NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF
NARCOTIC ENFORCEMENT

Electronic Prescribing

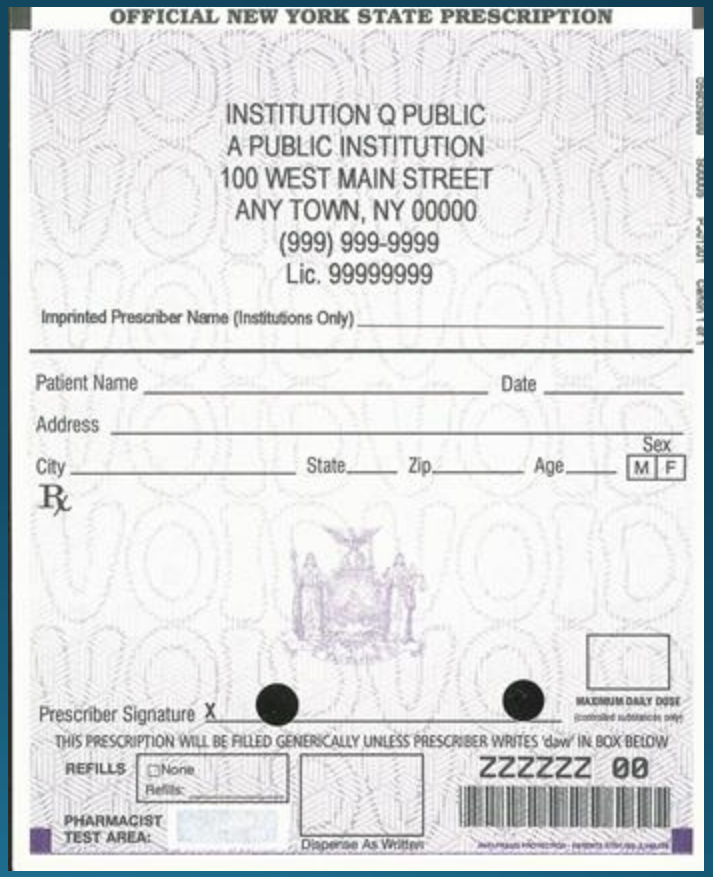
NYSDOH Nursing Home Provider Association Meeting

July 24, 2014

Judith L. Barrett, R.Ph.
Bureau of Narcotic Enforcement

Official Prescription Program

- NY issues forge-proof official prescription forms to all registered practitioners within the State
- Contain a number of security features
- Serial numbers can be tracked
- From 2006-2013 issued ~1.4 B prescription forms
- At a cost of $78.7 M


OFFICIAL NEW YORK STATE PRESCRIPTION

INSTITUTION Q PUBLIC
A PUBLIC INSTITUTION
100 WEST MAIN STREET
ANY TOWN, NY 00000
(999) 999-9999
Lic. 99999999

Imprinted Prescriber Name (Institutions Only) _____

Patient Name _____ Date _____

Address _____

City _____ State ____ Zip ____ Age ____ Sex M F

℞

Prescriber Signature X _____

MAXIMUM DAILY DOSE

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'daw' IN BOX BELOW

REFILLS ☐None Refills: _____

ZZZZZZ 00

PHARMACIST TEST AREA:

Dispense As Written

Prescription Drug Reform Act 2012

Part A: I-STOP

Part B: Electronic Prescribing

Part C: Controlled Substance Schedule Changes

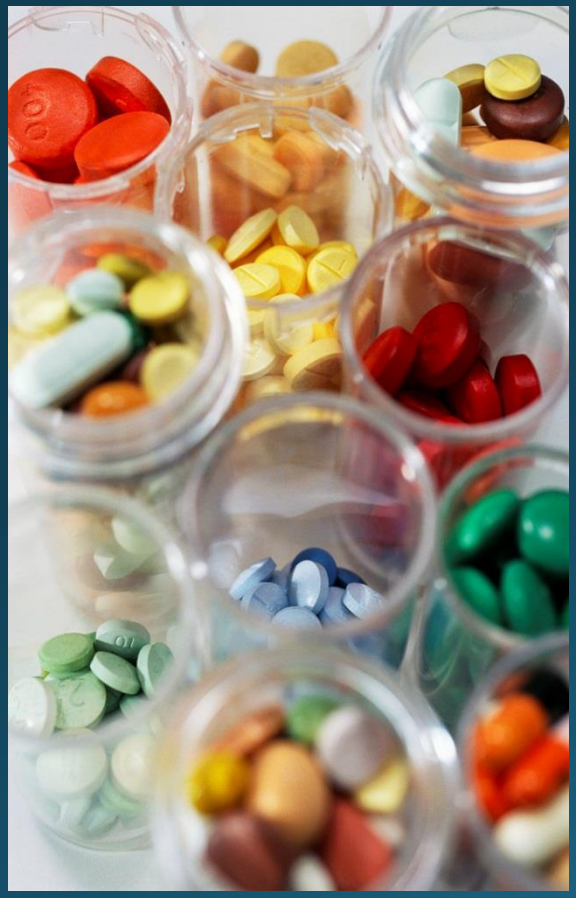
Part D: 3309 Work Group

Part E: Safe Disposal Program

Why Electronic Prescribing?

- Next step in medical technology
- Curtail forged and counterfeit prescriptions
- Reduce medication errors associated with bad handwriting
- Improved workflow

Electronic Prescribing



- Non-controlled Substances
- Controlled Substances

Electronic Prescribing

- NYS Regulations now allow for electronic prescribing of controlled substances (EPCS) effective March 27, 2013.

- Electronic prescribing of controlled and non-controlled substances becomes mandatory for all practitioners as of March 27, 2015.

Electronic Prescribing Exceptions

- Technological or electrical failure;
- EP would impact the patient's medical condition (up to 5 day supply for controlled substances);
- Prescriptions issued by a practitioner to be dispensed outside of New York State;
- Veterinarians;
- Practitioners who have received a waiver from the Department of Health.

Electronic Prescribing Waivers

- Practitioners may apply for a waiver from the requirement to electronically prescribe controlled substances.
- Waivers will be granted upon a proper showing of economic hardship, technological limitations outside of the practitioner's control or other exceptional circumstances.
- By statute, waivers are good for one year, after which a practitioner may apply for a renewal.

Electronic Prescribing for Controlled Substances (EPCS)

DEA Rule Overview

EPCS—DEA RULE Background

- **Federal DEA Rule**
- **Effective June 1, 2010, allows for electronic prescribing of controlled substances**
- http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf

EPCS—DEA Rule Background

- **21CFR Part 1300 Definitions**
- **21CFR Part 1311 Requirements for Electronic Prescriptions**

- The federal rule provides practitioners with the *option* of signing and transmitting prescriptions for controlled substances electronically

- Permits pharmacies to receive, dispense and archive electronic prescriptions

- Maintains a closed system for controlled substance prescribing and dispensing through rigorous security requirements and audit trails

- CII-V can be prescribed electronically

EPCS—Practitioner Requirements

- **Obtain and use a two factor authentication credential**
  - Something you have (token)
  - Something you know (password, PIN)
  - Something you are (biometric)

  Ensures prescription integrity and non-repudiation

- **Use a certified application** (software) that records, stores and transmits information required under Sections 1311 and 1306 of 21 CFR

- **Safeguard credentials**

EPCS—DEA Rule Institutional Practitioner

- 21 CFR Part 1311
  - Section 1311.110 **Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner**
    - **Allows for an entity within a DEA-registered institution that grants an individual practitioner privileges at the institution (e.g., a hospital credentialing office) to conduct identity proofing and authorize the issuance of the authentication credential**
  - Section 1311.130 **Requirements for establishing logical access control—Institutional practitioner**
    - **Must develop a list of individual practitioners who are permitted to use the institution's electronic prescription application**

EPCS—Pharmacy Application Requirements

- Must meet DEA's requirements
- May only process controlled substance prescriptions using a certified pharmacy application
- Application must be able to set access controls
- Application must be able to import, store and display prescription requirements and verify the practitioner's digital signature
- Application must allow for pharmacist annotations and for those annotations to be maintained electronically

