BNE Update

New York State Department of Health • Bureau of Narcotic Enforcement Spring 2013

New Schedule Classification for Hydrocodone-Containing Products

Effective 2/23/13, in New York State all strengths, formulations and combination products of hydrocodone will be removed from Schedule III and placed in the Schedule II controlled substance listing. Existing refills on a hydrocodone prescription are not valid for dispensing on or after 2/23/13. As with all Schedule II controlled substances, prescriptions for hydrocodone cannot be refilled and are limited to a 30-day supply of the drug. However, a practitioner may prescribe up to a three-month supply of hydrocodone for the relief of pain in patients suffering from conditions or diseases known to be chronic or incurable by indicating either the condition being treated or the notation 'Code D' on the prescription.

When an emergency prescription for up to a 5-day supply of hydrocodone is orally authorized by the practitioner, on or after 2/23/13, the practitioner is responsible for delivering the follow-up Official New York State Prescription Form to the pharmacist. If the pharmacist fails to receive the follow-up prescription, he or she shall notify the department in writing within 7 days from the date of dispensing the substance.

Manufacturers are required by the DEA to identify controlled substances on their container labels by denoting them as CII, CIII, CIV, and CV. However, these identifiers indicate only federal scheduling, not New York State scheduling, and whether a DEA-222 form is required when ordering controlled substances depends on the specific drug's placement on the federal Controlled Substance Act.

Records of all Schedule II controlled substances received, delivered or disposed shall be filed separately from Schedules III, IV, and V. In addition, Schedule II controlled substances prescriptions shall be maintained together in a separate file.

You may view the complete list of controlled substance schedules contained in Section 3306 of the NYS Public Health Law by visiting the New York State Legislature link from the bureau's web page at *health.ny.gov/professionals/narcotic/laws_and_regulations.htm*

Frequently asked questions can be viewed at the bureau's web page *health.ny.gov/professionals/narcotic/laws_and_regulations/part_c-chapter_447-laws_of_2012-faq.htm*

In this issue...

Electronic Prescribing and Dispensing of Controlled Substances is Now Permissible in New York State Effective March 27, 2013 – Updated April 2013

Amendments to Title 10 NYCRR Part 80 Rules and Regulations on 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.

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.

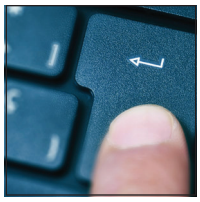
The federal requirements are included in the Drug Enforcement Administration Interim Final Rule regarding Electronic Prescriptions for Controlled Substances. The rule may be accessed via the U.S Department of Justice DEA Office of Diversion Control website.

NYS Education Department regulations may be accessed electronically: http://*www.op.nysed.gov/prof/pharm/pharmlaw.htm*

To view the Department of Health Recently Adopted Regulations, amendments to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances may be accessed electronically:

- Go to *www.health.ny.gov*
- On the right side of the Home Page click on Laws and Regulations
- Under Rules and Regulations click on Recently Adopted Regulations (Prior Six Months)
- Click on March 27, 2013 – Electronic Prescribing, Dispensing and Recordkeeping of Controlled Substances

Effective March 27, 2015, all prescriptions issued in New York State will be electronic prescriptions, with certain limited exceptions. Please continue to visit the Bureau's webpage (health.ny.gov/professionals/narcotic) for information pertaining to electronic prescribing of controlled substances.



Name Edit – Submission of Prescription Information

Beginning on August 27, 2013, all practitioners who prescribe a Schedule II, III or IV controlled substance will be required to view their patient's controlled substance history contained in the Department of Health's Prescription Monitoring Program Registry (PMP). The data contained within the registry is received from more than 6,000 separate reporting dispensers, including registered pharmacies throughout New York State.

In the past, the Bureau has received numerous submissions that contain incorrect information in the patient's first and/or last name fields. These errors directly affect the accuracy of the data presented to practitioners, as well as pharmacists who will also be granted access to the PMP Registry. To correct this problem, effective March 15, 2013, errors in these fields resulted in a submission rejection.

BNE closely analyzes all submitted prescription information. Pharmacies that submit incorrect or incomplete prescription information may be charged with violations of the controlled substance law and regulations. Such violations may result in commencement of legal action.

