

A National Web Conference

E-Prescribing and Medication Management: Current Realities and Future Directions

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E-prescribing: Current realities and future directions

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Overview

- Promise of e-prescribing
 - Multiple areas of medication use
- Evidence to date
 - Quantitative
 - Qualitative
- Remaining barriers



Areas of focus

- Safety
- Efficiency
- Medication costs
- Barriers to adoption and use

Take-home points

- E-prescribing has the potential to improve patient safety and increase the quality and efficiency of prescribing
- Evidence that these gains can be achieved in outpatient setting with current systems still being developed
- Barriers to full adoption must be addressed aggressively



Increasing safety - promise

- Address legibility problems
- Better information at point of prescribing
 - 25% fewer ADEs (CITL, 2003)
 - Avoid allergic reactions
 - Avoid drug-drug interactions
 - Use medications more safely
 - Doses, frequency, age

Increasing safety - proof

- Quantitative data from inpatient setting
(Bates, JAMA 1998; Bates, J Am Med Inform Assoc 1999; Raschke, JAMA 1998)
 - Improved antibiotic management
 - Evans, N Engl J Med 1998
 - Safer prescribing for the elderly
 - Peterson, Arch Intern Med 2005
 - Guiding use of high-risk medications
 - Fischer, Drug Safety 2004
- Qualitative data from outpatient setting
 - Review of medication history, identifying patients on high-risk drugs, no tampering



Increasing safety - pitfalls

- Limited quantitative outpatient data
- E-prescribing alone may not reduce errors (Ghandi, J Gen Int Med 2005)
- >90% of alerts overridden by prescribers (Isaac, Arch Int Med 2009; Weingart, Arch Int Med 2003; LaPane, J Gen Int Med 2008)
- Possibility of new errors
 - Selecting wrong patient/drug
 - Doses/formulations not in system



Increasing safety – challenges

- Defining true safety gains
 - vs. efficiency
- Improving alert acceptance (Shah, J Am Med Inform Assoc 2006)
- Data infrastructure to support safety
 - Connectivity to other systems
 - Link to EMRs
 - How to input additional clinical data



Increasing efficiency - promise

- 1 billion callbacks per year (HHS 2004)
 - Patients: time, adherence
 - Pharmacists: time, distraction
 - Prescribers: time, workflow
- Inefficient processes throughout the **system** (Flynn, Am J Hlth Syst Pharm 1999)



Increasing efficiency - proof

- Qualitative data on efficiency
 - Avoiding lost prescriptions
 - Reduced calls for offices/pharmacies
 - Ability to group prescribing tasks

Increasing efficiency – pitfalls and challenges

- No quantitative data
 - Role to providers not clear
- Connectivity and reliability problems
- Inability to transmit to PBMs
- Inability to e-prescribe schedule II meds



Controlling costs - promise

- Large potential savings from prescribing less expensive medications
 - Generic substitution (Haas, Ann Int Med 2005)
 - Therapeutic substitution (Fischer, JAMA 2004)
- Improved adherence for patients started on medications with lower copayment (Shrank, Arch Int Med 2006)



Controlling costs - proof

- Shift from brand to generic with e-prescribing (Fischer, Arch Int Med 2008)
 - 3.3% increase in generics
- Ability to discuss costs with patients
- Ability to identify patients on costly medications
 - e.g., when new generic available



Controlling costs – pitfalls and challenges

- Data need to be current and accurate to affect decisions
- Prescribing changes only seen when actually using e-prescribing

Improving medication adherence

- Non-adherence to chronic medications
 - Common
 - Limits medication effectiveness
- Potential of e-prescribing to improve adherence
 - Using medication history to identify non-adherence
 - Interventions delivered via e-prescribing



Major barriers to e-prescribing

- Adoption remains slow (Gans, Health Aff 2005; Fischer, J Gen Int Med 2008)
- Adoption barriers
 - Cost, learning curve
- Usability/reliability
 - Interoperability, connectivity
- Perceived patient resistance
- Data security concerns



Overcoming barriers to realize gains

- Make e-prescribing positive for practices
 - Smaller practices, support, interoperability
 - Address areas that matter to prescribers
- Demonstrate patient preference
- Ensure reliability and security

Summary

- E-prescribing has the potential to improve patient safety and increase the quality and efficiency of prescribing
- Evidence that these gains can be achieved in outpatient setting with current systems still being developed
- Barriers to full adoption must be addressed aggressively



Thank You!

