A Review of Federal & Illinois State Law:
As of February 26th, 2010

The speaker has no conflict of interest to disclose.

Learning Objectives

• Participants should be able to
  • discuss and contrast Federal & State CSA.
  • discuss the intent of recent changes in Schedule II prescription requirements.
  • discuss a pharmacist’s responsibility in processing prescriptions from mid-level practitioners.
  • discuss the steps hospital and health-system pharmacists must take to treat patients with addictions who are presenting themselves for other medical conditions or initial withdrawal treatment.
  • discuss the value and importance of the Illinois Prescription Monitoring Program (PMP).

Definitions

Federal

| Administer: | The direct application of a controlled substance to the body of a subject by 1) a practitioner or (in his presence) by his authorized agent, or 2) the subject at the direction and in the presence of the practitioner, whether such application is injection, inhalation, ingestion, or any other means. |
| Dispense: | To deliver a CS to an ultimate user, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a CS and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. |
| Practitioner: | An individual practitioner, other than a pharmacist physician assistant, licensed practical nurse, registered nurse, hospital laborator or pharmacist, a pharmacy, or an institutional practitioner. |

State

| Administer: | The direct application of a controlled substance to the body of a subject by 1) a practitioner or (in his presence) by his authorized agent, or 2) the patient or research subject at the lawful direction of the practitioner, or 3) a euthanasia technician as defined by the Humane Exhausnasia in Animal Shelters Act. |
| Dispenser: | Individual practitioner, institutional practitioner, pharmacy or, Pharmacist who dispenses a CS. |
| Dispenser: | A practitioner who dispenses. |

Federal

| Individual Practitioner: | A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. |
| Long Term Care Facility: | A nursing home, retirement care, mental care, or other facility or institution which provides extended health care to clients. |

State

| Practitioner: | A physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacist physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, hospital laborator or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the US or this State to distribute, dispense, or use in teaching a CS in the course of practice. |

Definitions

Federal

| Mid-level Practitioner: | An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist who is licensed, registered or otherwise permitted by the US or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. |
| Prescriber: | A physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist or veterinarian who issues a prescription, a physician assistant who issues a prescription for a controlled substance in accordance with Section 38.85, a written delegation, and a written supervisory agreement required under Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice nurse with prescriptive authority delegated under Section 65-40 of the Nursing Practice Act and in accordance with Section 80.08 a written delegation, and a written collaborative agreement under Section 65-30 of the Nursing Practice Act. |

State

| State (Practice Act and in accordance with Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice nurse) | A physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist or veterinarian who issues a prescription, a physician assistant who issues a prescription for a controlled substance in accordance with Section 38.85, a written delegation, and a written supervisory agreement required under Section 7.5 of the Physician Assistant Practice Act of 1987, or an advanced practice nurse with prescriptive authority delegated under Section 65-40 of the Nursing Practice Act and in accordance with Section 80.08 a written delegation, and a written collaborative agreement under Section 65-30 of the Nursing Practice Act. |
### Definitions

**Federal**
- **Pharmacist:** Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

**State**
- **Prescription:** A legal written, facsimile, or verbal order of a physician licensed to practice medicine in all its branches, dentist, podiatrist or veterinarian for any controlled substances, of an optometrist for a Schedule III, IV, or V controlled substance in accordance with Section 313 of the Illinois Opioid Prescriptions Practice Act of 1987, of a physician assistant for a controlled substance in accordance with Section 303.5, a written delegation, and a written supervisory agreement required under Section 7 of the Physician Assistant Practice Act of 1987, or of an advanced practice nurse with prescriptive authority delegated under Section 65-40 of the Nursing Practice Act who issues a prescription for a controlled substance in accordance with Section 303.5, a written delegation, and a written collaborative agreement made under Section 65-55 of the Nursing Practice Act.

### Valid Prescription requirements

**Federal**
- A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription: is not an order for medication dispensed for immediate administration to an ultimate user. (Example: orders to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

**State**
- A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription: is not an order for medication dispensed for immediate administration to an ultimate user. (Example: orders to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

- Must include: the patient’s full name and address, the quantity prescribed, the strength, the dosage form, directions for use, and any other information required by state law.
- Must also include: the pharmacist’s full name and address, and the DEA registration number of the pharmacist.
- Valid for a controlled substance as ordered in accordance with Section 303.5, a written delegation, and a written supervisory agreement made under Section 65-55 of the Nursing Practice Act.

### Who May Issue a Controlled Substance Prescription?

**Federal**
- Mid-level practitioners (MLPs)
- Are registered and authorized to dispense, administer and prescribe in the course of professional practice by the DEA and the state in which they practice.
- May receive a state issued DEA registration granting controlled substances privileges.
- Registration is contingent upon authority granted by the licensing state.
- Are registered by the DEA in those states clearly authorizing MLPs to prescribe, dispense and administer controlled substances in one or more schedules.
- A MLP issued a valid DEA registration number (beginning with the letter M) constitutes evidence that he/she is authorized to prescribe, dispense and/or administer one or more controlled substances.

