryptographic device or a one-time-password device that meets Federal Information Processing Standard 140-2 Security Level 1.

Q. What is a hard token?

A. A hard token is a cryptographic key stored on a hardware device (e.g., a PDA, cell phone, smart card, USB drive, one-time password device) rather than on a general purpose computer. A hard token is a tangible, physical object possessed by an individual practitioner.

Q. Is it permissible for a practitioner to have another staff person at the institutional practitioner maintain custody of the hard token?

A. No, the practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances.

Q. If an institutional practitioner wants to use a biometric as one factor of the two-factor authentication credential issued to persons prescribing controlled substances, does DEA have any special requirements?

A. DEA is establishing several standards for the use of biometrics and for the testing of the software used to read the biometrics. DEA wishes to emphasize that these standards do not specify the types of biometrics that may be acceptable. Any biometric that meets the criteria DEA has specified may be used as the biometric factor in a two-factor authentication credential used to indicate that prescriptions are ready to be signed and sign controlled substance prescriptions. The use of biometrics as one factor in the two-factor authentication protocol is strictly voluntary, as is all electronic prescribing of controlled substances.

Q. Are any additional steps needed to give practitioners the ability to sign controlled substance prescriptions?

A. Yes, once a person's identity has been confirmed by the credentialing office and a two-factor credential has been issued, another office must set access controls. The application must have the ability to assign permissions by name or role so that only authorized practitioners are allowed to sign controlled substance prescriptions. Two individuals must be involved in setting the access controls; one will enter the data based on information from the credentialing office and the second will approve the entry.

Accessing the Electronic Prescription Application or Electronic Health Record Application to Sign Controlled Substance Prescriptions

Q. When must a practitioner's permission to indicate that controlled substance prescriptions are ready to be signed and sign controlled substance prescriptions be revoked?

A. A practitioner's permission to indicate that controlled substance prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date it is discovered:

- If a hard token or any other authentication factor required by the two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.
- The individual practitioner's DEA registration expires, unless the registration has been renewed.
- For individual practitioners prescribing controlled substances under the registration of an institutional practitioner, when the institutional practitioner's DEA registration expires, unless the registration has been renewed.
- The individual practitioner's DEA registration is terminated, revoked, or surrendered.
- For individual practitioners prescribing controlled substances under the registration of an institutional practitioner, when the institutional practitioner's DEA registration is terminated, revoked, or surrendered.
- The individual practitioner is no longer authorized to use the electronic prescription application (e.g., when the individual practitioner leaves the practice).
- When an individual practitioner is no longer authorized to use the institutional practitioner's electronic prescription application (e.g.,

when the individual practitioner is no longer associated with the institutional practitioner).

Creating and Signing Prescriptions

Q. What information is an electronic prescription for a controlled substance required to contain?

A. As with paper prescriptions, all electronic prescriptions for controlled substances are required to contain the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. The prescription shall be dated as of the day when signed and shall be signed by the practitioner using his/her two-factor authentication credential. Where applicable, refill information must also be included, as well as any other information required by DEA regulations.

Q. Is a practitioner required to review a prescription before signing it?

A. All controlled substances must be reviewed by the prescribing practitioner. The practitioner must affirmatively indicate those prescriptions that are ready to be signed. A practitioner has the same responsibility when issuing an electronic prescription as when issuing a paper prescription to ensure that the prescription conforms in all respects with the requirements of the Controlled Substances Act and DEA regulations. This responsibility applies with equal force regardless of whether the prescription information is entered by the practitioner or a member of his staff.

Q. When a practitioner reviews a prescription, what information must be displayed?

A. All information required of any controlled substance prescription must be displayed, except for the patient's address. However, the patient's address must be part of the elements of the prescription that are digitally signed by the practitioner or the application and transmitted to the pharmacy.

Q. Must a practitioner separately attest to each prescription?

A. No, the application must include, on the prescription review screen, the following statement or its substantial equivalent: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner

whose name and DEA registration number appear above.” However, no keystroke is required to acknowledge the statement.

Q. Is it permissible to have a staff person in the practitioner’s office complete all of the required information for a controlled substance prescription and then have the practitioner review, sign, and authorize the transmission of the prescription?

A. Yes, however, if an agent of the practitioner enters information at the practitioner’s direction prior to the practitioner reviewing and approving the information, the practitioner is responsible in the event the prescription does not conform in all essential respects to the law and regulations.

Q. How will the two-factor credential be used?

A. The practitioner will use the two-factor credential to sign the prescription; that is, using the two-factor credential will constitute the legal signature of the DEA-registered prescribing practitioner. When the credential is used, the application must digitally sign and archive at least the DEA-required information contained in the prescription.

Q. May a practitioner use his/her own digital certificate to sign an electronic controlled substance prescription?

A. Yes, the interim final rule allows any practitioner to use his/her own digital certificate to sign electronic prescriptions for controlled substances. If the practitioner and his/her application provider wish to do so, the two-factor authentication credential can be a digital certificate specific to the practitioner that the practitioner obtains from a certification authority that is cross-certified with the Federal Bridge Certification Authority at the basic assurance level.

Q. How is an electronic controlled substance prescription signed?

A. The prescribing practitioner whose name and DEA registration number appear on the prescription must indicate those controlled substance prescriptions that are ready to be signed. When the registrant indicates that one or more prescriptions are to be signed, the application must prompt him/her to begin a two-factor authentication protocol. Completion of the two-factor authentication protocol legally signs the prescription(s).

