

Doctor Beware: *Regulation of Controlled Substances*

BY:



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On February 12, 2015, the United States Attorney for the Southern District of New York and the Assistant Director-in-Charge of the New York Office of the Federal Bureau of Investigation (FBI) announced the unsealing of a criminal complaint against a physician who is alleged to have participated in a scheme to issue medically unnecessary prescriptions for Oxycodone pills, a schedule II narcotic used to treat severe and chronic pain conditions. According to the U.S. Attorney press release, in a course of a two year period, the physician charged hundreds of thousands of dollars for “patient visits” that involved little, if any, actual examination.¹

Obviously, the vast majority of physicians administer, dispense and prescribe controlled substances responsibly and consistent with medical necessity.

However, because the dispensing, prescribing and administering of controlled substances are strictly regulated and subject to scrutiny by federal, state and local authorities, it is important for physicians to understand the numerous federal and state laws that regulate controlled substances.

A. Drug Enforcement Administration (DEA) Registration

DEA regulations require a separate registration to be obtained for each physician location at which a professional practice manufactures, distributes or dispenses controlled substances. A physician who is registered at one location, but who also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed. If the physician maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the physician must obtain a separate DEA registration for that location. It is recommended that physicians review the [DEA Practitioner’s Manual for Controlled Substances](#).

B. Ordering and Safeguarding

A practitioner may only order Schedule II, III, IV and V controlled substances from manufacturers or distributors licensed under Article 33 of the Public Health Law.

Department of Health Regulations -

10 N.Y.C.R.R. § 80.60.

a) Controlled substances must at all times be properly safeguarded and securely kept at the address on file with the Drug Enforcement Administration and which is used in the ordering of controlled substances, where they will be

available for inspection by authorized agents of the NYS Department of Health Bureau of Narcotic Enforcement (BNE).

b) Access to controlled substances stocks must be limited to the minimum number of employees actually required to handle the distribution, custody, dispensing, administration or handling of controlled substances.

10 N.Y.C.R.R. § 80.6.

C. Prescribing and Dispensing Controlled Substances

1. Legitimate Medical Purpose and Documentation

(a) Physicians and other authorized practitioners (or collectively “practitioners”) in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment, other than treatment for addiction to controlled substances, when the practitioner regulates the dosage and prescribes or administers a quantity of such drugs no greater than that ordinarily recognized by members of the profession as sufficient for proper treatment in a given case.

(b) The practitioner must maintain a written patient record of administration, dispensing and prescription for all controlled substances. The patient record must contain sufficient information to justify the diagnosis and warrant treatment. The record must contain at least the following information: patient identification data; chief complaint; present illness; physical examination as indicated; diagnosis or treatment; and the regimen including the amount, strength, and directions for use of the controlled substance.

10 N.Y.C.R.R. § 80.62.

2. Physician Monitoring Program (PMP) Registry

Prior to prescribing or dispensing a controlled substance listed on Schedule II, III, or IV of Public Health Law Section 3306, the practitioner must consult the prescription monitoring program (PMP) registry for the purpose of reviewing that patient’s controlled substance history. The patient’s controlled substance history must be obtained from the PMP no more than 24 hours prior to the practitioner prescribing or dispensing the controlled substance to the patient. A practitioner must document such consultation in the patient’s medical chart or, if the practitioner does not consult the PMP, the practitioner must document in the patient’s medical chart the reason the consultation was not performed. Among the exceptions to the requirement to consult the PMP, the duty to consult to PMP registry does not apply to:

- (i) Veterinarians;
- (ii) Methadone programs or other addiction treatment programs approved by the NYS Commissioner of Health;
- (iii) A practitioner administering a controlled substance;
- (iv) A practitioner prescribing or ordering a controlled substance (1) for a patient of an institutional dispenser as defined by Public Health Law Section 3302 for use on the premises, or during an emergency transfer from, the institutional dispenser;
- (v) A practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a 5 day supply;
- (vi) Prescribing a controlled substance to a patient under the care of a hospice;
- (vii) A practitioner under the following circumstances:
 - (a) It is not reasonably possible for the practitioner to access the PMP registry in a timely manner;
 - (b) No other practitioner or designee authorized the PMP is reasonably available; and

(c) The quantity prescribed does not exceed a 5 day supply.