**State**
- Per IL statue 720 ILCS 570/385.45 the Dept. of Financial and Professional Regulation shall license mid-level practitioners (physician assistants and advanced practice nurses) and anesthesia agencies to prescribe and dispense controlled substances under Section 303.
- A physician assistant or advanced practice nurse may receive delegated authority to prescribe Schedule II drugs.

### Who May Issue a Controlled Substance Prescriptions?

**Federal**
- Although the MLP has a DEA number, it is incumbent upon the pharmacist filling a prescription to ensure that the MLP issues a prescription within the parameters established by the state in which he/she practices.
- MLP authority to prescribe controlled substances varies by state.

**State**
- Do you know the MLP criteria for Illinois ?????????

### Who May Issue a Controlled Substance Prescription?

**Federal**
- A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, midlevel or other registered practitioner
  - Authorized by the jurisdiction in which the practitioner is licensed to practice.
  - Registered with DEA.
  - Exempted from registration. (Example: Public Health Service Federal Bureau of Prisons, or Military.)
  - An agent or employee of a hospital or other institution acting in the usual course of business or employment under the registration of the hospital or other institution which is registered.

**State**
- A prescription for a controlled substance may only be issued by:
  - A physician licensed to practice medicine in all its branches.
  - A dentist.
  - A podiatrist.
  - A veterinarian for any controlled substances, of an author for a Schedule III, IV or V controlled substance in accordance with Section 313 of the Illinois Opioid Prescriptions Practice Act of 1987.
  - A physician assistant (PA) in accordance with Section 303.5, a written delegation and supervision agreement required under Section 7 of the Physician Assistant Practice Act of 1987, or of an advanced practice nurse (APN), in accordance with Section 65-35 and 65-40 of the Nursing Practice Act 1998 and as amended in 2007.

### Who May Issue Controlled Substance Prescriptions?

**Federal**
- CSA requires separate registration for each practice site where CS are:
  1. Manufactured
  2. Distributed
  3. Dispensed

**State**
- A physician assistant and an advanced practice nurse are prohibited from prescribing medications and controlled substances not set forth in the required written delegation of authority.
### CII Dispensing

#### Federal

- Federal law
  - There are exceptions, but general rule is that all prescriptions for Schedule II controlled substances must be written, signed, and dated on the date written by the prescriber.
  - There is no time limit when a Schedule II prescription must be filled after being signed by the prescriber.
  - The pharmacist must determine that the prescription is still needed by the patient (e.g., a narcotic prescription filled several weeks after being written).

- DEA
  - In an emergency, a practitioner may call-in a prescription for a Schedule II controlled substance by telephone to the pharmacy.
  - The pharmacist may dispense the prescription provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
  - The prescribing practitioner must provide a written and signed prescription to the pharmacist within seven (7) days.
  - The pharmacist must notify DEA if the prescription is not received within the 7 days. [42 CFR Sec. 1306.11 (d) (4)]

### CII Dispensing

#### State

- Pharmacies and prescribers that dispense Schedule II must participate in the state’s prescription monitoring program by forwarding certain information within 7 days of dispensing.
- Exception: The medication is consumed on site.

### CII Dispensing

#### Federal

- Federal Regulations do not place a quantity limit on any prescriptions.
- DEA allows issuance of multiple prescriptions for Schedule II controlled substances as of September 21, 2007. [50 CFR Sec. 508.11]

### CII Dispensing

#### State

- Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

### CII Dispensing

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- The practitioner or the practitioner’s agent may transmit a Schedule II prescription to the pharmacy by facsimile. The practitioner’s agent may also transmit a prescription by facsimile to the dispensing pharmacy.

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#### Federal

- The facsimile of a Schedule II prescription may serve as the original prescription as follows:
  1. A practitioner prescribing Schedule II narcotic controlled substances to be compounded for the direct administration to a patient by a pharmacist, intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription as the original prescription and the prescription verification is required. All requirements of this paragraph must be followed.
  2. A practitioner prescribing Schedule II narcotic controlled substances to be compounded for the direct administration to a patient by a pharmacist, parenteral, intravenous, intramuscular, subcutaneous, or intrapleural infusion to a patient in a private residence, long-term care facility, or hospice program may transmit a prescription for a Schedule II controlled substance if otherwise than on a written prescription. | - The pharmacist must determine if the prescription is still needed by the patient (e.g., a narcotic prescription filled several weeks after being written). |

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A practitioner may prescribe methadone or any other narcotic to a dependent individual for either addiction. (The practitioner makes arrangements to refer the individual to a narcotic treatment program. The treatment cannot last more than three months and may not be renewed or extended.)