Q. Will a practitioner be allowed to simultaneously issue multiple prescriptions for multiple patients with a single signature?

A. A practitioner is not permitted to issue prescriptions for multiple patients with a single signature.

Q. If a practitioner is signing more than one controlled substance prescription for a single patient, how many executions of the two-factor authentication protocol are required?

A. Each controlled substance prescription will have to be indicated as ready for signing, but execution of a single two-factor authentication protocol can then sign all prescriptions for a given patient.

Q. Once an electronic controlled substance prescription is signed, must it be transmitted to the pharmacy immediately?

A. No, signing and transmitting an electronic controlled substance prescription are two distinct actions. Electronic prescriptions for controlled substances should be transmitted as soon as possible after signing, however, it is understood that practitioners may prefer to sign prescriptions before office staff add pharmacy or insurance information. Therefore, DEA is not requiring that transmission of the prescription occur simultaneously with signing the prescription.

Other Issues

Q. If a mid-level practitioner practices in a state that requires the controlled substance prescription to contain the mid-level practitioner's supervisor's DEA number as well as the mid-level practitioner's DEA number, is this possible with electronic controlled substance prescriptions?

A. Multiple DEA numbers can appear on a single prescription, if required by state law or regulations, provided that the electronic prescription application clearly identifies which practitioner is the prescriber and which is the supervisor.

Q. Practitioners who work in a group practice with multiple practitioners may have all of the practitioners' names printed on the practice's prescription pads. Can all of the practitioners' names appear on the practice's electronic controlled substance prescriptions?

A. No, for electronic prescriptions, only one prescribing practitioner's name and DEA number will appear. If a practitioner needs to sign a prescription originally created and indicated as ready for signing by another practitioner in a practice, he/she must change the practitioner name and DEA number to his/her own. The only exception to this rule is if required by state law or regulations, multiple DEA numbers can appear on a single prescription provided that the electronic prescription application clearly identifies which practitioner is the prescriber and which is the supervisor.

Q. Can a qualified practitioner who prescribes schedules III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically

for use in maintenance or detoxification treatment use electronic prescriptions for controlled substances for this purpose?

A. Yes, a qualified practitioner may use electronic prescriptions for controlled substances to prescribe schedules III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment if the audit or certification report the practitioner receives from the application provider specifically states that the application meets DEA's requirements for those prescriptions.

Q. How can a practitioner obtain his/her prescribing history?

A. DEA is requiring that the electronic prescription application be able to generate a log, upon request by the practitioner, of all electronic prescriptions for controlled substances the practitioner issued using the application over at least the preceding two years. This log is required to be sortable at least by patient name, drug name, and date of issuance.

Transmitting Prescriptions to the Pharmacy and Printing Prescriptions

Q. What is an intermediary?

A. An intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and the pharmacy.

Q. If transmission of an electronic prescription fails, may the intermediary convert the electronic prescription to another form (e.g. facsimile) for transmission?

A. No, an electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. If an intermediary cannot complete a transmission of a controlled substance prescription, the intermediary must notify the practitioner. Under such circumstances, if the prescription is for a schedule III, IV, or V controlled substance, the practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy. This prescription must indicate that it was originally transmitted to, and provide the name of, a specific pharmacy, the date and time of transmission, and the fact that the electronic transmission failed.

Q. What are the DEA requirements regarding the storage of electronic prescription records?

A. Once a prescription is created electronically, all records of the prescription must be retained electronically. As is the case with paper

prescription records, electronic controlled substance prescription records must be kept for a minimum period of two years.

Reporting Security Incidents

Q. Is a person who administers logical access controls required to report security incidents?

A. Yes, the application is required to run an internal audit for potential security incidents daily and generate a report of any such incidents. If the application generates a report and, upon investigation, the person(s) designated to administer logical access controls for the practice or institutional practitioner determines that the issuance or records of controlled substance prescriptions has been compromised or could have been compromised, it must be reported to the application provider and DEA within one business day. In general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access.



Topical Review Electronic Prior Authorizations (ePA)

June 20, 2011

Electronic Prior Authorization technology is coming soon. Standards have already been developed and are currently being revised in anticipation of widespread adoption. This document will help identify current best practices and how those practices may change when this new technology becomes available.

Getting Ready for Electronic Prior Authorizations: Medical Office

1. Invest time to develop a prior authorization workflow that works best for your practice. Consider addressing the following points.
 - a. Today, document your current process for prior authorizations and save the work for later use
 - i. Who manages the process currently?
 - ii. Who starts a prior authorization? Who finishes it? Who delivers it?
 - b. When your vendor indicates ePA is on their list of planned upgrades, meet with staff and stakeholders to discuss electronic prior authorizations.
 - i. How will ePA change roles and responsibilities?
 1. For example, some e-prescribing workflows shift work from staff to prescribers. Will the staff then be expected to have a larger role with managing ePA?
 - ii. How will patients be informed of ePA processes?
 1. Electronic prior authorizations put the medical office prescriber and staff in the best position to provide this education instead of the pharmacy.
 - iii. How will communications with the pharmacy change?
 - iv. What situations require a change to an approved therapy versus completing the authorization requirements for the intended therapy?
 - v. What medications have acceptable alternatives? Under what conditions?
 1. Consider creating a list of acceptable alternatives for staff reference.
 - c. When ePA is available, create written protocols for staff and prescribers to use as a guide.
 - i. Define how prior authorizations are started from new prescriptions and renewal requests.
 - ii. Define responsibilities of staff and prescribers.
 - iii. Define how patients will be educated and informed regarding any prior authorization process that affects them.
 - iv. Define how new staff and providers will be educated and informed regarding the prior authorization process.
 - v. Define how to communicate the office's management of prior authorizations to local pharmacists.
 1. Consider creating an FAQ that can be readily faxed to pharmacies as needed.
2. Use electronic prescribing, preferably in an electronic health record that has formulary alerts.

