BNE Update

New York State Department of Health • Bureau of Narcotic Enforcement Fall 2015

Electronic Prescribing of Controlled Substances (EPCS): General Overview

Amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances allowing for the electronic prescribing of controlled substances have been adopted and became effective as final regulations on March 27, 2013. The amendments authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V and allow a pharmacist to annotate, dispense and electronically archive such prescriptions. The amendments also require all practitioners and pharmacists engaging in electronic prescribing and dispensing of controlled substances to utilize computer applications that meet State and federal security requirements, and to register such computer applications with the Department of Health, Bureau of Narcotic Enforcement (BNE).

Pursuant to Public Health Law Section 3302 (37), an electronic prescription for controlled substances may only be issued in accordance with Department of Health regulations, as well as NYS Education Department regulations and federal requirements.

The federal requirements are included in the Drug Enforcement Administration Interim Final Rule (IFR) regarding Electronic Prescriptions for Controlled Substances. The rule may be accessed via the U.S Department of Justice, DEA Office of Diversion Control website.

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Electronic prescribing provides practitioners and pharmacies with the ability to use modern technology to issue and dispense controlled substance prescriptions while maintaining a secure, closed system of controls on controlled substance dispensing. Electronic prescribing reduces paperwork and streamlines workflow for practitioners and pharmacies who prescribe and dispense controlled substances and has the potential to reduce prescription forgery. It also has the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions.

NYS Education Department regulations related to prescribing of non-controlled substances may be accessed electronically at: *www.op.nysed.gov/prof/pharm/pharmlaw.htm*

New York State Regulations Related to Electronic Prescribing of Controlled Substances may also be accessed electronically: *http://www.health.ny.gov/regulations/recently_adopted/docs/2013-02-13_electronic_prescribing_dispensing_and_recordkeeping_of_controlled_substances.pdf* In addition, please visit BNE's website for Frequently Asked Questions (FAQs) about electronic prescribing of controlled substances in New York State which may be accessed electronically: *http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/docs/epcs_faqs.pdf*

Effective March 27, 2016, all prescriptions issued in New York State will be electronic prescriptions, with certain limited exceptions. Please continue to visit the Bureau's webpage (www.health.ny.gov/professionals/narcotic) for information pertaining to electronic prescribing of controlled substances.

Please carefully review the following important information about electronic prescribing of controlled substances.

1. **An electronic prescription is a prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the NYS Commissioner of Health and the Commissioner of Education and consistent with federal requirements.** A prescription generated on an electronic system that is printed out on Official New York State Prescription (ONYSRx) paper and manually signed or an ONYSRx transmitted via facsimile is not an electronic prescription.
2. **The computer software application utilized by prescribers and pharmacies in New York State for electronic prescribing, dispensing and archiving of controlled substance prescriptions must meet the federal security requirements set forth by the DEA.** The federal requirements are included in the DEA IFR, Electronic Prescriptions for Controlled Substances (EPCS). The rule may be accessed via the U.S Department of Justice, DEA Office of Diversion Control electronic prescribing web page at: *www.deadiversion.usdoj.gov/ecomm/e_rx/index.html.*

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Review the IFR and contact your software vendor to determine if the computer software application you are using has been certified that it meets the above mentioned requirements. If your software application has been certified for EPCS, your vendor should be able to provide you with proof of that certification. Certification is required every two years, or whenever functions related to creating and signing or processing of controlled substance prescriptions are altered, whichever occurs first.

3. **Prior to prescribing or dispensing electronic prescriptions for controlled substances, the prescriber/pharmacy must register the certified computer software application with the Department of Health, Bureau of Narcotic Enforcement (BNE).** The certified computer software application must be registered with BNE at least every two years. Prescribers can register their certified software application online through the Health Commerce System. Pharmacies may complete EPCS registration form DOH-5120. Instructions on each registration process and a Frequently Asked Questions document for practitioners and pharmacies may be obtained by accessing the Electronic Prescribing page of the Bureau of Narcotic Enforcement (BNE) webpage at: *www.health.ny.gov/professionals/narcotic/*.

   Please be aware this registration process is separate and apart from the computer software application certification process. Registration with BNE should be completed once the software has been certified that it meets the security requirements of the DEA. The Department of Health does not certify computer software applications for EPCS, nor does it publish a list of certified computer software applications.