EPCS—Pharmacy Application Requirements

- Must be capable of retrieving controlled substance prescriptions by practitioner name, patient name, drug name and date dispensed
- Must allow downloading of prescription data into a database or spreadsheet that is readable and sortable
- Must maintain an audit trail of a number of actions (e.g., receipt, annotation, alteration, changes in logical access)
- Must conduct internal audits and protect records
- Retain archived records electronically

EPCS—Transmission

- EPCS application must transmit the electronic prescription as soon as possible after signature by the practitioner
- Electronic prescription may be printed only if practitioner has been notified of transmission failure
- Printed version must contain information relating to original electronic transmission failure

EPCS—Transmission

- Copies of EPCS transmitted prescription—must state “Copy only—not valid for dispensing.”
- EPCS application must not allow for electronic transmission if original was printed prior to electronic transmission
- At no time may an intermediary convert the electronic prescription to another form (e.g., facsimile) for transmission

Electronic Prescribing NYS Regulations

Electronic Prescribing NYS Regulations

- 10 NYCRR Part 80--Adopted March 27, 2013
  - 80.1, 80.63, 80.64, 80.67, 80.68, 80.69, 80.70, 80.73, 80.74, 80.75, 80.77, 80.78, 80.84, 80.100, 80.106, 80.125

- EPCS permissive now
- Mandatory for non-controlled substances and for controlled substances effective March 27, 2015

EPCS—NYS Regulations

- Authorizes a practitioner to issue an electronic prescription in Schedules II-V
- Authorizes a pharmacist to annotate, dispense, endorse and electronically archive electronic prescriptions for controlled substances

EPCS—NYS Regulations

- Requires all practitioners and pharmacists engaging in electronic prescribing and dispensing of controlled substances to utilize computer applications that meet federal security requirements and to **register** such computer applications with the NYS DOH/BNE

- Provides for exceptions for mandatory e-prescribing

EPCS—NYS Regulations

- Registering Certified Application with BNE
  - Forms are available on BNE webpage
  - Contact BNE, forms will be provided
  - Ultimately—online registration process

- Once Registration Form is Received by BNE
  - About one week to process
  - Registrant will receive an email advising that application has been registered with NYS

EPCS—NYS Regulations

- Electronic prescriptions can serve as follow-up to oral prescriptions—must be associated with or linked to the oral prescription
- Proper safeguarding of credentials
- Recordkeeping—5 years
- Records must be readily retrievable

EPCS—NYS Regulations

- Fax does not equate to electronic
- For Pharmacies: Oral prescriptions may be reduced to electronic memorandum

What's Next

- Read the DEA Rule
- Contact your software vendor to determine if the software meets federal security requirements (including a DEA certification or third party audit)
- If an institution: understand the federal rules associated with credentialing and logical access and implement accordingly
- If a pharmacy: ensure that your software meets federal security requirements and that you are submitting controlled substance data to BNE in ASAP 4.2 standard
- For practitioners, pharmacies and institutions—ensure that your certified software is **registered** with BNE
- Check BNE's website often for more information

EPCS—Take Aways

- Permissive now—Electronic prescribing mandated for **ALL** prescriptions March 27, 2015
- Practitioners and pharmacists are required to use a certified application
- Certified application must be **registered** with BNE
- If the prescription starts electronically, it remains electronic
- Fax does not equate to electronic
- Current practitioner applications probably do not meet the requirements for EPCS

Regulations

- **Federal Rule Electronic Prescriptions for Controlled Substances**
- http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf

- **10 NYCRR Part 80 Rules**
  - http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/
  - Click on the link to New York State Regulations related to Electronic Prescribing of Controlled Substances

Bureau of Narcotic Enforcement

www.nyhealth.gov/professionals/narcotic

Riverview Center
150 Broadway
Albany, NY 12204
Phone: (866) 811-7957
E-mail: narcotic@health.state.ny.us

Regional Offices:
NYC: (212) 417-4103
Buffalo: (716) 847-4532
Syracuse: (315) 477-8459
Rochester: (585) 423-8043