Getting Ready for Electronic Prior Authorization: Pharmacies

1. Invest time to develop a prior authorization workflow that works best for your pharmacy. Consider addressing the following points
 - a. Today, document your current process for prior authorizations
 - i. Who manages the process currently? How is it documented? How is it followed up?
 - b. When your vendor indicates ePA is on their list of planned upgrades, meet with staff and stakeholders to discuss electronic prior authorizations
 - i. How will roles and responsibilities change within the pharmacy? With providers?
 - ii. How will patients be informed?
 - iii. How will provider interactions change?
 - iv. What criteria determine whether a patient is referred to their provider or managed in the pharmacy?
 - c. When ePA is available, create written protocols for staff and prescribers to use as a guide
 - i. Define responsibilities of staff and pharmacists
 - ii. Define how patients will be educated and informed regarding any prior authorization process that affects them
 1. Consider working with local providers to determine whether general expectations fall to pharmacy to provide this education or to the providers
 - iii. Define how new staff and providers will be educated and informed regarding the prior authorization process
 - iv. Define how to communicate the pharmacy's management of prior authorizations to local providers
 1. Consider creating an FAQ that can be readily faxed to providers and be made available for patients
2. Reach out to local providers to understand their electronic prior authorization processes

References and further information

Brief summary of the state of ePA: <http://www.healthit.gov/buzz-blog/from-the-onc-desk/eprescribing-standards-eprior-authorization/>

NCPDP progress on ePA standards: http://www.ncdp.org/PDF/NCPDP_prior_auth_workflow.ppt
http://www.pocp.com/images/pdfs/ePrior_Auth_-_AMCP_-_Final_Final.pdf

Minnesota ePA work: <http://www.health.state.mn.us/asa/drugauth122109mtgmat2.pdf>

ePA Prescriptions

Bottom Line: Work shifts from the pharmacy to prescribers and staff

Current Best Practice:	Expected change after ePA:
<p>Providers often learn of the need for prior authorization when creating and renewing prescriptions in one of two ways.</p> <ul style="list-style-type: none"> • When responding to an electronic renewal request – a formulary alert appears and suggests a prior authorization is needed. <ul style="list-style-type: none"> ○ In offices where support staff is the initial responders to renewal requests, this prior authorization information may be forwarded to the prescriber. • The prescription is already written and the pharmacy discovers the need for prior authorization when transmitting the claim to the insurer. The pharmacy usually faxes this as a request back to the prescriber for review, which is also mediated by the office support staff. Both paths lead to a common next step: starting the prior authorization process. <p>In most cases, office staff will initiate or complete the prior authorization form and give it to the prescriber for review and approval. Then, office staff sends the form to the insurer and answer any future pharmacy questions regarding the status of the prior authorization.</p>	<p>An electronic prior authorization alters the current best practice in several fundamental ways.</p> <ul style="list-style-type: none"> • Responding to an electronic renewal request (or creating a prescription) where prior authorization is required generates a formulary alert. This immediately places the prescriber in a position of reviewing and authorizing the submission of the prior authorization as part of finishing the prescription; alternative medications can be chosen and justifications can be documented. <ul style="list-style-type: none"> ○ If the ePA cannot be completed at that moment, the prescription itself may be placed on hold until the prior authorization can be resolved. • The provider or office staff needs to inform and educate the patient regarding the prior authorization and any prescription delays. <ul style="list-style-type: none"> ○ In offices where office staff is the initial responders to electronic renewal requests, business rules are needed to define how this prior authorization alert should be handled. <p>In some cases, the prescription is already written and the pharmacy discovers the need for prior authorization when transmitting the claim to the insurer, assuming the prescriber’s system allowed the prescription to be sent without a completed ePA present. The pharmacy will need to follow up with the insurer or the provider’s office staff to determine the status of the ePA.</p>

Rationale: Electronic prior authorizations remove several steps in the prior authorization process. This shifts much of the burden of management to the prescriber while many of the secretarial functions of putting information into a form are now computerized and automatically completed. This shifts the discovery of the need for prior authorization away from the pharmacy to the provider’s office, and carries the burden of patient education with it.

ePA Documentation

Bottom Line: Automation helps save time, but work may be assumed for reports and quality assurance.

Current Best Practice:	Expected change after ePA:
<ul style="list-style-type: none">• Prior authorizations are generally documented by office staff in a separate binder, as part of the chart, or not at all.• Pharmacists often make notations on the reverse of the prescription to document prior authorization activities, or add an electronic note to the patient's profile.	<ul style="list-style-type: none">• Prior authorizations will be recorded in the prescriber's software and may be tagged as approved when they arrive at the pharmacy.• In some electronic health records, this information may also be pushed to other data consumers such as patient portals, HIE¹s, and other parts of the patient's internal record. Software vendors will determine the robustness of adhoc documentation available for ePA.• Certain offices may want to use ePA for the generation of reports, suggesting additional work might be taken on by office staff to manage the data reporting.• Reports on ePA activity can be used for quality improvement, measuring outcomes, nonadherence reports, measures of workload, and more. Again, potentially more work assumed.