Submission of Prescription Information in ASAP 2007 Version 4.0, Version 4.1 or Version 4.2 Format

Effective 04/05/2013, the Bureau of Narcotic Enforcement (BNE) accepts controlled substance prescription information only in the ASAP 2007 version 4.0 and version 4.1 formats. BNE no longer accepts submissions using the ASAP 1995 format. Any pharmacy that is not submitting data in version 4.0 or 4.1 should contact their software vendor to ensure compliance with the submission requirement.

Starting late August 2013, BNE will also accept version 4.2. Version 4.2 will be necessary to accommodate electronic prescribing.

Pharmacies that fail to submit prescription information may face administrative enforcement action.

Safeguarding Official New York State Prescription Forms

The Department of Health's Bureau of Narcotic Enforcement (BNE) provides millions of secure Official New York State Prescription (ONYSRx) Forms annually to more than 95,000 prescribing practitioners across New York State. The official prescription forms are issued to registered practitioners authorized to write prescriptions and to certain registered institutional facilities. 10 NYCRR §910.5, §80.75 and §80.77 require practitioners and facilities to adequately safeguard their official prescription forms against theft, loss, destruction or unauthorized use.

BNE frequently receives reports of theft and loss of both practitioners' prescription pads as well as blank Electronic Medical Record (EMR) prescription paper. The prescription forms are being stolen from hospitals and other health care facilities, counterfeited and/or forged, and are presented at pharmacies both in New York State and out of state.

Practitioners

10 NYCRR §910.5 and §80.77 require practitioners to provide adequate safeguards and security measures to assure against the loss, destruction, theft or unauthorized use of the official prescription forms. Practitioners shall maintain a record of the disposition of all forms including, but not limited to, use as a prescription, cancellation, return, loss, destruction, unauthorized use and non-receipt. The forms may be used only by the practitioner to whom they are issued and are not transferrable.

- Practitioners must maintain a system of control and security for all forms received. Shipments of ONYSRx forms received must match the shipping invoice. Serial numbers received must be documented. Trusted personnel should be aware when a shipment is expected, and where the shipment is expected to arrive. Contact the bureau toll-free at 1-866-811-7957 option 1 with any discrepancies with the shipment.
- BNE investigations have revealed that theft is most likely to occur once the ONYSRx forms leave secured areas and are distributed throughout a practice. A record of the serial numbers of the forms assigned to practitioners within a medical practice should be kept when removing prescriptions from secure storage.
- Storage of the forms should be in a secure area or in locked printers that are monitored by trusted personnel or video surveillance. Do not leave blank forms in treatment rooms or at workstations. Prescriptions should be kept under lock and key when not in use.
- Inventory prescription forms on a pre-defined schedule. Perform random audits.
- Office practices should have written policies in place regarding the proper recordkeeping of ONYSRx forms. This becomes particularly important if loss or unauthorized use is suspected.
- Practitioners should maintain a sufficient, but not excessive, supply of prescriptions. Excessive prescription supplies create greater potential for theft by individuals seeking to use them illegally to divert drugs.

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Facilities

10 NYCRR §910.5 and §80.75 require facilities to provide adequate safeguards and security measures to assure against the loss, destruction, theft or unauthorized use of the official prescription forms. It is the responsibility of a registered facility to obtain all official prescription forms for use, to assign such forms to its staff practitioners and to ensure the security of all such forms. A system must be established whereby ONYSRx forms are surrendered to the facility by staff practitioners to whom they were assigned when their affiliation with the facility is terminated. A responsible person or persons within each facility should be designated to oversee a system of control and security for ONYSRx forms and to ensure compliance with the abovementioned regulations. If the responsible person is not part of the facility's prescription ordering process, that process should be monitored as well.