4. **Pharmacies accepting electronic prescriptions for controlled substances must submit their controlled substance dispensed data to BNE using the American Society for Automation in Pharmacy (ASAP) version 4.2.** Pharmacies must report the following additional fields using ASAP version 4.2 for electronic prescriptions; Electronic Prescription Reference Number (DSP20) and Electronic Prescription Order Number (DSP21). In addition, the serial number (AIR02) must be reported with eight E's (EEEEEEEE).

All controlled substance data, regardless if it was dispensed from a paper or electronic prescription or directly from a practitioner's office, must be submitted using ASAP version 4.2.

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Definitions relating to Electronic Prescribing

Electronic prescription – means a prescription issued with an electronic signature and transmitted by electronic means in accordance with regulations of the commissioner of health and the commissioner of education and consistent with federal requirements. A prescription generated on an electronic system that is printed out and manually signed or transmitted via facsimile is not considered an electronic prescription.

Electronic – relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities. "Electronic" shall not include facsimile.

Electronic record – a paperless record that is created, generated, transmitted, communicated, received or stored by means of electronic equipment and includes the preservation, retrieval, use and disposition in accordance with regulations of the commissioner of health and the commissioner of education and in compliance with federal law and regulations.

Electronic signature – an electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record, in accordance with regulations of the commissioner of health and the commissioner of education.

Certified software – a software application that has been audited by a third party auditor or a DEA certifying body to certify that each electronic prescription and pharmacy application used to sign, transmit, or process controlled substances prescriptions is in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.

EPCS Registration – the process by which a practitioner or pharmacy attests which certified software application is being used to issue or accept electronic prescriptions for controlled substances.

Identity proofing - the process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person.

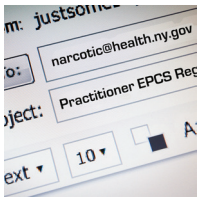
Two-factor authentication credentials – the security credentials that allow the practitioner to sign an electronic prescription. The DEA is allowing the use of two of the following – something you know (a knowledge factor), something you have (a hard token stored separately from the computer being accessed), and something you are (biometric information).

Intermediary – any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy.

Computer Systems for Electronic Prescribing of Controlled Substances

BNE does not endorse a specific electronic prescribing software application for practitioners to use. Practitioners may research different options on the internet, which may include stand-alone applications that can be accessed on a hand-held device versus an extensive EMR system that has a built-in e-prescribing module, or speak to professional colleagues or professional associations to determine what options are available. Practitioners may also wish to contact their current Electronic Health Record (EHR) software application provider if they are currently using EHR.

The software application company should be able to provide cost estimates. In all cases, it is important to verify that the e-prescribing software application meets all federal security requirements for electronically prescribing controlled substances.



New York State EPCS Registration Process

New York State regulations require practitioners and pharmacies to register their certified EPCS computer software applications with the New York State Department of Health, Bureau of Narcotic Enforcement (BNE), prior to issuing and receiving electronic prescriptions for controlled substances.

Practitioners

If you are a practitioner who has:

- completed individual identity proofing, and
- received two-factor authentication credentials, and
- implemented a certified EPCS software application that meets the federal security requirements

then please register the certified EPCS software application with BNE using an online application called ROPES: Registration for Official Prescriptions and E-prescribing Systems. This application will allow the practitioner to renew their registration for the Official Prescription Program and to register their EPCS software in two easy steps. ROPES can be accessed through the Health Commerce System (HCS). Additional information regarding ROPES can be found on BNE's webpage.

A Physician Assistant may register their certified software application by completing the Practitioner EPCS Registration form, DOH-5121.
www.health.ny.gov/forms/doh-5121.pdf.

Email the completed form to *narcotic@health.ny.gov* with "Practitioner EPCS Registration" in the subject line prior to issuing electronic prescriptions for controlled substances. Once the registration form is processed, practitioners will receive an email from BNE confirming that the registration process is complete.