(viii) A practitioner acting in circumstances under which consultation of the PMP registry would, as determined by the practitioner, result in the patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of the patient; provided that the quantity does not exceed a 5 day supply.

(ix) A situation where the PMP registry is not operational as determined by NYS DOH or where it cannot be accessed due to a temporary technological or electric failure. The practitioner must seek to correct any cause for the failure that is reasonably within his or her control.

(x) A practitioner who has been granted a waiver (e.g. such as due to technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstances demonstrated by the practitioner).

If a practitioner claims that consultation with the PMP registry is not performed because of (vii) or (viii), the practitioner must, in addition, document in the patient's medical chart a description of the circumstances supporting the practitioner's conclusion.

A practitioner may authorize a designee to consult the PMP registry on his or her behalf, provided that the ultimate decision as to whether or not to prescribe or dispense the controlled substance remains with the practitioner.

10 N.Y.C.R.R. § 80.63(c).

The New York State Department of Health website provides numerous informational resources regarding the PMP Registry, including [Frequently Asked Questions](#).

3. Requirement for Examination of Patient

(1) No controlled substance prescription may be issued prior to the examination of the patient.

(2) Once the initial examination has been completed, the frequency and necessity for future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner:

(i) has direct access to the patient's medical records and such records warrant continued controlled substance prescribing; or

(ii) has direct and adequate consultation with the original prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner must document the activity for his or her own record and transmit to the initial prescriber the prescription information. The initial prescriber must include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if:

(i) the prescriber has a previously established physician/patient relationship;

(ii) an emergency exists; and

(iii) the prescription does not exceed a 5 day supply.

10 N.Y.C.R.R. § 80.63(d).



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4. Electronic Prescribing Requirement

Effective March 27, 2016 electronic prescribing of controlled substances and non-controlled substances is required, subject to limited exceptions. Computer applications utilized to prescribe controlled substances must meet federal security requirements. Computer applications that meet federal security requirements must be registered with the Department of Health Bureau of Narcotic Enforcement.

Public Health Law §281; 3302(37); 10 N.Y.C.R.R. § 80.64(b).

Exceptions

Prescriptions excepted from the electronic prescribing requirement include prescriptions that are:

- (1) Issued by veterinarians
- (2) Issued are 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 manner that it reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit on electronic prescription for a controlled substance.
- (3) Issued by practitioner to whom the Commissioner of Health has granted a waiver.
- (4) Issued by a practitioner under circumstances where 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 5 day supply.
- (5) Issued by a practitioner to be dispensed by a pharmacy out of state.

Notification Process – Use of an Electronic Prescribing Exception

Each time a practitioner uses one of the exceptions listed below, the practitioner must report the use of the exception to the Department of Health:

- Temporary Technological or Electrical Failure – Notify us as soon as practicable but no more than 72 hours following the end of the failure.
- Practitioner reasonably determines it would be impractical for the patient to obtain the substances prescribed by electronic prescription in a timely manner – Notify within 48 hours of the date of issue.
- To be dispensed by a pharmacy located outside of the state, or on federal property. Notify within 48 hours.

For more information on Electronic Prescribing Requirement, visit the N.Y.S. Department of Health website.

Frequently asked questions:

[New Waiver FAQs 133-135](#)

[Practitioner Notification process – Use of an Electronic Prescribing Exception](#)

[New York State Department of Education Office of the Professions FAQs - Electronic Transmittal of Prescriptions in NYS](#)



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5. Legitimate Medical Purpose

A prescription may be issued for legitimate medical purposes only. The responsibility for the proper prescribing and dispensing of controlled substances is placed upon the physician or other authorized practitioner, but a corresponding liability is placed on the pharmacist who fills the prescription.

10 N.Y.C.R.R. § 80.65.

6. Prescription Requirements

There are differing requirements for prescriptions depending upon the schedule:

- (1) Schedule II and certain substances known as Benzodiazepines - 10 N.Y.C.R.R. § 80.67.
- (2) Emergency oral prescriptions for Schedule II, Substances and Benzodiazepines - 10 N.Y.C.R.R. § 80.68.
- (3) Schedule III, IV, and V substances - 10 N.Y.C.R.R. § 80.69.
- (4) Oral Prescriptions for Schedule III, IV and V substances - 10 N.Y.C.R.R. § 80.70.