- Facilities must have a safeguarding system in place for proper record-keeping of ordering, assigning and ensuring the security of the ONYSRx forms. This becomes particularly important if loss or unauthorized use is suspected.
- Facilities should maintain a system of control and security that includes a record of all forms received. Shipments of ONYSRx forms received must match the shipping invoice. Serial numbers received must be documented. Trusted personnel should be aware when a shipment is expected, and where the shipment is expected to arrive. Contact the bureau toll-free at 1-866-811-7957 with any discrepancies with the shipment.
- Forms issued to a facility may be used by staff practitioners only for patients of the facility.
- Facilities that operate off-site clinics must ensure that systems of control and security of ONYSRx forms are in place at the off-site clinics. Clinics should maintain a sufficient, but not excessive, supply of the forms.
- Theft is most likely to occur once the ONYSRx forms leave secured areas and are distributed. A record of the serial numbers of the forms assigned to staff practitioners throughout a facility must be kept when removing prescriptions from secure storage.
- Storage of the forms once distributed should be in a secure area or in locked printers that are monitored by trusted personnel or video surveillance. Do not leave blank forms unsecured in treatment areas or at workstations.
- Inventory prescription forms on a pre-defined schedule. Perform random audits.
- Prescriptions are required by regulation to be kept under lock and key when not in use. Locked printers are recommended when printers are used to generate prescriptions.
- Facilities must maintain a sufficient, but not excessive, supply of prescriptions. Excessive prescription supplies create greater potential for theft by individuals seeking to use them illegally to divert drugs.

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10 NYCRR §910.5, §80.75 and §80.77 require practitioners and facilities to immediately notify the Department upon their knowledge of the loss, destruction, theft or unauthorized use of any Official New York State Prescription Form issued to them. Practitioners and facilities shall immediately notify the Department if they fail to receive the ONYSRx forms within a reasonable time after ordering them. The notification form required for reporting this information may be accessed via the bureau's web page: *health.ny.gov/forms/doh-4387.pdf*

10 NYCRR §910.5 requires practitioners and facilities to immediately notify the Department upon their knowledge of any diversion or suspected diversion of drugs pursuant to the loss, theft or unauthorized use of prescription forms.

Prescription fraud is an increasing problem that drives up health care costs and poses a threat to the safety of all New York State citizens. Practitioners and facilities must provide effective controls and procedures to guard against the theft, loss or unauthorized use of Official New York State Prescription Forms. Failure to provide appropriate safeguarding mechanisms may result in regulatory compliance actions.

Limited English Proficiency (LEP) and New York State Prescription Forms

Recently enacted legislation requires all prescriptions issued in New York State to include a section wherein prescribers may indicate whether an individual is limited English proficient (LEP), as defined in Section 6829 of the education law, along with a line where a prescriber may specify the preferred language indicated by the patient.

This law took effect March 30, 2013. Official prescription forms ordered by practitioners and facilities that are received after March 30, 2013 include the requirements for LEP. Prescription forms received by practitioners and facilities that do not include the LEP indication are valid for dispensing. However, the practitioner may indicate on the front of the prescription if the patient is limited English proficient and the patient's preferred language.

Please see the department's website for further information. The recently adopted regulations can be found at *http://www.health.ny.gov/regulations/recently_adopted/* See March 27, 2013

NYS PMP

PRESCRIPTION MONITORING PROGRAM REGISTRY

The New York State Department of Health's Bureau of Narcotic Enforcement maintains an online Prescription Monitoring Program (PMP) Registry.

The online program, formerly referred to as the Controlled Substance Information program (CSI), allows you to review your patients' recent controlled substance prescription history at any time, giving you more information to exercise your professional judgment in treating your patients.

Currently, any New York State licensed prescriber who holds a valid DEA registration may access the PMP registry. Each prescriber must have an individual Health Commerce System Account (HCS) to gain access. Instructions on how to establish an account are available at the following website: *https://hcsteamwork1.health.state.ny.us/pub/top.html*

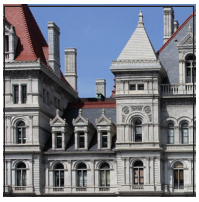
How to Access the PMP Registry

1. Go to the HCS at: https://commerce.health.state.ny.us
2. Log onto the system with your user ID and password (If you can't remember your password, call the Commerce Account Management Unit at 1-866-529-1890, Option 1, for assistance).
3. Select "Applications" at the top of the page. Click on the letter 'P.'
4. Scroll down to "Prescription Monitoring Program Registry."
5. Click the green plus sign under the Add/Remove column to add this application to your "Favorites" so you don't have to scroll down each time in the HCS [optional].
6. Click to open the program.
7. Enter all required information.
8. Review the Frequently Asked Questions within the application for further information.