Pharmacies

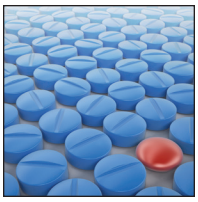
If you are a pharmacy that has:

- a certified EPCS software application that meets the federal security requirements, and
- is submitting controlled substance data in ASAP version 4.2

then please register the certified EPCS software application with BNE by completing the Pharmacy EPCS Registration form, DOH-5120.
www.health.ny.gov/forms/doh-5120.pdf

Email the completed form to *narcotic@health.ny.gov* with "Pharmacy EPCS Registration" in the subject line prior to accepting electronic prescriptions for controlled substances. Once the registration form is processed, pharmacies will receive an email from BNE confirming that the registration process is complete.

In the future, pharmacies will also be able to register their certified EPCS software application with BNE using an online application on the Health Commerce System (HCS). Please monitor BNE's webpage for more information regarding this new online registration process.



Electronic Prescribing Exceptions

Electronic prescribing of both controlled substances (Schedules II – V) and non-controlled substances becomes mandatory for all practitioners, with certain specified exceptions, on March 27, 2016. Prescriptions excepted from the electronic prescribing requirement set forth in Article 2-a of the public health law include prescriptions:

(a) Issued by veterinarians;

(b) Issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure. Temporary technological or electrical failure is defined as: any failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption to a computer system, application, or device in such a manner that it reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this section and federal requirements. In the instance of a temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control;

(c) Issued by practitioners to whom the commissioner of health has granted a waiver, or a renewal of a previously granted waiver, from the requirement to use electronic prescribing.

(d) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to electronically prescribe, the 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.

Any prescription issued based on one of the abovementioned exceptions shall be issued on an Official New York State Prescription form or via an oral prescription in accordance with Title 10 NYCRR Part 80 Sections 80.63, 80.67, 80.68, 80.69 and 80.70.

Veterinarians Exempt from Electronic Prescribing

The mandate requiring practitioners to electronically issue prescriptions for both controlled and non-controlled substances effective March 27, 2016 specifically exempts veterinarians. Veterinarians who choose to electronically prescribe controlled substances must use an electronic prescribing computer application that meets federal security requirements for EPCS, and must register their certified electronic prescribing application with the Department of Health, Bureau of Narcotic Enforcement. (See Section on NYS EPCS Registration Process).

Pharmacies and Other Dispensers of Electronic Data Transmission – Field Requirements for Electronic Prescriptions

All pharmacies accepting electronic prescriptions for controlled substances MUST report to BNE the following data elements using the ASAP 4.2 standard:

Field Name	Data Element	Description of Edit
State Issued Rx Serial Number	AIR02	This field is required. For electronic prescriptions, AIR02 = 'EEEEEEEE'.
Electronic Prescription Reference Number	DSP20	This field is required if AIR01 = 'NY' and AIR02 = 'EEEEEEEE' (electronic prescription). The value must be alphanumeric.
Electronic Prescription Order Number	DSP21	This field is required if AIR01 = 'NY' and AIR02 = 'EEEEEEEE' (electronic prescription). The value must be alphanumeric.

All reporting organizations should inform their pharmacy vendor service of the additional field requirements for electronic prescriptions. **It is important to note that data files that are rejected or records that are processed with errors do not display in the PMP Registry and are not available for practitioner or pharmacist review.**

All controlled substance data, regardless if it was dispensed from a paper or electronic prescription or directly from a practitioner's office, must be submitted using ASAP version 4.2. Please refer to BNE's **Submitter's Guide to Electronic Data Transmission Appendix A** for all data file specifications. **Appendix A** is available on BNE's webpage at the following link: *www.health.ny.gov/professionals/narcotic/electronic_data_transmission/*.

Electronic Prescriptions for Controlled Substances - Transmission Failure

When a practitioner is notified that the electronic prescription for a controlled substance was not successfully transmitted to the pharmacy, he or she can issue a replacement prescription in written or oral format. The replacement prescription should indicate that the prescription was originally transmitted electronically, to which pharmacy the prescription was originally transmitted, and that the original transmission failed.

When a pharmacist receives a prescription for a Schedule II, III, IV or V controlled substance that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall check their records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

When a pharmacist receives a prescription for a Schedule II, III, IV or V controlled substance that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist shall check with an employee at that pharmacy to determine whether the prescription was received and dispensed.

- If the other pharmacy did receive the original electronic prescription but did not dispense the prescription, the other pharmacy shall mark the electronic version as void or cancelled.
- If the other pharmacy did receive the original electronic prescription and dispensed the prescription, the pharmacy with the written version shall not dispense the prescription and shall mark the prescription as void.