Rationale

The digitized and archival form of ePA lead immediately to ways the data can be transformed to information. Since the relative accessibility of this information is almost solely determined by vendors, there will likely be a large variety of documentation capability from one product to another. The robustness of documentation options may lead to the assumption of more work by office support staff in the form of reports and quality assurance activities even as automation and workflows shift work to the prescribers.

¹ HIE = Health Information Exchange

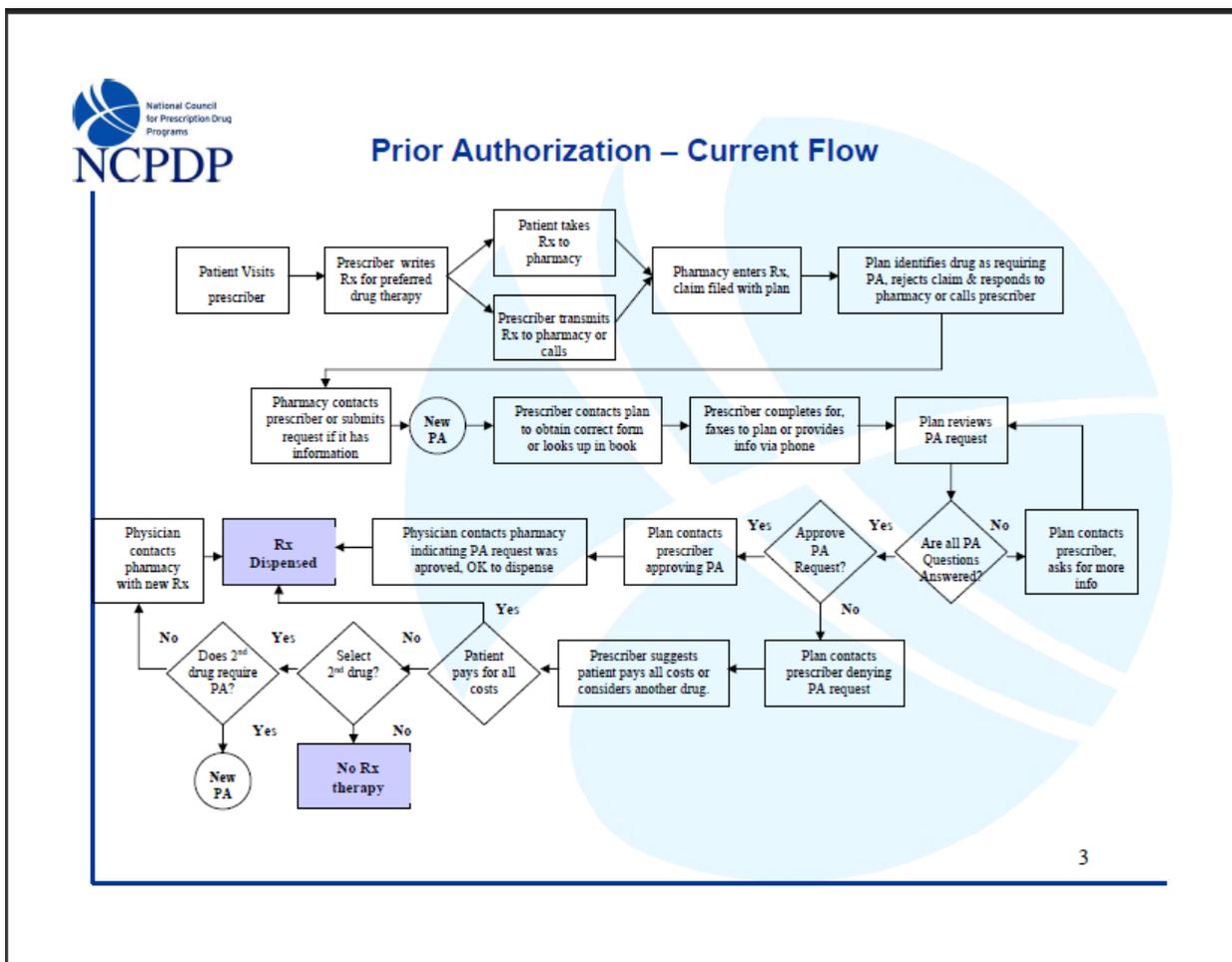
ePA Patient and Staff Education

Bottom Line: Work shifts from the pharmacy to the prescriber and office staff.

Current Best Practice:	Expected change after ePA:
<p>Patients learn about prior authorizations most often when there is a delay in getting their medication. In a rough order of frequency, patients learn from:</p> <ul style="list-style-type: none">• The pharmacist, when the patient presents for a prescription held up for prior authorization• The prescriber's office, when the patient calls for a renewal and is told it cannot be processed• By the prescriber or staff at the time the prescription is written• By the insurance company, when the patient calls to make a complaint or get information about the prior authorization process <p>The following is a suggested best practice:</p> <ol style="list-style-type: none">1. If the prescriber is aware that prior authorization is required, there is a discussion with the patient during the visit.2. The patient decides if they will pay for the prescription if the PA is denied	<ol style="list-style-type: none">1. The need for prior authorization is flagged during prescribing in the system2. The prescriber or support staff have a discussion with patient during the visit regarding the prior authorization3. The patient decides if they will pay for the prescription if the ePA is denied

Rationale

The patient can be much more involved at the prescriber's office due to the ePA information arriving at the point of care. Coupled with the automatic population of information already contained in the electronic health record, the ePA can be completed quickly and efficiently. This limits the phone calls and follow-up required with the patient. The workflow is substantially changed, shifting the burden of patient education from the pharmacy to the prescriber and support staff, primarily because the discovery of the need for prior authorization is moved from the pharmacy during claims submission to the prescriber at the point of care.



