

Up the Down Staircase: Practices and Pitfalls of Mandatory E-Prescribing

Richard Hanover, MD, JD, FCLM

New York, NY

Objectives

- Identify obstacles and facilitators to:
- Promote ways to improve patient safety and well-being through mandatory e-prescribing
- Address issues faced by e-prescribers, pharmacists, and insurers/payers
- Understand the medical and legal framework in which mandatory e-prescribing takes place

What is “Mandatory E-Prescribing”?

Some Fundamental Issues

- Are patients interests first?
- Consent for Care
 - Diagnosis – Access Info – EHR?
 - Treatment Plan: Medication –
Controlled Substance?
- E-prescribing Hardware : Compatibility
 - Computer
 - Tablet
 - Smartphone
- E-prescribing Software:
 - Authorized
 - Prescriber Authentication
 - Data Encryption
- Prescription Transmitted Electronically over the Internet
via High-Speed Connection

Pharmacist Notification

- Patient Must Choose Specific Pharmacy
- No Centralized Prescription Repository for another Pharmacy to access
- Difficult for Patient to “Shop Around”
- Difficult for Patients who Vacation or Travel
- Easy to Transmit Medication Refills, but to a Specific Pharmacy Only

Electronic Prescription Networks

- E-Prescriptions are transmitted to the specific pharmacy through a pharmacy-linking organization which supports these transmissions electronically
- **Surescripts** is a for-profit entity owned by pharmacy associations and pharmacy benefit management companies: the National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), CVS Health and Express Scripts (1)
- As of 2014, 70% of U.S. physicians and 96% of U.S. community pharmacies used this network (2)
- As of 2015 Surescripts linked more than 93% of US pharmacies (3)
- In 2008 Surescripts merged with RxHub LLC, a joint-venture electronic prescription company which had been formed by a consortium of pharmacy benefit managers, CVS Caremark Corp., Express Scripts, Inc. and Medco Health Solutions, Inc. (3)
- Surescripts certifies e-prescribing software – whether the program is a part of an EHR software package or is a just an e-prescribing program alone

¹Surescripts.com, accessed Jan.16, 2017

²Gabriel, Office of the National Coordinator for Health IT, Sept. 5, 2015

³Clancy, Fortune, Sept. 9, 2015

E-Prescribing Software Requirements

- Accept the prescriber's input
- Integrate patient demographics and any formulary information
- Correlate any insurance or pharmacy benefit management authorization
- Warn of drug allergies, interactions, incorrect dosing or route of administration, or other potential adverse events
- Electronically transmit (may print receipt)

Medicare Incentives and Penalties

- PRESCRIBER MUST USE AN APPROVED E-PRESCRIBING PROGRAM
- 2009-10 2% Bonus
- 2011-12 1% Bonus
- 2012 1% PENALTY for NOT E-Prescribing
- 2013 0.5% Bonus; 1.5% Penalty
- 2014 and onward 2% Penalty
- Exemptions for low volume, too few pharmacies, unavailability of high speed internet

Mandatory E-Prescribing



WHAT'S GOOD

- Legible
- Inclusive: complete required fields
- Reminds prescriber of dx, dosing, frequency, number in bottle, daily max, formulary, tier and insurance issues
- Warns of allergies, interactions, contraindications
- Prevents patient harm and associated costs

WHAT'S GOOD (cont'd)

- Fast
- Ensures that Rx gets directly to pharmacy
- Eases pharmacy work flow; reduces costs
- Fewer phone calls from pharmacists to prescriber for Rx clarification
- Potentially less wait time for patient
- Ease of record-keeping by prescriber and pharmacy
- Facilitates eligibility verification and quality/utilization audits by PBM/Insurer

What's Bad

- Mandatory means MANDATORY!!!
- Easily duplicates wrong info – e.g. QD instead of BID
- Pharmacist must seek clarification – pharmacy workflow interrupted; costs to pharmacy increase; patient must wait
- Prescriber must clarify – or Rx won't be filled – or WORSE: INCORRECTLY FILLED!!!
- PATIENT HARMED?