This information is defined in **Section 80.73** and **Section 80.74** of Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link:
www.health.ny.gov/regulations/nycrr/title_10/

Out-of-State Electronic Prescriptions for Controlled Substances

Pharmacists may dispense out-of-state prescriptions in Schedule II through V that have been created, signed and transmitted electronically, provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in Part 80 and with federal requirements for electronic prescribing of controlled substances.

Out-of-state prescriptions shall be dispensed in conformity with provisions set forth in Part 80 for Official New York State Prescriptions and electronic prescriptions. Prescription information from all out-of-state prescriptions for a controlled substance shall be filed with the Department of Health, BNE, in accordance with **Section 80.73(f)** of Part 80. Out-of-state prescription dispensing is defined in **Section 80.78** Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.

Electronic Recordkeeping of Controlled Substances

Effective March 27, 2013, amendments to Title 10 Part 80 Rules and Regulations on Controlled Substances allow for electronic recordkeeping of controlled substance records, orders and prescription data. The records, orders and prescription data maintained electronically must remain readily retrievable for inspection by authorized representatives of the Bureau of Narcotic Enforcement (BNE). Records requested by representatives of the BNE shall be accessible at the premises where the licensed activity is conducted and producible in a hard copy format that is readily understandable. In addition, records maintained electronically must be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.

Records of all transactions concerning controlled substances required to be kept by manufacturers, distributors, importers, exporters, institutional dispensers, persons conducting research, instruction, analytical or maintenance treatment programs, pharmacies and practitioners shall be kept for five years from the date of transaction. Recordkeeping requirements are defined in **Section 80.100**, Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.

Pharmacies: Electronic Archiving of Prescriptions for Controlled Substances

If a prescription for a Schedule II, III, IV, or V controlled substance is created, signed, transmitted and received electronically, all records related to that prescription shall be retained electronically. Pharmacy recordkeeping requirements are defined in **Section 80.106** Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.

When a pharmacist fills a prescription that would allow him or her to change or add information, authorized by the prescribing practitioner, which must be documented on the written prescription, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record. Pharmacy dispensing requirements are defined in **Section 80.73** and **Section 80.74** Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.

Electronic Archiving of Prescription Refills

An electronic prescription shall contain the same information required on a written prescription, except the electronic prescription shall contain an electronic signature and shall be transmitted and received by electronic means.

The pharmacist filling the prescription shall endorse the prescription with his or her signature, the date of filling and the number under which it is recorded in the pharmacy. Electronic prescriptions shall be endorsed electronically by the pharmacist. When a prescription is received electronically, the prescription and all required annotations shall be retained electronically.

Refills

On refills, the dispensing pharmacist shall indicate on the prescription the amount dispensed, the date dispensed, and the signature of the dispensing pharmacist. Refill documentation on written prescriptions (non-electronic prescriptions) may be recorded manually on the prescription, or in an electronic recordkeeping system. Refill documentation on electronic prescriptions shall remain electronic within the electronic recordkeeping system. When refills are recorded in an electronic recordkeeping system, the pharmacist shall ensure that the computer application used for such recordkeeping shall:

- Provide online retrieval of original prescription information; **and**
- Provide online retrieval of the current refill history for Schedule III, IV (non-benzodiazepines) and V controlled substance prescriptions.

Refill Documentation

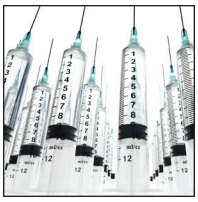
Refill documentation on written prescriptions (non-electronic prescriptions) may be recorded manually on the prescription, or in an electronic recordkeeping system. When a pharmacy utilizes an electronic recordkeeping system for refill documentation of official New York State prescriptions or out-of-state written prescriptions for Schedule III, IV (non-benzodiazepines) or V controlled substances, the dispensing pharmacist shall document that the refill information entered into the computer has been reviewed and is correct by **manually signing:**

- A hard copy printout of each day's controlled substance prescription refill data, **or;**
- A bound log book containing a statement that the refill information entered into the computer that day has been reviewed and is correct as shown.

Refill Documentation Access

The pharmacy shall employ a procedure to be used for documentation of refills of Schedule III, IV (non-benzodiazepines) and V controlled substance prescriptions in the event of system downtime. The procedure shall ensure that refills are authorized by the original prescription and that the maximum number of refills authorized has not been exceeded.