Today, health plans and Pharmacy Benefit Managers (PBMs) have a number of processes in place for providers to request prior authorizations. An electronic tool may be offered that is available 24/7 through a website to submit requests and get answers any time. The system prompts providers for the information needed to decide whether the request meets the proper criteria. If the request meets the criteria, approval will be sent immediately. If the request doesn't meet the criteria, it will be forwarded for review and a response will be given within 48 hours. Status of requests can be accessed online. There are also paper processes in place to request PAs, which are generally faxed to reviewers and responded to within 24 hours.

Advantages of electronic submission are editing for required fields, no handwriting interpretation, no longer needing to key information in and the ability to apply logic to simple requests. Industry standards for ePA are required to enable electronic prior authorization via eRx/EHR systems. This has been challenging in the past because all health plans and PBMs have different PA requirements and in order for ePA to work, there would need to be consensus on the requirements across the industry.

Assuming this was to occur, providers would be able to request PA directly from their eRx/EHR system and send the completed form electronically to the appropriate plan/PBM and/or authorization might be real-time based on a plan's logic and viewed via the eRx/EHR. Rural states still have massive high speed access limitations, so if ePA is required, technology issues remain.

The ideal ordering system is integrated with the PA process without leaving the application, not launching to another application. The ordering provider will be able to experience real-time prior authorization with the insurer, replacing the traditional phone or fax means of requesting prior authorization.

1. A formulary alert should display according to patient formulary and benefit plan (drug benefit)

If patient online access is available, entering an order for medication should also alert the patient of the PA process. The patient can initiate entry of information relevant to demographic and other necessary information to assist in the PA process. This would be part of renewal process of PA.

2. Provider should process electronic PA real time to support the following workflows:

- ✓ The prescriber can proceed with the PA if the patient chooses to pay. When the real-time approved PA is received, the prescriber proceeds to transmit the eRX to the Pharmacy.
- ✓ The prescriber can choose an alternative medication if the patient cannot pay, then proceeding to send the chosen alternative medication and transmit the eRX to the Pharmacy.
- ✓ The prescriber can abandon the ePA without leaving the ordering application.

Having real-time PA with approval and transmitting the eRX to the pharmacy is expected to increase patient satisfaction, eliminating the waiting time for approval from payer and also the back and forth fax and phone exchange between the payer, pharmacy, and the prescriber's office.

ePA is expected to reduce administrative burden on providers who currently complete PA request forms, and on health plans that must review the request and send authorization. Patients would not have to wait for this process to occur in order to receive their prescription, which may have safety benefits through reducing the delays to therapy.

Foremost, some consideration should be given to the enormous changes facing the industry right now with 5010 and ICD-10, but standards and expectations must be identified and deadlines established well in advance to allow for all of the changes to be done. To help:

- Collaborate with payers with regards to standardization of the questions and answer used in PA fulfillment.
- Collaborate with software vendors on the best way integrate drugs with PA needs according to payer's formulary in real-time.

E-Prescribing and Standards for E-Prior Authorization

May 2, 2011, 9:09 am

Doug Fridsma Director Office of Interoperability and Standards and Steven Posnack Director Federal Policy Division, DHHS

Recently, colleagues have raised questions about pending state legislation related to electronic prescribing (e-prescribing) and in particular the concept of electronic prior authorization (ePA) for medications. We thought it would be helpful to discuss what we know about the current state of e-prescribing and ePA. E-prescribing provides significant advantages in contrast to its paper analog. Coupled with other complementary technologies, such as drug-drug interaction checking, e-prescribing can improve patient safety, increase prescribing accuracy and efficiency, and lower costs by notifying providers of generic or preferred drug list alternatives.

Over the past three years, Congress has signaled its support for e-prescribing by promoting its use in two major laws: Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act covers certain eligible professionals seeking to become meaningful users of certified electronic health record (EHR) technology in the Medicare and Medicaid EHR Incentive Programs. The HITECH Act specifically identified e-prescribing as a requirement for eligible professionals participating in the EHR incentive programs, and therefore it is part of the "core set" of meaningful use objectives and measures (which also includes objectives and associated measures for using computerized provider order entry [CPOE], maintaining active medication and medication allergy lists, and implementing clinical decision support). MIPPA focuses on Medicare eligible professionals to encourage e-prescribing with a separate incentive program requiring use of a qualified e-prescribing system. Below are a few points that address some of the questions raised by our state colleagues as they consider e-prescribing related legislation.

It is useful to keep apprised of the technical requirements (capabilities and technical standards) that are currently part of Federal health IT programs to ensure consistency and avoid potential conflicts. While ONC requires as a condition of certification (for the purposes of meaningful use) that EHR technology be capable of generating and transmitting electronic prescriptions, certification does not require that EHR technology also be capable of performing electronic prior authorization. We are not aware of a widely adopted, common, industry transaction standard that has been demonstrated to support real-time ePA, nor are we aware of a common or universal electronic format that has been demonstrated to facilitate distribution of prior authorization forms. We are aware of work that has been done by the National Council for Prescription Drug Programs (NCPDP) to create an XML-based ePA messaging standard and a real-time eligibility check messaging standard. We understand that these are draft standards that have not yet been tested in pilots and have not been fully "balloted" (voted on) through NCPDP's process or been finalized as American National Standards Institute (ANSI)-accredited standards.