What's Bad (cont'd)

- Poor programming design problems:
restrictive and confusing dropdown menus
- Poor screen design and web browser and/or
operating system incompatibility
- Risky Auto-fill functions
- Programming “bugs”
- Internet down time
- Server down time

What's Bad (cont'd)

- Costs: software development and improvement
- Prescriber must choose an E-Rx platform
- Pharmacy must accept the prescription router's program; independent pharmacies have less bargaining power than chains
- Start-up and training costs
- Steep learning curve
- Maintenance and transaction fees

62J.497 MINNESOTA STATUTES 2016

A PROTOTYPE STATUTE

FOR MANDATORY E-PRESCRIBING

62J.497 ELECTRONIC PRESCRIPTION DRUG PROGRAM. Subdivision 1. Definitions. For the purposes of this section, the following terms have the meanings given.

(a) "Backward compatible" means that the newer version of a data transmission standard would retain, at a minimum, the full functionality of the versions previously adopted, and would permit the successful completion of the applicable transactions with entities that continue to use the older versions.

(b) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(c) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription.

(d) "Electronic media" has the meaning given under Code of Federal Regulations, title 45, part 160.103.

(e) "E-prescribing" means the transmission using electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or group purchaser, **either directly or through an intermediary, including an e-prescribing network.** E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser and two-way transmissions related to eligibility, formulary, and medication history information.

(f) "Electronic prescription drug program" means a program that provides for e-prescribing.

(g) "Group purchaser" has the meaning given in section 62J.03, subdivision 6.

(h) "HL7 messages" means a standard approved by the standards development organization known as Health Level Seven.

(i) "National Provider Identifier" or "NPI" means the identifier described under Code of Federal Regulations, title 45, part 162.406.

(j) "NCPDP" means the National Council for Prescription Drug Programs, Inc.

(k) "NCPDP Formulary and Benefits Standard" means the National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(l) "NCPDP SCRIPT Standard" means the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005, or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act, and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance. Subsequently released versions of the NCPDP SCRIPT Standard may be used, provided that the new version of the standard is backward compatible to the current version adopted by the Centers for Medicare and Medicaid Services.

(m) "Pharmacy" has the meaning given in section 151.01, subdivision 2.

(n) "Prescriber" means a licensed health care practitioner, other than a veterinarian, as defined in section 151.01, subdivision 23. Copyright © 2016 by the Revisor of Statutes, State of Minnesota. All Rights Reserved.

(o) "Prescription-related information" means information regarding eligibility for drug benefits, medication history, or related health or drug information.

(p) "Provider" or "health care provider" has the meaning given in section 62J.03, subdivision 8. Subd.

2. Requirements for electronic prescribing. (a) **Effective January 1, 2011, all providers, group purchasers, prescribers, and dispensers must establish, maintain, and use an electronic prescription drug program.** This program must comply with the applicable standards in this section for transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media.

(b) If transactions described in this section are conducted, they must be done electronically using the standards described in this section. Nothing in this section requires providers, group purchasers, prescribers, or dispensers to electronically conduct transactions that are expressly prohibited by other sections or federal law.

(c) Providers, group purchasers, prescribers, and dispensers must use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity, it must use the NCPDP SCRIPT Standard or other applicable standards required by this section. Any pharmacy within an entity must be able to receive electronic prescription transmittals from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any Health Insurance Portability and Accountability Act (HIPAA) requirement that may require the use of a HIPAA transaction standard within an organization

Subd. 3. **Standards for electronic prescribing.** (a) Prescribers and dispensers must use the NCPDP SCRIPT Standard for the communication of a prescription or prescription-related information. The NCPDP SCRIPT Standard shall be used to conduct the following transactions:

- (1) get message transaction;
- (2) status response transaction;
- (3) error response transaction;
- (4) new prescription transaction;
- (5) prescription change request transaction;
- (6) prescription change response transaction;
- (7) refill prescription request transaction;
- (8) refill prescription response transaction;
- (9) verification transaction;
- (10) password change transaction;
- (11) cancel prescription request transaction; and
- (12) cancel prescription response transaction.

(b) Providers, group purchasers, prescribers, and dispensers must use the NCPDP SCRIPT Standard for communicating and transmitting medication history information.

