

Prescribing Controlled Substances in New Jersey for Advanced Practice Nurses

Dr. Mary Kamienski, APN FAEN
University of Medicine and Dentistry of New Jersey
School of Nursing

WELCOME TO THE UMDNJ SCHOOL OF NURSING

- In order to be eligible for continuing education contact hours please be sure to:
 - Sign in
 - Stay for the entire lecture
 - Hand in your evaluation before you receive your Certificate

Vested interest

I am not receiving any commercial support of this activity.
There are no products or devices discussed in this presentation.

I do not intend to discuss a non-FDA–approved or investigational use of any products or device.

NJ Board of Medical Examiners

- "Controlled substance" means a drug classified in any of the schedules (I through V) of the Controlled Dangerous Substances Act, N.J.S.A. 24:21-5 to 24:21-8.1, recognized to have a potential for abuse or to lead to physical or psychological dependence.



Definition

- Controlled substances are those drugs covered by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and are classified according to their use and abuse potential.

Comprehensive Drug Abuse Prevention and Control Act of 1970

- Effective in 1971
- This act is enforced by the US Drug Enforcement Administration (DEA)

<http://www.usdoj.gov/dea/agency/csa.htm>

Drug Enforcement Administration (DEA)



- Responsible for the control, addition to a schedule, decontrol, remove from control, reschedule, or transfer a substance from one schedule to another
- Refers for medical and scientific evaluation which are binding to the DEA
- A Health and Human Services recommendation that a substance not be controlled is also binding to the DEA.

Schedule of Controlled Substances

- There are five schedules
- Schedules are based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction.
- Schedule I is reserved for the most dangerous substances that have no recognized medicinal use.
- Examples are heroin, marijuana (cannabis), tetrahydrocannabinols, LSD, mescaline, peyote, psilocybin, methaqualone
- Requires an approved protocol for any use



Schedule II

- II – High abuse potential with accepted medicinal uses –
- May lead to severe physical and/or psychologic dependence
- Requires written Rx – no refills allowed
- Container must have a warning label

- Examples: Opium, morphine, hydromorphone, meperidine, codeine, oxycodone, methadone, secobarbital, pentobarbital, dextroamphetamine, methylphenidate, cocaine, and others



Schedule III

- III – Less abuse potential than I and II with accepted medicinal uses
- May led to moderate/low physical dependence or high psychologic dependence
- Written or oral Rx required
- Rx expires within a 6-month period
- Container must have warning label

- Examples: Preparations containing limited opioid quantities or combined with one or more active ingredients that are noncontrolled substances; acetaminophen with codeine, aspirin with codeine, etc. Also, paregoric, nandrolone, stanozolol, testosterone, etc.



Schedule IV

- Lower abuse potential than Schedule III with accepted medicinal uses
- May led to limited physical or psychologic dependence
- Written or oral Rx required
- Rx expires in 6 months with no more than 5 refills allowed
- Container must have warning label

- Phenobarbital, chloral hydrate, meprobamate, fenfluramine, chlordiazepoxide, diazepam, oxazepam, clorazepate, flurazepam, lorazepam, propoxyphene, Examples: pentazocine, mazindol, alprazolam, and others



Schedule V

- V – Lower abuse potential than Schedule IV with accepted medicinal use
- May lead to limited physical or psychologic dependence
- May require written Rx or be sold with Rx depending on state law

- Examples: Medications generally for relief of coughs or diarrhea containing limited quantities of certain opioid controlled substances such as terpin hydrate with codeine, etc.

Click on the web address to obtain an alphabetical list of controlled substances with the Schedule assignment

<http://www.deadiversion.usdoj.gov/schedules/alpha/alphabeticl.htm>

How to write prescriptions for controlled substances in New Jersey

- Write RX on a NJ prescription blank pursuant to P.L. 2003, c.280 (C.45:14-40 et seq.) which includes:
- The prescribing practitioner's full name, address, telephone number, license number, and proper academic degree or identification of professional practice for which licensed;



- The full name, age and address of the patient;
- The date of issuance;
- The name, strength and quantity of the drug prescribed;

- Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg;

How to write a Rx (continued)

- The number of refills permitted or time limit for refills, or both;
- The handwritten original signature of the prescribing practitioner;
- An explicit indication, by initials placed next to "do not substitute" (see (e) below), if it is the prescribing practitioner's intention that a specified brand name drug be dispensed;



- The prescribing practitioner's D.E.A. number, if the drug is a controlled substance; and
- Each practitioner shall use only written prescription blanks which shall be imprinted with the words "substitution permissible" and "do not substitute," with a space for the prescribing practitioner's initials next to the chosen option, and which shall not include preprinted information designed to discourage or prohibit substitution.

More about writing prescriptions

- When using health care facility or multi-prescriber prescription blanks, the full name and license number of the prescribing practitioner shall be legibly printed at the top of the prescription or the identity of the prescriber shall be designated by a checkmark or other legible means.
- Each prescription for a controlled substance shall be written on a separate NJPB.

Other requirements

- The physician is present or readily available through electronic communications
- Periodic review of the charts and patient records treated by the APN is conducted by the collaborating physician and the APN
- Joint protocols that have been developed by the collaborating physician and the APN are reviewed, revised and signed at least once a year



Why you are here today.....

- Completion of six (6) contact hours (in addition to the NJ BON pharmacology educational requirements for initial certification and recertification) of continuing professional education in pharmacology related to controlled substances, including pharmacologic therapy and addiction prevention and management, in accordance with regulations adopted by the New Jersey Board of Nursing.