There is a lack of established and fully vetted standards to support ePA and the current lack of capability to support ePA in implemented EHR systems. Therefore, requiring real-time electronic prior authorization as a prerequisite technical capability before health care providers could e-prescribe and/or access drug formulary information may be difficult to implement, and could otherwise prevent providers from being able to e-prescribe. If such requirements prevent providers from being able to e-prescribe, it could also keep them from being able to participate in the incentive programs noted above.

We look forward to continued work and collaboration with our state colleagues through all of the ONC-administered HITECH programs and hope that this blog provides useful context.

States with alerts language in statute – in context

SUMMARY

- FL, ND and NH address alerts as part of electronic prescribing laws
- ME and VT address alerts as part of regulating advertising of prescription drugs

Florida

CHAPTER 456 - HEALTH PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS

456.42 Written prescriptions for medicinal drugs.—A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats and must be dated with the abbreviated month written out on the face of the prescription. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

History.—s. 1, ch. 2003-41; s. 2, ch. 2006-271; s. 2, ch. 2009-202.

456.43 Electronic prescribing for medicinal drugs.—

(1) Electronic prescribing shall not interfere with a patient’s freedom to choose a pharmacy.

(2) *Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.*

(a) The term “prescribing decision” means a prescribing practitioner’s decision to prescribe a certain pharmaceutical.

(b) The term “point of care” means the time that a prescribing practitioner or his or her agent is in the act of prescribing a certain pharmaceutical.

(3) Electronic prescribing software may show information regarding a payor’s formulary as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

History.—s. 3, ch. 2006-271.

FL. Senate Bill 1408. Enacted; 2006.

New Hampshire

HB134 2007 - AN ACT relative to electronic prescribing for prescription drugs.

Be it Enacted by the Senate and House of Representatives in General Court convened:

320:1 Statement of Intent. The general court recognizes the benefit of new technologies in the area of health care. The general court recognizes the sanctity of confidential and secure health care information. The general court further recognizes the goal of the New Hampshire Citizen's Health Initiative to improve patient health and safety through electronic prescribing. The general court believes that the goal of electronic prescribing is best met through an environment that is confidential, secure, and free from commercial intrusion that may interfere with medical care and the patient-prescriber relationship. Therefore, the general court hereby establishes the framework to encourage electronic prescribing for the benefit of patients, prescribers, and payers of health care.

320:2 Prescriptions; Electronic Prescribing. Amend RSA 318:47-c to read as follows:
318:47-c Prescriptions.

I.(a) A prescription may be written, oral, or electronically transmitted. All oral prescriptions shall be immediately reduced to writing by the pharmacist or authorized technician receiving the oral prescription and shall indicate at least the name of the patient; the name, strength, and quantity of the drug prescribed; any directions specified by the prescriber; the name of the practitioner prescribing the medication; the date the prescription was ordered; a statement that the prescription was presented orally; and the name of the pharmacist who took the verbal order. The pharmacist who dispensed an original prescription shall indicate on the face of the prescription at least the assigned prescription identification number; the date of dispensing; the quantity actually dispensed; and his or her name or initials. The prescription shall be filed numerically by the assigned identification number for a period not less than 4 years. Such prescription files shall be open to inspection by the pharmacy board and its agents.

(b) A patient shall be entitled to receive a paper prescription instead of an oral or electronically transmitted prescription.

II.(a) A prescription that is electronically generated by a licensed prescriber, transmitted and received at the pharmacy by computer systems shall contain at least the name of the patient, the name, strength, and quantity of the drug prescribed, any directions specified by the prescriber, the name of the practitioner prescribing the medication, and shall be dated and signed by the prescribing practitioner on the day issued, and such signature shall be in an electronic format as defined in RSA 294-E:2, VIII.

(b) Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(c) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered by or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(d) Electronic prescribing software may show information regarding a payor's formulary, co-payment, or benefit plan as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

(e) No person who has access to electronic prescription information solely by transmitting or facilitating the transmission of prescriptions between the licensed prescriber generating the prescription and the pharmacy receiving the prescription, or any intermediary, shall retain the prescription or any information it contains for longer than is mandated by federal or state law, after which time the prescription information shall be destroyed. No such person shall sell, use, or otherwise make available the prescription information for any purpose other than transmission of prescriptions, prescription refills, and clinical information displayed to the prescriber or pharmacist.

320:3 Effective Date. This act shall take effect 60 days after its passage.

Approved: July 16, 2007

Effective: September 14, 2007

NH. House Bill 134. Enacted.; 2007.

North Dakota

CHAPTER 23-01 - ELECTRONIC DRUG PRIOR AUTHORIZATION AND TRANSMISSION - LIMITATIONS

1. Effective August 1, 2013, a drug prior authorization request must be accessible to a health care provider with the provider's electronic prescribing software system and must be accepted electronically, through a secure electronic transmission, by the payer, by the insurance company, or by the pharmacy benefit manager responsible for implementing or adjudicating or for implementing and adjudicating the authorization or denial of the prior authorization request. For purposes of this section, a facsimile is not an electronic transmission.