A hospital that has no narcotic treatment program on the premises may administer narcotics to a drug dependent individual for either detoxification or maintenance purposes, if the individual is being treated for a medical condition other than narcotic addiction.
Guide to Prescription Fraud continued

Prevention Techniques

- Know the prescriber and his/her signature & prescription trends.
- Know the prescriber’s DEA registration number.
- Know the patient.
- Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?
- If there is a question about any aspect of the prescription, call the pharmacist for verification.
- If you believe you have a forged, altered, or bogus prescription, don’t fill it.

- Where there appears to be a pattern of prescription abuses, the pharmacist’s refusing to dispense may not be enough. Abusers will simply go elsewhere, possible to another pharmacist with whom the prescriber has an understanding. In such cases, the pharmacist should contact the State Board of Pharmacy, Professional Regulations, or the local DEA Diversion Field Office.

IL Controlled Substance Act: 570/102

- Paragraph (u): “Good Faith” Practice Standards for Dispensing – (continued)
  - The pharmacist shall be guided by accepted professional standards including but not limited to the following in making the judgment:
    - Lack of consistency of doctor-patient relationship,
    - Frequency of prescriptions for same drug by one prescriber for large numbers of patients,
    - Quantities beyond those normally prescribed,
    - Unusual dosages,
    - Unusual geographic distances between patient, pharmacist and prescriber,
    - Consistent prescribing of habit-forming drugs.

Controlled Substance Monitoring

Intent

- To advocate the legitimate and appropriate use of “controlled” prescription drugs,
- To not interfere with legitimate physician prescribing practices.

IL Controlled Substance Act: (ILCS 570/102)

- Paragraph (u): “Good Faith” Definition
  - “Good faith” means the prescribing or dispensing of a controlled substance by a practitioner in the regular course of professional treatment to or for any person who is under his treatment for a pathology or condition other than that individual’s physical or psychological dependence upon or addiction to a controlled substance, except as provided herein; and application of the term to a pharmacist shall mean the dispensing of a controlled substance pursuant to the prescriber’s order which in the professional judgment of the pharmacist is lawful.

National All Schedules Prescription Electronic Reporting Act (U.S. P.L. 109-60) (NASPER)

- Purpose
  - “…foster establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions…”

Treatment Center Listing from SAMHSA

- Providers can find a treatment center.
Dispensed Schedule II Medications
**Prescriptions increased 111.83% in 10 years.**

<table>
<thead>
<tr>
<th>Calendar Month Records Received</th>
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<th>2001</th>
<th>2002</th>
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Medical Users - Internet Access

Dispensed Schedule III, IV & V Medications
**Reporting began January 1, 2008**

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Prescription Information Library (PIL)

**Secure, HIPAA compliant, Internet based, Health Care Provider Access only**

- PIL user applications will be approved or denied by the PMP administrator.
- Upon approval a secure User ID will be assigned to the requestor.
- PIL user can query the library via the internet.
- All inquiries will be logged and audited for security purposes only.
Questions: Controlled Substance Lecture

1. Which of the following is true for a Prescriber of Controlled Substances in Illinois with multiple locations?
   a. Separate registration required for each practice location.
   b. Separate registration required for each practice site storing, administering, or dispensing controlled substances.
   c. Separate registration required for each practice site with mid-level practitioners.
   d. None of the above.

Controlled Substance Lecture Questions Continued

2. Which of the following would not be indicative of inappropriate prescribing?
   a. No physical examination performed.
   b. Prescriptions issued in exchange for sexual favors.
   c. Logical relationship between the medication prescribed and medical condition being treated.
   d. Warnings to patient to fill prescriptions at different pharmacies.

Controlled Substance Lecture Questions Continued

3. Mid-level practitioner prescribing of Schedule II CS is limited to all except the following:
   a. Under a physician’s written delegation of authority.
   b. For 5 Schedule II substances via all routes.
   c. Mid-level practitioner must discuss clinical outcomes monthly with supervising physician.
   d. All Mid-level Schedule II prescriptions must be limited to no more than 30 days oral dosage.
Controlled Substance Lecture Questions
Continued

4. The Federal Controlled Substances Act limits the time between CS Schedule II prescriptions issuance and filling to:
   a. 7 Days
   b. 14 Days
   c. 90 Days
   d. None of the above.

Controlled Substance Lecture Questions
Continued

5. Which of the following is allowed for the use of Methadone outside of a Narcotic Treatment Program:
   a. A practitioner may prescribe methadone or other narcotic for analgesic purposes.
   b. A practitioner who is not part of a NTP may administer narcotic substances to an addicted individual to relieve that individual's acute withdrawal while being referred to a treatment program.
   c. A hospital that has no NTP on premises may administer narcotics to a drug dependent individual for either detoxification or maintenance purposes if pt. treated for medical condition.
   d. All of the above