These regulations are available on the website of the [NYS Department of Health](#). Click “Laws and Regulations”, then select “Title 10”

7. Dispensing Requirements

Dispensing of controlled substances must comply with 10 N.Y.C.R.R. § 80.71. With limited exceptions, the quantity dispensed may not exceed a 30 day supply.

When dispensing a controlled substance, the physician or other practitioner must submit dispensing information for all controlled substances dispensed, electronically to the Department of Health, utilizing a transmission format acceptable to the Department, not later than 24 hours after the substance was delivered. The Department may issue a waiver to allow a physician or other practitioner to make such filing within a longer period of time upon showing of economic hardship, technological limitations that are not reasonably within the control of the physician or practitioner, or other exceptional circumstances. If the waiver is granted, the filing period will not exceed the 15th day of the next month following the month in which the substance was delivered. The information that must be filed with the Department includes, but is not limited to:

- (1) Dispenser identifier
- (2) Patient name
- (3) Patient address
- (4) Patient date of birth
- (5) Patient’s gender
- (6) Date of controlled substance dispensed
- (7) Metric quantity
- (8) National drug code number of the drug
- (9) Number of days’ supply
- (10) Prescriber’s DEA number
- (11) Payment method and
- (12) Species code

When applicable, a physician or practitioner must file a “zero report” with the Department. A zero report is a report that states no controlled substance was dispensed during the relevant period of time. - 10 N.Y.C.R.R. § 80.71.



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A physician is only required to file zero reports if the physician is considered to be a “dispensing practitioner”. If a physician has never dispensed a controlled substance, does not currently dispense controlled substances and will not dispense controlled substances in the future, then he or she is not considered to be a dispensing practitioner and is not required to file zero reports. If a physician will no longer be a dispensing practitioner, the physician may apply to the BNE for a waiver from the zero reporting requirement.

8. Addicts or Habitual Users

Controlled substances may not be prescribed for, or administered or dispensed to, addicts or habitual users of controlled substances except as permitted by a specific provision in the Public Health Law or Department of Health regulations.

Public Health Law § 3350; 10 N.Y.C.R.R. § 80.76.

- (1) Controlled substances may be prescribed for, or administered or dispensed to an addict or habitual user:
 - (a) during emergency medical treatment unrelated to abuse for controlled substances;
 - (b) who is a bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis; and
 - (c) who is aged, infirm, or suffering from serious injury or illness and the withdrawal from controlled substances would endanger the life or impede or inhibit the recovery of such person;
- (2) Controlled substances may be ordered for use by an addict or habitual user by a physician and administered by a physician, or registered nurse to relieve acute withdrawal symptoms.
- (3) Methadone, or such other controlled substance designated by the Commissioner of Health as appropriate for such use, may be ordered for use of an addict by a physician and dispensed or administered by the physician as interim treatment for an addict on a waiting list for admission to an authorized maintenance program.
- (4) Methadone, or such other controlled substance designated by the Commissioner of Health as appropriate for use, may be administered to an addict by a physician, as part of a regime designed and intended to withdraw a patient from addiction to controlled substances.
- (5) Methadone, or such other substance designated by the Commissioner as appropriate for use, may be administered to an addict by a physician as part of a substance abuse or chemical dependence approved pursuant to specific provisions of the Mental Hygiene Law.

Public Health Law §3351.

9. Pain Management Guide

Controlled substances, including opioid analgesics, may be used in the treatment of acute or chronic pain (both malignant and non-malignant) if the treatment is based on accepted medical practice and sound clinical judgment. See [NYSDOH “Pain Management Guide for Physicians”](#).

D. Safeguards and Security Measures

- (a) Adequate safeguards and security measures must be undertaken by practitioners holding official NYS prescription forms to assure against the loss, destruction, theft or unauthorized use of the forms. Practitioners must 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.
- (b) Practitioners must immediately notify the NYS Department of Health of the loss, destruction, theft or unauthorized use of any official NYS prescription form, as well as the failure to receive official NYS official prescription forms within a reasonable time after ordering them from the Department.
- (c) Practitioners must retain sole possession and safeguard credentials used to sign electronic prescription for controlled substances and may not share such credentials with any other person. The practitioner may not allow any other person to use such credentials to sign prescriptions for controlled substances.
- (d) The practitioner must immediately notify the BNE that his or her credentials used to sign electronic prescription for controlled substances have been lost, stolen or compromised.