2. Effective August 1, 2013, electronic transmission devices used to communicate a prescription to a pharmacist may not use any means or permit any other person to use any means, including advertising, commercial messaging, and popup advertisements, to influence or attempt to influence through economic incentives the prescribing decision of a prescribing practitioner at the point of care. Such means may not be triggered by or be in specific response to the input, selection, or act of a prescribing practitioner or the prescribing practitioner's staff in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy. Any electronic communication sent to the prescriber, including advertising, commercial messaging, or popup advertisements must be consistent with the product label, supported by scientific evidence and meet the federal food and drug administration requirements for advertising pharmaceutical products.

ND. House Bill 1422. Enacted; 2011.

Maine

Title 22: HEALTH AND WELFARE

Subtitle 2: HEALTH

Part 5: FOODS AND DRUGS

Chapter 605: PRESCRIPTION DRUG ADVERTISING HEADING: PL 2005, C. 392, §1 (NEW)

§2700-A. Prohibitions and required disclosures

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit. [2005, c. 392, §1 (NEW).]

B. "Manufacturer of prescription drugs" or "manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999). [2005, c. 392, §1 (NEW).]

B-1. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice. [2007, c. 362, §1 (NEW).]

C. "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is:

(1) Broadcast on television or radio from a station that is physically located in the State;

(2) Broadcast over the Internet from a location in the State; or

(3) Printed in magazines or newspapers that are printed, distributed or sold in the State. [2005, c. 392, §1 (NEW).]

[2007, c. 362, §1 (AMD) .]

2. Regulated advertisement requirement. Beginning October 15, 2005, a manufacturer may not present or cause to be presented in the State a regulated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules.

[2005, c. 392, §1 (NEW) .]

2-A. Software prohibition. *Beginning January 1, 2008, a person may not sell or distribute in the State computer software that influences or attempts to influence a prescribing decision of a prescriber to prescribe a certain drug or that directs a patient to a certain pharmacy. Features of computer software that are prohibited include, but are not limited to, pop-up and other advertisements, instant messages and economic incentives that are triggered by or in specific response to a selection, act or other input or designation of pharmacy by the prescriber or an agent of the prescriber. This subsection does not apply to in-house equipment provided within a hospital for use by prescribers and the hospital pharmacy or to information provided to a prescriber about prescription drug formulary compliance, patient care management or pharmacy reimbursement.*

[2007, c. 362, §2 (NEW) .]

3. Disclosure of clinical trials of prescription drugs. Beginning October 15, 2005, a manufacturer or labeler of prescription drugs that is required to report marketing costs for prescription drugs pursuant to section 2698-A shall post, with regard to those prescription drugs, on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October 15, 2002:

- A. The name of the entity that conducted or is conducting the clinical trial; [2005, c. 392, §1 (NEW).]
- B. A summary of the purpose of the clinical trial; [2005, c. 392, §1 (NEW).]
- C. The dates during which the trial has taken place; and [2005, c. 392, §1 (NEW).]
- D. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug. [2005, c. 392, §1 (NEW).]

In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department.

[2005, c. 392, §1 (NEW) .]

4. Fees. Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254-D shall pay a fee of \$1,000 per calendar year to the State. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection 3 and other relevant sites, assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection 5 and the prescription drug academic detailing program under section 2685. One half of the annual revenues from this subsection must be allocated to and used for the academic detailing program under section 2685. Revenues received under this subsection, with the exception of funding designated for the academic detailing program under section 2685, must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection.

[2007, c. 327, §2 (AMD) .]

5. Public education initiative. The department shall undertake a public education initiative to inform residents of the State about clinical trials and drug safety information and shall coordinate the public education program with the prescription drug academic detailing program under section 2685.

[2007, c. 327, §3 (AMD) .]

6. Penalties. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

[2005, c. 392, §1 (NEW) .]

7. Rulemaking. The department may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[2005, c. 392, §1 (NEW) .]

SECTION HISTORY

2005, c. 392, §1 (NEW). 2005, c. 589, §2 (AMD). 2005, c. 683, §B17 (AMD). 2007, c. 327, §§2, 3 (AMD). 2007, c. 362, §§1, 2 (AMD).

ME. House Bill 1009. Enacted; 2007, c. 362, §2.

Vermont

TITLE 9 Commerce and Trade

PART 3 Sales, Assignments and Secured Transactions

CHAPTER 63. CONSUMER FRAUD

Subchapter 1. General Provisions

§ 2466a. Consumer protections; prescription drugs.

(a) A violation of 18 V.S.A. § 4631 shall be considered a prohibited practice under section 2453 of this title.

(b) As provided in 18 V.S.A. § 9473,, a violation of 18 V.S.A. § 9472 shall be considered a prohibited practice under section 2453 of this title.

(c) (1) It shall be a prohibited practice under section 2453 of this title for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202.

(2) For purposes of this section:

(A) "Manufacturer of prescription drugs" means a person authorized by law to manufacture, bottle, or pack drugs or biological products, a licensee or affiliate of that person, or a labeler that receives drugs or biological products from a manufacturer or wholesaler and repackages them for later retail sale and has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

(B) "Regulated advertisement" means:

(i) the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is broadcast on television, cable, or radio from a station or cable company that is physically located in the state, broadcast over the Internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state; or

(ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:

(I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or

(II) at a conference or other professional meeting occurring in Vermont.