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Enabling E-Prescribing of Controlled Substances

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Project Collaborators

- MA Department of Public Health, Drug Control Program
- DrFirst, Inc., Rockville, MD
- eRx Network, *an Emdeon company*
- Brandeis University, Heller School for Social Policy and Management
- Berkshire Health Systems, Inc.
- U. S. Department of Justice, Drug Enforcement Administration
- Supported by a grant from the U.S. Agency for Healthcare Research and Quality



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Agenda

- Current status of e-prescribing of controlled substances (EPCS)
- Requirements for EPCS
- Research and demonstration project on EPCS
- Preliminary findings (including potential barriers to adoption of EPCS)
- Expected project outcomes



Challenges Unique to EPCS

- Currently there is a lack of approved security standards for the electronic prescribing of controlled substances (EPCS).
- Security standards for EPCS are a unique challenge because of the need to prevent pharmaceutical (or drug) diversion.



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Challenges Unique to EPCS

- Pharmaceutical (or drug) diversion is the channeling of licit controlled substances or other pharmaceuticals for illegal purposes or abuse.
- Diversion may include, but is not limited to, theft, burglary and robbery; tampering; stealing, forging and counterfeiting prescriptions; doctor shopping; indiscriminate prescribing; and illegal sales of prescriptions and pharmaceuticals.

Source: Alliance of States with Prescription Monitoring Programs, 1999



Challenges Unique to EPCS

- Controlled substances prescriptions estimated to comprise 326M prescriptions¹ (ca. 8.8%) of total 3,700M U.S. prescriptions²
- Prevalence of non-medical use of prescription psychotherapeutics in U.S. estimated at 7M current users³
- Incidence of non-medical use of prescription psychotherapeutics in U.S. estimated at 2.2M new users³

¹U.S. Drug Enforcement Administration, 2008

²IMS Health, 2006

³U.S. Substance Abuse and Mental Health Services Administration, 2006



Challenges Unique to EPCS

The lack of approved standards has contributed to a delay in realizing the full patient safety, clinical benefits, and risk reductions that are known to result from e-prescribing, including

- Better medication management and coordination of care
- Better decision support
- Clinician workflow improvement
- Prevention of medication errors



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Benefits Unique to EPCS

In addition, there are potential benefits unique to EPCS:

- Reductions in non-medical use and abuse of federally controlled pharmaceuticals
- Increase in adoption of e-prescribing of non-controlled (legend) medications
 - Elimination of need for two separate systems (i.e., e-prescribing for legend medications and paper for controlled medications)



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Security Requirements

The U.S. Drug Enforcement Administration (DEA) has identified a set of security elements that must be included in a health IT solution for EPCS



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Background: Security Requirements

Authentication Positively identifying the signer and establishing who is sending and receiving data

Non-repudiation That parties to an activity cannot reasonably deny having participated in the activity

Record Integrity Data and signature have not been altered after signature



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Background: Security Requirements

Legal Sufficiency

Litigation strength for prosecution, i.e., the ability to be proven beyond a reasonable doubt