Currently, this program is available only to New York State prescribers of controlled substances, but coming soon, this program will also be available to pharmacists. Check the BNE website for new information.

QUESTIONS?

Call **1-866-811-7957** (Option 1)



Prescription Drug Reform Act Summary

The Bureau of Narcotic Enforcement (BNE) in the Department of Health (DOH) has worked with the Governor's office and the legislature to pass a historic bill that presents a comprehensive approach to addressing the prescription drug abuse epidemic. The legislation accomplished the following:

1. Improves New York's Prescription Monitoring Program (PMP) (a.k.a. I-STOP)

a. New York first began monitoring prescriptions in 1972. The current system is underutilized and has information that is not reported in a timely fashion. Since the on-line PMP's inception in 2010, less than 4% of the 96,000 DEA-licensed prescribers in NY State have ever accessed the database. During this period, only 308,000 searches were conducted, despite more than 60.9 million prescriptions for controlled substances being dispensed over the same time period.

b. The new legislation will allow BNE to modernize the PMP, increasing accessibility. By allowing BNE to collect more current information from pharmacies, the PMP will have more valuable and timely data that will be shared with appropriate entities as permitted under §3371 of Public Health Law, all while ensuring that people's private medical information is protected.

c. The new legislation will require prescribers to check the PMP before prescribing a controlled substance. With increased use of the real-time PMP, prescribers will be able to identify addiction-related behavior, including doctor-shopping. It will also allow prescribers to spot a potentially dangerous drug interaction. The law allows for certain exceptions. (APPENDIX A)

d. The new legislation will give pharmacists access to patients' controlled substance history and provide additional information to pharmacists who may have concerns about the legitimacy of a prescription. Pharmacists are not mandated to access the PMP.

e. Practitioners and pharmacists may authorize a designee, as permitted by regulation, to consult the registry on his or her behalf.

f. The PMP Registry will still be accessed via the DOH Health Commerce System (HCS). Practitioners may obtain an HCS account and access the registry today. Pharmacists may obtain an HCS account and should be advised to monitor the BNE web page for information pertaining to pharmacist access to the registry.

APPENDIX A

The duty to consult the PMP registry shall not apply to:

- veterinarians;
- a practitioner dispensing pursuant to subdivision three of Article 33 §3351 (methadone interim treatment, ordered and dispensed or administered by a practitioner, for an addict on a waiting list for admission to an authorized maintenance program);
- a practitioner administering a controlled substance;
- a practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser pursuant to Article 33, §3342;
- a practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of prescribed controlled substance does not exceed a five-day supply;
- a practitioner prescribing a controlled substance to a patient under the care of a hospice;
- a practitioner acting in compliance with regulations that may be promulgated as to circumstances under which consultation of the registry would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient;
- a practitioner when:
  - it is not reasonably possible for the practitioner to access the registry in a timely manner;
  - no other practitioner or designee authorized to access the registry is reasonably available; and
  - the quantity of prescribed controlled substance does not exceed a five-day supply;
- a situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in regulation;
- a practitioner who has been granted a waiver due to technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner, pursuant to a process established in regulation.

2. Electronic prescribing will be the standard for prescribing non-controlled substances and controlled substances

a. Two years after the proposed regulations for electronic prescribing of controlled substances (EPCS) are enacted, all prescriptions in NYS will be electronic prescriptions. This will make NYS a leader in adopting medical technology as well as eliminating the need for prescription paper, which is a common source of diverted drugs. Electronic prescribing also enables a faster and more streamlined flow of controlled substance information between prescribers, pharmacists and the PMP.

b. Adopted regulations for EPCS can be found on the Department of Health's web site: *www.health.ny.gov/regulations/recently_adopted/* See March 27, 2013.

c. Some limited exceptions apply. (APPENDIX B)

APPENDIX B

Limited exceptions to electronic prescribing include prescriptions:

- issued by veterinarians;
- issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;
- issued by practitioners who have received a waiver for a specified period determined by the Commissioner of Health, not to exceed one year, from the requirement to use electronic prescribing. A waiver may be issued due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- issued by a practitioner when the practitioner reasonably determines that it would be impractical for the patient to obtain medications electronically prescribed in a timely manner, and such delay would adversely impact the patient's medical condition. If such prescription were for a controlled substance medication, the prescription may not exceed a five-day supply; or
- issued by a practitioner to be dispensed by a pharmacy located outside of New York State.