Rules

- Rules about this legislation have been written.
- NJ Board of Nursing published them in September
- **All APNs** must take this course even if they do not plan to prescribe controlled substances
- There will be a grace period of 6 months after the final adoption of the regulations to take the course and revise joint protocols.
- New Rx pads have already been issued to APNs

Advanced Practice Nurse (A.P.N.) D.E.A. Application Guidelines

- The Drug Enforcement Administration (DEA) is accepting A.P.N. requests for DEA controlled substance registration applications. Once the A.P.N. has obtained her/his N.J. CDS registration, she/he will have to provide the following to the DEA, in order to receive the DEA application:
- A copy of her/his current N.J. professional license/biennial registration;
- A copy of her/his N.J. CDS registration (or, at minimum, a signed CDS registration confirmation letter);

- Her/His Social Security number;
- Her/His date of birth;
- Her/His residence and business telephone numbers, including the area codes; and
- Her/His full name, including the middle name.
- DEA-Newark would like the above faxed to them, @ fax number 973-776-7055.

DEA in New Jersey

- **DEA**
80 Mulberry St. , 2nd Fl.
Newark, NJ 07102
- If the A.P.N. needs to telephone the DEA regarding DEA registration application, she/he may telephone Donna Deans at 973-776-1156(54). The website for DEA is: www.deadiversion.usdoj.gov
- If you have any comments or questions, our
- e-mail address is: askconsumeraffairs@lps.state.nj.us

For NEW APPLICANTS ONLY and not for renewal of registration.

Form DEA-224 (New Applicants Only)

The application fee is \$551 and is not refundable.

http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

National Provider Identifier (NPI)

- **National Provider**

- The Administrative Simplification provisions of the *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* mandated the adoption of a standard unique identifier for health care providers. The National Plan and Provider Enumeration System (NPPES) collects identifying information on health care providers and assigns each a unique **National Provider Identifier (NPI)**.

- <https://nppes.cms.hhs.gov/NPPES/StaticForward.do?forward=static.npstart>

- **HCFA Changes**

- Changes in the HCFA 1500 form to accommodate the NPI number take place January 1, 2007. It was optional to use an NPI number on the HCFA form until March 30, 2007. It became mandatory April 2, 2007. The new HCFA form will have new fields for identifier numbers on lines 17b, 32a and 33a.

Guidelines for the Use of Controlled Substances by APNs



- **Evaluation of the Patient**

A complete history and physical examination must be obtained. The record should include:

- A complete description of the pain-use a pain scale
- Etiology of the pain if known
 - If the etiology of the pain is not known, what is the plan to determine what is causing the pain
- What is being done about the pain and what has been done in the past
- History of treatment for coexisting or underlying conditions
- What effect the pain is having on physical and psychological functioning including ADLs
- Is there any known history of substance abuse including alcohol

Plan

- State measurable objectives such as
 - Patient report of pain will be alleviated to 4 or below on a scale of 0/10.
 - Specific expectations
 - Plan for further diagnostic evaluation if necessary
 - Use of other treatment modalities such as a rehabilitation program or music therapy
 - Plan to evaluate effectiveness of pain management program prescribed

Informed Consent and Agreement for Treatment

- Discuss the risks and benefits
- If there are concerns about addiction this could include requiring the patient to sign an agreement, requiring periodic urine/serum testing, requiring that all Rx's be filled in the same pharmacy and counting the number of refills and clear guidelines about the reasons drug therapy might be discontinued



Periodic Review

- The schedule for this review will depend upon the etiology of the patient's pain
- Modification of the treatment can include increasing the dose or changing the drug to be used, adding additional medications, and including alternative treatment modalities.
- This review should include a monitor of patient compliance with medication usage and other treatment plans
 - Side effects (expected and unexpected) should be evaluated and treated if necessary to improve patient compliance

Consultation

- Patients may need a referral to another provider for
 - Further evaluation of presenting complaint
 - Evaluation of underlying conditions
- Patients with underlying psychiatric conditions careful monitoring and may require a referral



Patient Record

- The NP should maintain an accurate, complete, and current record of the following:
 - History and physical examinations
 - Diagnostic testing with results
 - Consultations
 - Treatment plan
 - Discussion of risks and benefits of treatment plan with patient consent
 - Treatments including medications date, type, dosage, and quantity
 - Patient and family education
 - Periodic review of plan

How much can you order?

- Schedule II – You may order a 120 dose unit up to a 30 day supply with NO refills.
- Exceeding this depends upon:
 - A treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness.
 - The plans has stated objectives.

- A prescription for an implantable infusion pump may provide up to a 90-day supply as long as the NP evaluates and documents the patient's continued need at least every 30 days.
- When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:
 - Review plan q 3 months
 - Shall remain alert to problems associated with physical and psychological dependence



- Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

Schedule III, IV, and V

- Order only 30 day supply of drug
- Can be refilled
- Must use within 6 months
- Some Schedule V drugs are OTC



Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions

- Unless registered with the New Jersey Department of Health and Senior Services to **conduct a narcotic treatment program pursuant to N.J.S.A. 24:21- 10 and N.J.A.C. 8:65-11.2**, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

Exceptions

- To relieve acute withdrawal symptoms, provided that:
 - Such treatment shall not exceed 72 hours;
 - No more than one day's supply of the drug is provided to the patient at a time; and
 - Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or
- As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility

Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines

- A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

Prohibitions and special limitations on prescribing, administering or dispensing anabolic steroids

- **Unless an accepted medical necessity exists, a practitioner shall not prescribe, order, dispense, administer, sell or transfer any anabolic steroid or human growth hormone, for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight.**



Facsimile and electronically transmitted prescriptions

- May be done for Controlled Substances by physicians as per 13:35-7.4 however we need to wait and see the Rules put forth for the APN by the Board of Nursing
- Electronically transmitted prescriptions are also permitted under the Board of Medical Examiners act.