(c) Providers, group purchasers, prescribers, and dispensers must use the NCPDP Formulary and Benefits Standard for communicating and transmitting formulary and benefit information.

(d) Providers, group purchasers, prescribers, and dispensers must use the national provider identifier to identify a health care provider in e-prescribing or prescription-related transactions when a health care provider's identifier is required.

(e) Providers, group purchasers, prescribers, and dispensers must communicate eligibility information and conduct health care eligibility benefit inquiry and response transactions according to the requirements of section 62J.536.

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, 2016, 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; 2012 c 253 art 1 s 1; 2014 c 291 art 6 s 1; 2016 c 158 art 1 s 19

MAINE

OPIOID PRESCRIPTION MONITORING PROGRAM

3. **Electronic prescribing.** An individual licensed under this chapter whose scope of practice includes prescribing opioid medication and who has the capability to electronically prescribe **shall prescribe all opioid medication electronically by July 1, 2017.** An individual who does not have the capability to electronically prescribe must request a waiver from this requirement from the Commissioner of Health and Human Services stating the reasons for the lack of capability, the availability of broadband infrastructure and a plan for developing the ability to electronically prescribe opioid medication. The commissioner may grant a waiver for circumstances in which exceptions are appropriate, including prescribing outside of the individual's usual place of business and technological failures.

NEW YORK

Why will electronic prescribing of controlled and non-controlled substances be mandatory effective March 27, 2016?

New York Education Law Article 137 §6810 requires that all prescriptions be transmitted electronically three years from the Department of Health's promulgating regulations allowing for the electronic prescribing of controlled substances. These regulations became effective on March 27, 2013. Utilizing modern prescription technology has the **potential to minimize medication errors** for patients in New York State. Electronic prescribing also allows for the **integration** of prescription records directly into the patient's electronic medical record. Electronic prescribing has the potential to **reduce prescription theft and forgery**.

Q7: Can I **electronically prescribe controlled substances** before it becomes mandated on March 27, 2016?

A7: EPCS became permissible in NYS on March 27, 2013. Practitioners can electronically prescribe controlled substances if:

- The EPCS software application meets all of the federal security requirements for EPCS, which can be found on the DEA's web page.

http://www.deadiversion.usdoj.gov/ecommm/e_rx/

Note that federal security requirements include a third party audit or DEA certification of the software.

- The practitioner has completed identity proofing as defined in the federal requirements and
- The practitioner has obtained **a two-factor authentication** as defined in the federal requirements and
- The practitioner has **registered their DEA certified EPCS software** application with the **Bureau of Narcotic Enforcement (BNE)**. Please refer to the Registration instructions included below in the section titled "Registration for Official Prescriptions and E-prescribing Systems" or "Physician Assistant and Pharmacy EPCS Registration Form", whichever is applicable.

NO FAX!!!

Q11: Is an electronic facsimile of a prescription considered an electronic prescription?

A11: **No.** A definition of an electronic prescription can be found in Section 3302 Article 33 Public Health Law and specifically states that a prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription. Click on the following link for Section 3302: Section 3302 Article 33 Public Health Law.

Q17a: Will practitioners be required to electronically prescribe non-prescription items, including **durable medical equipment**?

A17a: **No**, an electronic prescription will not be required. Section 281 (1) of the Public Health Law specifically references the use of electronic prescriptions for **prescription drugs only**.

Q18: Can an **agent or employee** of the prescriber create or **prepare** an electronic prescription?

A18: **Yes**. Education law 6802 and Sections 80.67 and 80.69 of Title 10 NYCRR Part 80 do not prohibit an agent of the practitioner from preparing an electronic prescription for his or her review and electronic signature.

Q19: Can an agent or employee of the prescriber electronically **sign** an electronic prescription?

A19: **No**. Practitioners are authorized to prescribe by virtue of his or her license to practice medicine or dentistry. Therefore, **only the practitioner may review and sign the prescription.**

Q23: Can a **physician assistant** register for EPCS if their supervising physician does not?

A23: **Yes.** The supervising physician is not required to register for EPCS if they have no intention of electronically prescribing controlled substances.