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(e) The practitioner must immediately notify BNE upon discovery that one or more prescriptions issued under the practitioner's DEA registration were prescriptions that the practitioner had not signed or were not consistent with the prescription the practitioner signed.

10 N.Y.C.R.R. § 80.77.

E. Recordkeeping and Reporting

Physicians and other practitioners must maintain records of all transactions concerning controlled substances for at least 5 years following the date of the event or transaction. Such records must be made available during business hours for inspection and copying on request of BNE officers or employees. Every record required to be maintained, including prescriptions, must be maintained at the premises where the physician or practitioner conducts the licensed activity.

Public Health Law §3370; 10 N.Y.C.R.R. § 80.100.

Every physician or other practitioner must keep a record of all controlled substances purchased by the physician and a record of all such drugs dispensed or administered out of the physician's own stock. Records of controlled substances purchased must include date of delivery, type, and quantity of drugs and the name and address of the supplier of the drug. A duplicate invoice or separate itemized list furnished by the vendor is sufficient to satisfy the requirement for schedule III, IV and V controlled substances provided it includes all required information and is retained in a separate file. In addition, duplicate copies of Federal order forms for schedule I and II controlled substances must be retained. Records of disposition of controlled substances must include date of dispensing or administering of such drug, name and address of patient, and type and quantity of drug.

10 N.Y.C.R.R. § 80.105.

The attending or consulting practitioner must include report promptly to the Department of Health the name, if possible, the address and such other data as may be required by the Department with respect to any person under treatment if he or she finds that such person is an addict or a habitual user of any narcotic drug. The Department of Health is required to maintain the report confidential and to utilize the report solely for statistical, epidemiological or research purposes, except for reports which originate in the course of a criminal proceeding are subject to the confidentiality requirements of Public Health Law §3371.

Public Health Law §3370; 10 N.Y.C.R.R. § 80.108.

Each incident or alleged incident of theft, loss or possible diversion of controlled substances must be reported to the Bureau of Narcotic Enforcement of the NYS Department of Health.

10 N.Y.C.R.R. § 80.110.

PENALTIES

Under the Federal Controlled Substances Act, criminal penalties are provided for the unlawful distribution, dispensing, possession and manufacture of controlled substances, which includes imprisonment and fines.

21 U.S.C. §841.3.

The New York State Penal Law establishes criminal penalties for the illegal possession and sale of controlled substances, which include imprisonment and fines.

N.Y.S. Penal Law Article 220.



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It is unlawful for any person to manufacture, sell, prescribe, dispense, administer, possess, have under control, abandon or transport controlled substances except as expressly allowed by Article 33 of the Public Health Law.

Caution: Advise Patients of the Risks and Possible Side Effects of Medication and Document!

On December 16, 2015, the N.Y.S. Court of Appeals, the state's highest court, in *Davis v. South Nassau Communities Hospital*, held that physicians and hospitals may be liable to the general public if a patient is not warned of the risks of side effects of certain types of medication which can impair the patient's driving ability. Any member of the public who is injured in an accident with the patient may now sue the physician or hospital if the injured individual alleges that the physician failed to warn the patient of the side effects of the medication. Accordingly, it is strongly recommended that physicians not only warn patients of the risks and potential side effects of medications, but such warning should be documented in the patient's medical record. The documented warning should include the potential side effects of the medication, including, as appropriate, that the medication potentially may impair the patient's ability to drive or operate machinery.

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The federal and state regulation of controlled substances is very comprehensive and complex. A physician should consult a personal attorney who is experienced in the regulation of medicine if the physician has any questions.

Kern Augustine, P.C., Attorneys to Health Professionals, DrLaw.com, is solely devoted to the representation and defense of physicians and other health care professionals. The author may be contacted at 1-800-445-0954 or via email at info@DrLaw.com.

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¹ The U.S. Attorney Press Release is found under Press Releases for February 2015 at: <http://www.justice.gov/usao/nys/>.