Signature Verification

Ascertainment that an identified signer intended to endorse a writing

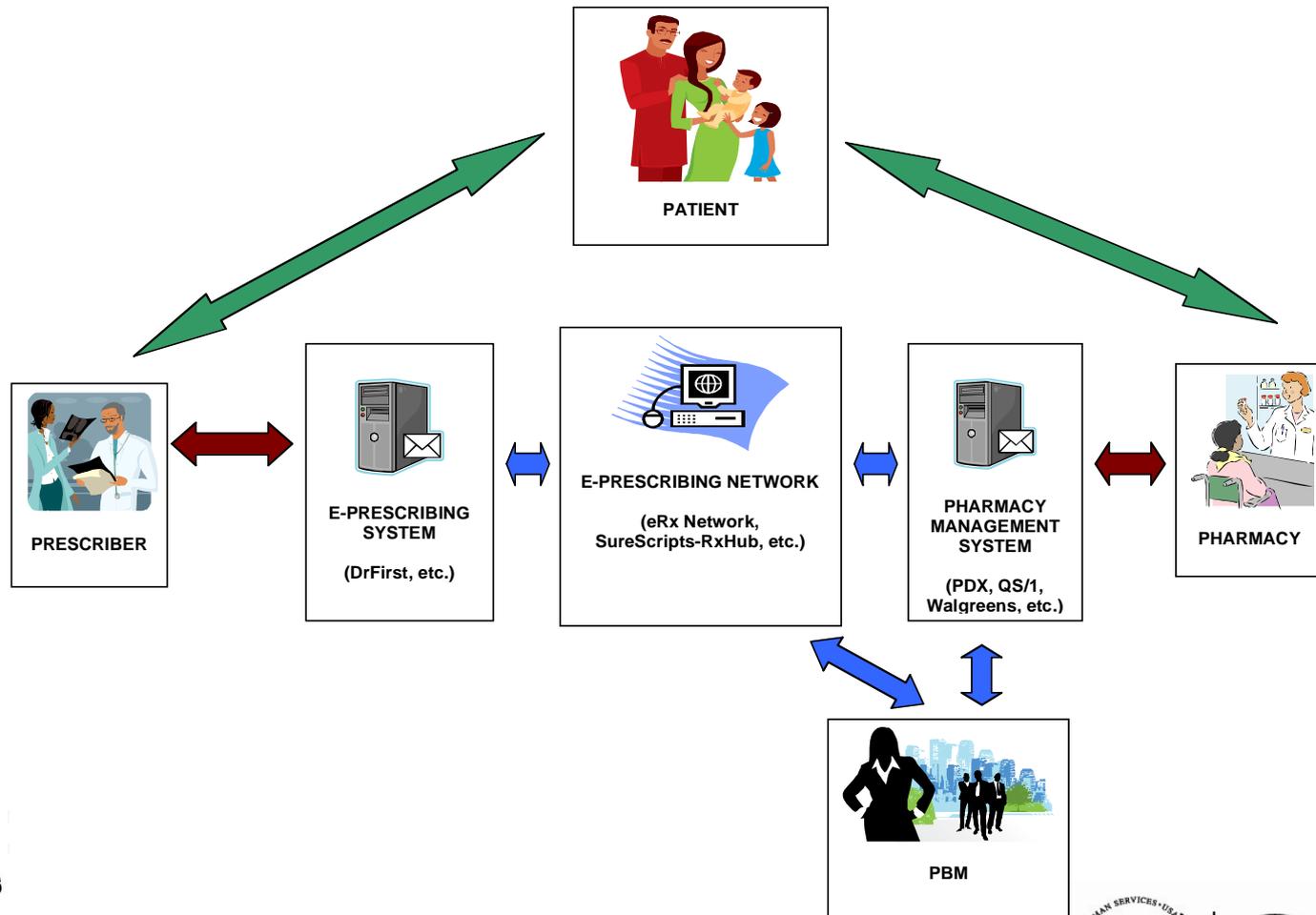
Confidentiality

Only authorized persons have access to the data

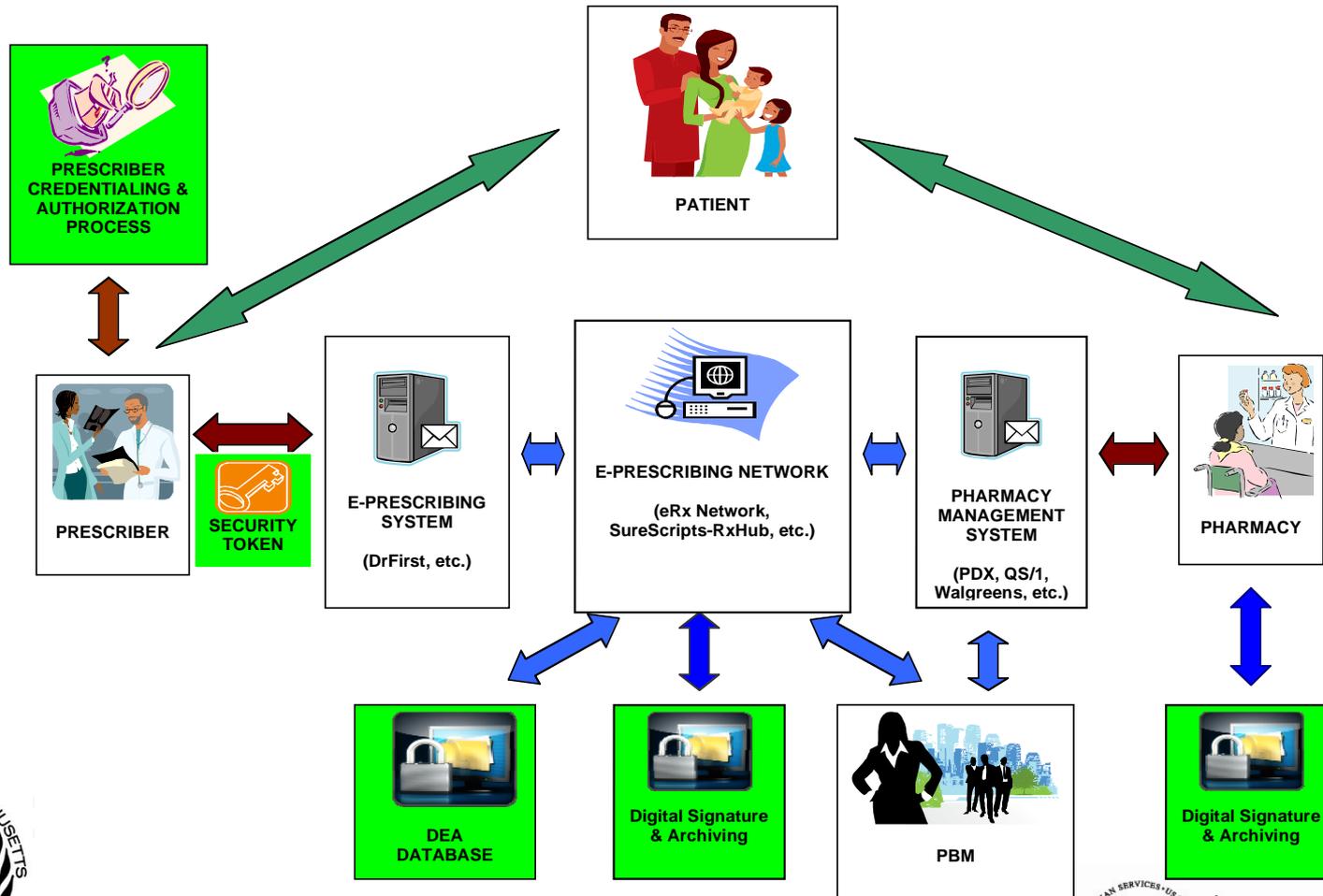


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E-prescribing Transaction Current (non-EPCS)



EPCS Transaction



Project Purpose and Method

- Encourage the expansion, adoption and diffusion of e-prescribing, a key component of health IT and electronic health records, to improve medication management by ambulatory care clinicians at the point-of-care.
- Test and demonstrate the safety, security, quality and effectiveness of electronic transmission of prescriptions for federally controlled medications in the ambulatory care setting.



Project Protocol: Key Elements

- Study site: Berkshire Health Systems catchment area
- Obtain DEA waiver to allow e-prescribing of Schedule II-V drugs at Berkshire Health Systems (Memorandum of Agreement)
- Develop authentication process for use by providers
- Conduct provider and pharmacy interviews/surveys



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Project Protocol: Key Elements

- Providers prescribe controlled substances (including digital signature)
- Prescriptions transmitted to participating pharmacies and dispensed
- Evaluate processes and outcomes
- Independent security analysis



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Project Protocol: DEA Memorandum of Agreement

- MOA completed in Sept. 2008
- DEA published Notice of Proposed Rulemaking on EPCS in June 2008¹
- There are similarities and differences in the requirements in the MOA and NPRM



¹ Federal Register: June 27, 2008, v.73, no. 125, pp. 36721-36782



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MOA - NPRM Comparison

Topic	MOA	NPRM
Identity Proofing	Done by Vendor/BHS. NIST SP 800-63 Validation Level 3	Done by State Lic. Board, hosp. med. Staff, or state/local law enforcement agency. Specific NIST validation level not specified
Prescriptions	Must contain full information including DOB, address, etc.	Must contain full information including DOB, address, etc.
Authentication Protocol	NIST SP 800-63 Level 4. Token validated FIPS 140-2 Level 2 or higher. Physical Security Level 3 or higher	NIST SP 800-63 Level 4. Token validated FIPS 140-2 Level 2 or higher. Physical Security Level 3 or higher