(d) No person shall sell, offer for sale, or distribute electronic prescribing software that advertises, uses instant messaging and pop-up advertisements, or uses other means to influence or attempt to influence the prescribing decision of a health care professional through economic incentives or otherwise and which is triggered or in specific response to the input, selection, or act of a health care professional or agent in prescribing a specific prescription drug or directing a patient to a certain pharmacy. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

Added 2007, No. 80, § 21; 2007, No. 89 (Adj. Sess.), § 5, eff. March 5, 2008.

VT. Senate Bill 115. Enacted; 2007.

States with electronic prior authorization language in statute – in context

SUMMARY

- MN and ND address the availability of standardized prior authorization forms and electronic access to the prior authorization process

Minnesota

62J.497 ELECTRONIC PRESCRIPTION DRUG PROGRAM.

Subd. 4. Development and use of uniform formulary exception form.

(a) The commissioner of health, in consultation with the Minnesota Administrative Uniformity Committee, shall develop by July 1, 2009, a uniform formulary exception form that allows health care providers to request exceptions from group purchaser formularies using a uniform form. Upon development of the form, all health care providers must submit requests for formulary exceptions using the uniform form, and all group purchasers must accept this form from health care providers.

(b) No later than January 1, 2011, the uniform formulary exception form must be accessible and submitted by health care providers, and accepted and processed by group purchasers, through secure electronic transmissions.

Subd. 5. Electronic drug prior authorization standardization and transmission.

(a) The commissioner of health, in consultation with the Minnesota e-Health Advisory Committee and the Minnesota Administrative Uniformity Committee, shall, by February 15, 2010, identify an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions.

(b) By January 1, 2014, the Minnesota Administrative Uniformity Committee shall develop the standard companion guide by which providers and group purchasers will exchange standard drug authorization requests using electronic data interchange standards, if available, with the goal of alignment with standards that are or will potentially be used nationally.

(c) No later than January 1, 2015, drug prior authorization requests must be accessible and submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.

History:

[2008 c 358 art 4 s 3](#); [2009 c 79 art 4 s 3-6](#); [2009 c 102 s 3,4](#); [2009 c 173 art 1 s 1](#); [2010 c 336 s 4,5](#)
Minnesota state code. §62J.497(5).

North Dakota

CHAPTER 23-01 - ELECTRONIC DRUG PRIOR AUTHORIZATION AND TRANSMISSION - LIMITATIONS

SECTION 2. ELECTRONIC DRUG PRIOR AUTHORIZATION STANDARDIZATION AND TRANSMISSION - REPORT TO LEGISLATIVE MANAGEMENT. During the 2011-12 interim, the health information technology advisory committee shall establish an outline on how best to standardize drug prior authorization request transactions between providers and the payers, insurance companies, and pharmacy benefit managers responsible for adjudicating the authorization or denial of the prescription request. The outline must be designed with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions and alignment with standards that are or will potentially be used nationally. By June 30, 2012, the health information technology advisory committee shall provide a report to the legislative management regarding the outline on how best to standardize drug prior authorization request transactions.

ND. House Bill 1422. Enacted; 2011.

States with PBM transparency language in statute – in context

SUMMARY

- ME passed the first PBM transparency law in the U.S. in 2003; the law requires the PBM to act as a fiduciary, pass all rebates through to the payer and disclose financial arrangements
- MS passed the first law in the U.S. requiring the Board of Pharmacy to license and oversee PBM business activities (SB 2445, enacted 2011)
- TX passed a study bill to evaluate how PBMs use Rx data to manage the drug benefit

Maine

§2699. PRESCRIPTION DRUG PRACTICES

F. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity. [2003, c. 456, §1 (NEW).]

G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except that disclosure may be ordered by a court of this State for good cause shown or made in a court filing under seal unless or until otherwise ordered by a court. Nothing in this paragraph limits the Attorney General's use of civil investigative demand authority under the Maine Unfair Trade Practices Act to investigate violations of this section.

[2003, c. 688, Pt. C, §11 (AFF); 2003, c. 688, Pt. C, §9 (AMD).]

Texas

Subchapter B, Chapter 1369, Insurance Code, is amended by adding Section 1369.0551 to read as follows:

Sec. 1369.0551. STUDY. (a) The department shall conduct a study to evaluate the ways in which pharmacy benefit managers use prescription drug information to manage therapeutic drug interchange programs and other drug substitution recommendations made by pharmacy benefit managers or other similar entities. The study must include information regarding pharmacy benefit managers:

(1) intervening in the delivery or transmission of a prescription from a prescribing health care practitioner to a pharmacist for purposes of influencing the prescribing health care practitioner's choice of therapy;

(2) recommending that a prescribing health care practitioner change from the originally prescribed medication to another medication, including generic substitutions and therapeutic interchanges;

(3) changing a drug or device prescribed by a health care practitioner without the consent of the prescribing health care practitioner;

(4) changing a patient cost-sharing obligation for the cost of a prescription drug or device, including placing a drug or device on a higher formulary tier than the initial contracted benefit level; and

(5) removing a drug or device from a group health benefit plan formulary without providing proper enrollee notice.

(b) Not later than August 1, 2010, the department shall submit to the governor, the lieutenant governor, the speaker of the house of representatives, and the appropriate standing committees of the legislature a report regarding the results of the study required by Subsection (a), together with any recommendations for legislation.

TX. HB 4402. Enacted 2010.