Note: Both the supervising physician and physician assistant must maintain active registrations for the Official Prescription Program.

NEW YORK

PUBLIC HEALTH LAW S. 281

1. In addition to the requirements of section sixty-eight hundred ten of the education law or article thirty-three of this chapter, **all prescriptions** written in this state by a person authorized by this state to issue such prescriptions **shall be on serialized official New York state prescription forms** provided by the department. Such forms shall be furnished to practitioners authorized to write prescriptions and to institutional dispensers, and shall be non-reproducible and non-transferable. The commissioner, in consultation with the commissioner of education, may promulgate emergency regulations for the electronic transmission of prescriptions from prescribers to pharmacists or for ordering and filling requirements of prescription drugs for prescriptions written for recipients eligible for medical assistance pursuant to title eleven of article five of the social services law, for participants in the program for elderly pharmaceutical insurance coverage pursuant to title three of article two of the elder law and for prescriptions written pursuant to article thirty-three of this chapter. Nothing in this section shall prohibit the commissioner in consultation with the commissioner of education from promulgating any additional emergency regulations in furtherance of this subdivision.

2. The commissioner, in consultation with the commissioner of education, shall promulgate regulations requiring that **prescription forms and electronic prescriptions include:** (a) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and (b) if the patient is limited English proficient, **a line where the prescriber may specify the preferred language indicated by the patient.** Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

3. On or before December thirty-first, two thousand twelve, the commissioner shall promulgate regulations, in consultation with the commissioner of education, establishing standards for electronic prescriptions. Notwithstanding any other provision of this section or any other law to the contrary, **effective two years subsequent** to the date on which such regulations are promulgated, **no person shall issue any prescription in this state unless such prescription is made by electronic prescription** from the person issuing the prescription to a pharmacy in accordance with such regulatory standards, **except** for prescriptions:

except for prescriptions: (a) issued by **veterinarians**; (b) issued in circumstances where **electronic prescribing is not available due to temporary technological or electrical failure**, as set forth in regulation; (c) issued by practitioners who have received a **waiver** or a renewal thereof for a specified period determined by the commissioner, not to exceed **one year**, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the commissioner, in consultation with the commissioner of education, due to **economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance** demonstrated by the practitioner; (d) issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subdivision, such **practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition**, provided that if such prescription is for a controlled substance, the quantity of **controlled substances does not exceed a five day supply** if the controlled substance were used in accordance with the directions for use; or (e) issued by a practitioner to be dispensed by a pharmacy located **outside the state**, as set forth in regulation.

4. In the case of a prescription for a controlled substance issued by a practitioner under paragraph (b) [E-PRESCRIBING UNAVAILABLE] of subdivision three of this section, the **practitioner shall file information** about the issuance of such prescription with the department **as soon as practicable**, as set forth in regulation. 5. In the case of a prescription for a controlled substance issued by a practitioner under paragraph (d) [Rx DELAY ADVERSE TO HEALTH] or (e) [OUT-OF-STATE PHARMACY] of subdivision three of this section, the practitioner shall, upon issuing such prescription, **file information** about the issuance of such prescription with the department **by electronic means**, as set forth in regulation. 6. The waiver process established in regulation pursuant to paragraph (c) of subdivision three of this section shall provide that a practitioner prescribing under a waiver must notify the department in writing **promptly upon gaining the capability to use electronic prescribing, and that a waiver shall terminate** within a specified period of time after the practitioner gains such capability - See more at: <http://codes.findlaw.com/ny/public-health-law/pbh-sect-281.html#sthash.mmYllds6.dpuf>

WAIVER REQUEST

- Technological limitations
- Not reasonably within practitioner's control
- Other exceptional circumstances
- Dates expected for full and appropriate operational capability
- Steps being taken to meet the mandate

MANDATORY E-PRESCRIBING

KEY POINTS

E-Prescribing mandates endeavor to promote safety and well-being of patients and the public, but obstacles to these goals are inevitably present.

Issues created by E-prescribing mandates impact patients, e-prescribers, the pharmacy-linking liaison, pharmacists, and insurers/payers