

NEW YORK STATE DEPARTMENT OF HEALTH BUREAU OF NARCOTIC ENFORCEMENT

Electronic Prescribing

New York State Health Facilities
Association

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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

Inprinted Prescriber Name (Institutions Only) _____

Patient Name _____ Date _____

Address _____

City _____ State _____ Zip _____ Age _____ Sex M F

Rx

Prescriber Signature **X** _____

THIS PRESCRIPTION WILL BE FILLED GENERALLY UNLESS PRESCRIBER WRITES "NO" IN BOX BELOW

REFILLS None Refills _____

PHARMACIST _____

DISPENSER ALL OTHERS _____

ZZZZZZ 00

MAXIMUM DAILY DOSE _____

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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

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Electronic Prescribing - Defined

A prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the commissioner and the commissioner of education and consistent with federal requirements.

A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and must be manually signed.

Public Health Law §3302

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Electronic Prescribing - Defined

Mandatory Electronic Prescribing Effective March 27, 2015

Electronic prescribing is a paperless process.

A prescription generated on an electronic system that is printed out to the Official New York State Prescription form or faxed is **NOT** an electronic prescription.

http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/

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Why Electronic Prescribing?



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

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Electronic Prescribing



- Non-controlled Substances
- Controlled Substances

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Electronic Prescribing for Controlled Substances (EPCS)

Drug Enforcement Administration (DEA) Rule Overview

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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



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EPCS—DEA Rule Background

- 21CFR Part 1300 Definitions and 21CFR 1311 Requirements for Electronic Orders & Prescriptions
- 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

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EPCS—Practitioner Requirements

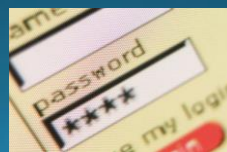
- **Identity-proofing** - the process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person
- **Obtain and use a two factor authentication credential**
 - Something you have (token)
 - Something you know (password, PIN)
 - Something you are (biometric)

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EPCS—Practitioner Requirements

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

Ensures prescription integrity and non-repudiation



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EPCS—Practitioner Requirements

Logical Access Controls

- Access is the ability to do something with a computer resource
- Logical access controls are set to provide access to e-prescribing applications
- Requires verification that DEA registration and State authorization to practice are current and in good standing
- Grants permission to sign electronic prescriptions on the computer application

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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

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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

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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

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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 be maintained electronically

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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

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Electronic Prescribing NYS Regulations - EPCS

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Electronic Prescribing NYS Regulations

- 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.

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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
- Electronic Prescribing of Controlled Substances is permissive now



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Electronic Prescribing NYS Regulations

- Mandatory for non-controlled substances and for controlled substances effective March 27, 2015
- Additional information pertaining to electronic prescribing of *non-controlled substances* is available on the NYSED Office of the Professions Website

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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

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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

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EPCS—NYS Regulations

- Registering Certified Application with BNE
 - Forms are available on BNE webpage
 - Contact BNE, forms to be completed 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

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Electronic Prescribing Exceptions

- Technological or electrical failure;
- Use of 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.

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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.

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EPCS—NYS Regulations

- Proper safeguarding of credentials
- Recordkeeping—5 years
- Records must be readily retrievable

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EPCS—NYS Regulations

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

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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
- 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

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EPCS—Take Aways

- Permissive now--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

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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](#)

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Other Resources

- **State Education Department Office of the Professions**
 - <http://www.op.nysed.gov/prof/>

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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

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