3. Changes to Controlled Substance Schedules (Public Health Law §3306)

Effective November 25, 2012,
the following changes were made to the controlled substance schedules in Section 3306 of the New York State Public Health Law. Where applicable, some common brand name pharmaceutical preparations containing the controlled substances are listed in bold:

Schedule II Additions

Tapentadol (**Nucynta™**)

Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP)

Boldione (androsta-1,4-diene-3,17-dione)

Desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol) (a.k.a., madol)

19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)

Schedule II Amendments

Language defining an anabolic steroid was amended: Unless specifically excepted or unless listed in another schedule, "anabolic steroid" shall mean any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids and dehydroepiandrosterone).

Schedule III Amendments

Language to clarify the description of dronabinol.

Schedule IV Additions

Fospropofol (**Lusedra™**)

Carisoprodol (**Soma®**)

Schedule V Additions

Ezogabine (**Potiga™**)

Lacosamide (**Vimpat®**)

Effective February 23, 2013,
the following changes were made to the controlled substance schedules in Section 3306 of the New York State Public Health Law. Notably, all versions of hydrocodone are now classified as Schedule II controlled substances. Where applicable, some common brand name pharmaceutical preparations containing the controlled substances are listed in bold:

Schedule II Additions

Hydrocodone (dihydrocodeinone) (**Vicodin®, Lortab®, Tussionex®**) This action renders all products containing hydrocodone, including but not limited to, hydrocodone in combination with acetaminophen or ibuprofen, Schedule II.

Schedule III Deletions

Hydrocodone (dihydrocodeinone) (**Vicodin®, Lortab®, Tussionex®**). This action renders all products containing hydrocodone, including but not limited to hydrocodone in combination with acetaminophen or ibuprofen, Schedule II.

Schedule IV Additions

Tramadol (**Ultram®, Ultracet®, Ryzolt™**)

Practitioners and pharmacists are responsible for ensuring prescriptions for all controlled substances including the medications listed above conform to all requirements of the law and regulations, both federal and state. Article 33 of the Public Health Law and Title 10 Part 80 Rules and Regulations on Controlled Substances in New York State may be accessed via the Bureau of Narcotic Enforcement web page: *health.ny.gov/professionals/narcotic/laws_and_regulations.htm*

Visit the BNE web page for Frequently Asked Questions pertaining to schedule changes.

4. Enhances education of individuals in the medical profession on the dangers of abuse and methods of preventing addiction.

a. The bill creates a workgroup, comprised of practitioners of varying specialties, pharmacists and patient advocates who will help guide DOH in educating practitioners, pharmacists, patients and the general public.

b. This workgroup will help DOH provide evidence-based guidelines for the safe and effective use of prescription painkillers.

5. Provides opportunities for individuals to safely dispose of their unused, controlled substance prescriptions.

a. This bill creates a safe disposal program that will provide members of the public a continuous opportunity to anonymously dispose of unwanted medications at police stations around the state.

b. Visit the BNE web page for a map and listing of medication drop boxes by county *health.ny.gov/professionals/narcotic/medication_drop_boxes/*

6. Increases information sharing.

a. The bill allows DOH to share information with additional appropriate entities, including local health departments. This increased sharing will allow DOH to partner with individual counties to find more solutions tailored for specific regions and their particular patterns of abuse.

Contact Us

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www.health.ny.gov/professionals/narcotic/
Email: narcotic@health.state.ny.us

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)
addictionmedicine@oasas.ny.gov
877-8 HOPENY (877-846-7369)

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

New York State Education Department/Board of Pharmacy
pharmbd@mail.nysed.gov
518-474-3817, Ext. 130

New York State Medicaid Policy
518-486-3209

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