MOA - NPRM Comparison

Topic	MOA	NPRM
Prescriber Workflow	Not defined	Must display all Rx info inc. patient address on summary screen. Must select CS Rx's individually. Accept statement each time CS Rx's signed. Review CS Rx log monthly
Archiving Signatures: Service Providers	Service Provider that authorized the prescriber must digitally sign and archive	1st Service Provider must digitally sign and archive
Check CSA Database	Service Provider that authorized the prescriber must check weekly. Any one service provider or pharmacy must also check for each CS Rx	Prescribing practitioner's Service Provider must check weekly. Any one service provider or pharmacy must also check for each CS Rx



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MOA - NPRM Comparison

Topic	MOA	NPRM
Archiving Signatures: Pharmacies	Digitally sign <i>or wet-sign</i> prescriptions and archive	Digitally sign Rx's and archive. Pharmacy <i>system</i> may digitally sign and pass to pharmacy to archive
Audit	Not defined. MDPH protocol includes independent security analysis, but less than SysTrust or WebTrust	Annual SysTrust or WebTrust



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Project Protocol:

Medication Adherence

- A secondary Aim of project is to develop and test interfacing of the e-prescribing system with the Massachusetts Prescription Monitoring Program (PMP)
- PMP collects records of dispensing of prescriptions for Schedule II controlled substances
- Reconciliation of prescribing and dispensing records may provide a measure of medication adherence (in addition to drug diversion activity)



Preliminary Findings: Prescriber Perspectives on EPCS

- 246 BHS prescribers surveyed Jan. – May 2009 (64% response rate)
- 43.1% use e-prescribing (non-controlled substances)
- Controlled substances comprise 25.1% of prescriptions

Source: Thomas, C.P. et al., Poster Presentation, AHRQ 2009 Annual Conference, in preparation.



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Preliminary Findings: Prescriber Perspectives on EPCS

- 25.3% expect EPCS to be initially disruptive to practice
- 65% expect EPCS to improve quality
- 44.9% expect hard token for digital signature to be large inconvenience
- 25.8% expect advantages of EPCS will not outweigh burden of hard token



Source: Thomas, C.P. et al., Poster Presentation, AHRQ 2009 Annual Conference, in preparation.



Preliminary Findings:

State Preparedness for EPCS

- State laws differ on allowing EPCS
 - CA, MA, NY: laws allow for EPCS pending DEA regulations
 - FL law requires written prescription for Schedule II drugs¹
 - TX law prohibits e-prescribing of Schedule II prescriptions and requires manual signature^{2,3}
- Time needed to change state laws and regulations may be significant

¹Fla. Statutes, Chapter 893

²Tex. Health & Safety Code, Chapter 481

³Tex. Admin. Code, Title 22, §291.34



Preliminary Findings:

Certification of System Security

- Many states place responsibility for security and validity of prescriptions on prescribers and pharmacies, both of which are regulated/licensed at state and federal levels
- Transaction system providers (e.g., e-prescribing software, transmission network and switches, pharmacy software) are not separately regulated/licensed
- How will prescribers and pharmacies be assured that systems meet security requirements?



Preliminary Findings: Third-party Reimbursement

- Currently electronic prescriptions for controlled substances are rejected automatically by Medicaid
- Will need to change reimbursement mechanisms to allow EPCS by Medicaid and other third-party payors



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Preliminary Findings: Medication Adherence

- Reconciliation of e-prescribing and dispensing (prescription monitoring) records (to measure medication adherence and drug diversion) will require a key field for linking databases
- Will need to change prescription monitoring data transmission standards to provide for transmission of a key field



Expected Project Outcomes

- Facilitate and expedite adoption and expand diffusion of electronic prescribing through:
 - Field testing security standards prior to finalization and implementation of DEA proposed regulations governing EPCS
 - Identifying unexpected barriers and outcomes prior to implementation



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Expected Project Outcomes

- Earlier adoption and expanded diffusion of e-prescribing is expected to result in benefits such as:
 - Improved medication management by ambulatory care clinicians at the point-of-care
 - Increases access to needed pharmaceuticals, particularly by those with chronic medical conditions
 - Reduced non-medical use and abuse of controlled substances



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Thank You!



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Questions & Answers

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