Electronic archiving of refill requirements are defined in **Section 80.69** Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.



Hypodermic Needles and Hypodermic Syringes Electronic Prescriptions and Electronic Archiving

Effective October 9, 2013, amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances allow for electronic prescribing and recordkeeping of hypodermic needles and syringes. The amendments specify the manner in which a practitioner may issue a prescription, including an electronic prescription, for hypodermic needles and syringes and specify how a pharmacist should dispense and electronically archive such prescriptions. Effective March 27, 2016, prescriptions for needles and syringes are mandated to be electronically prescribed.

Any prescription for one or more hypodermic needles or syringes prefilled with a controlled substance shall be issued and dispensed according to the requirements in **Sections 80.67, 80.68, 80.69, 80.70, 80.73** and **80.74** of Part 80 Rules and Regulations on Controlled Substances. Needles and Syringe regulations are defined in **Section 80.131** Title 10 Part 80 Rules and Regulations on Controlled Substances and can be accessed through the following link: *www.health.ny.gov/regulations/nycrr/title_10/*.

Adopted regulations allow the following:

- A practitioner *may* issue a prescription for hypodermic needles and syringes electronically.
- A pharmacist *may* accept and archive a prescription for hypodermic needles and syringes electronically.
- A pharmacist *may* transfer refills of a prescription for hypodermic needles and syringes to another pharmacy as permitted under NYS Education Law.
- A practitioner *may* prescribe hypodermic needles and syringes to patients in a Residential Health Care Facility (RHCF) pursuant to a patient specific prescription form permitted under NYS Education Law.
- Prescriptions for hypodermic needles and syringes are not subject to quantity limitations.
- Prescriptions for hypodermic needles and syringes are not subject to refill limitations.
- Prescriptions for hypodermic needles and syringes are valid for two years from the date the prescription was signed.
- Prescriptions for hypodermic needles and syringes shall be retained on file for a period of five years and be readily accessible for inspection.

Oral Prescriptions for Hypodermic Needles and Syringes

- Oral prescriptions for hypodermic needles and syringes are *not* subject to quantity limitations.
- Oral prescriptions for hypodermic needles and syringes are *not* subject to refill limitations.
- Oral prescriptions for hypodermic needles and syringes do *not* require a follow-up hard copy prescription.
- An employee of the prescribing practitioner *may* orally communicate a prescription on behalf of that practitioner for hypodermic needles and syringes to the pharmacist (only the prescribing practitioner may orally prescribe a controlled substance medication contained within a hypodermic needle/syringe).
- A health care professional in a RHCF *may* orally communicate a prescription on behalf

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of a practitioner for hypodermic needles and syringes to the pharmacist.

- A pharmacist *may* reduce an oral prescription for hypodermic needles and syringes to an electronic or written memorandum.
- Oral prescriptions for hypodermic needles and syringes shall be retained on file for a period of five years and be readily accessible for inspection.

Refills for Hypodermic Needles and Syringes

- A pharmacist *may* electronically archive/annotate dispensed refill(s) authorized on a prescription for hypodermic needles and syringes.
- Prescriptions for hypodermic needles and syringes are *not* subject to refill limitations (prescriptions are valid for up to two years).
- A pharmacist *may* transfer refills of a prescription for hypodermic needles and syringes to another pharmacy as permitted under NYS Education Law.

Contact Us

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Fax: 518-402-0709
www.health.ny.gov/professionals/narcotic/
Email: narcotic@health.ny.gov

Regional Offices

NYC (212) 417-4103

Buffalo (716) 847-4532

Syracuse (315) 477-8459

Rochester (585) 423-8043

Additional Resources

Drug Enforcement Administration (DEA)
www.deadiversion.usdoj.gov/index.html
877-883-5789

NYS Office of Alcoholism and Substance Abuse Services (OASAS)
www.oasas.ny.gov
877-8 HOPENY (877-846-7369)

Substance Abuse and Mental Health Services Administration (SAMHSA)
www.*samhsa.gov*
866-287-2728

New York State Education Department/Board of Pharmacy
www.op.nysed.gov
518-474-3817, Ext. 130

New York State Medicaid Policy
518-486-3209

Commerce Accounts Management Unit (CAMU)
866-529-1890

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