Controlled Substances: Law and Practice

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Disclosures | Conflict of Interest

- Dr. Yildiz and Mr. Reynolds declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

- Dr. Bogdan is the owner of Law Offices of Joseph J. Bogdan. Dr. Bogdan declares additional no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

Pharmacist Objectives

- Discuss new controlled substances laws and regulations on both the Federal and Illinois levels.
- Discuss existing controlled substances laws and regulations to ensure proper implementation and compliance.
- Review scenarios concerning controlled substances law and regulation regarding pharmacy practice and delivery of patient care.
- Review scenarios concerning controlled substances and when a pharmacist should seek legal advice.

Technician Objectives

- Discuss new controlled substances laws and regulations on both the Federal and Illinois levels.
- Discuss existing controlled substances laws and regulations to ensure proper implementation and compliance.
- Review scenarios concerning controlled substances law and regulation regarding pharmacy practice and delivery of patient care.
- Review scenarios concerning controlled substances and when a pharmacist should seek legal advice.

Pre-Test Question 1

Which of the following best describes the pharmacist's responsibility when reviewing new controlled substance laws and regulations?

A) Only review federal law changes, as state laws are always consistent.

B) Implement and comply with both federal and state law updates.

C) Rely on prescribers to stay updated on controlled substance regulations.

D) Follow only the pharmacy's internal policies without verifying external requirements.

Pre-Test Question 2

A pharmacist receives a prescription for a controlled substance that does not meet legal documentation requirements. What should the pharmacist do first?

A) Contact the prescriber for clarification or necessary corrections.

B) Dispense the medication as long as the patient provides verbal verification.

C) Modify the prescription details without prescriber authorization. \

D) Refuse to fill the prescription and report the prescriber immediately.

Pre-Test Question 3

When reviewing a patient's history in the Illinois Prescription Monitoring Program (PMP), what is the pharmacist's primary obligation?

A) Verify past controlled substance prescriptions for potential misuse or doctor shopping.

B) Only check PMP records when required by the patient's insurance provider.

C) Document PMP reviews only for patients with a prior history of opioid use.

D) Rely solely on the prescriber's judgment regarding controlled substance appropriateness.

Pre-Test Question 4

Which of the following situations would require a pharmacist to seek legal counsel regarding controlled substances?

A) A prescriber consistently issues high doses of opioids without documentation.

B) A patient requests an early refill due to an upcoming vacation.

C) A pharmacy technician miscounts inventory but corrects the error immediately.

D) A patient complains about side effects from a prescribed controlled substance.

Legal Updates: Federal

Halt All Lethal Trafficking of Fentanyl Act

- HALT Fentanyl Act
  - Introduced 01/03/2025 | Representative Morgan Griffith (VA-9, R)
- Reschedule fentanyl-related substances permanently to Schedule I.
  - Exception for existing Schedule II, Fentanyl derivatives.
- Increases penalties for possession of fentanyl (illicit).
- Research permitting still available for Schedule I/II.

- Status: Passed the House 312-108 (02/06) | Senate: Judiciary (02/10)

Reference: https://www.congress.gov/bill/119th-congress/house-bill/27

Cannabis Rescheduling

- Proposed Change:
  - Moving cannabis from Schedule I to Schedule III.
  - HHS: recommendation in August 2023
  - DEA: formal hearings began in December 2024
- Pharmacy Implications:
  - Increased research opportunities.
  - Changes in prescription and dispensing guidelines.
  - Impact on DEA licensing requirements for handling cannabis-based medications.

Reference: https://www.dea.gov/stories/2024/2024-11/2024-11-26/dea-hold-hearing-rescheduling-marijuana

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21 July 2024

The Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive, Springfield, Virginia 22152

Re: Docket No. DEA-1362 (DEA-2024-0059-0001)– electronically submitted

To Whom It May Concern:

On behalf of the Illinois Pharmacists Association (IPhA) Board of Directors and our members, we are proudly submitted our comments in support of the rescheduling of cannabis from Schedule I. IPhA supports completely removing cannabis from the Controlled Substances Act schedules but concedes that the proposed rescheduling to Schedule III is significant and much need progress forward.

The following is our policy stance on cannabis medication and recreational use:

> ***Medical and Recreational Cannabis – 2011, 2018***
>
> IPhA supports that pharmacies be the only mechanism for medical and recreational cannabis to be distributed safely to the public utilizing the same legislative manner used currently to store, record, and distribute controlled substances.
>
> IPhA supports pharmacist direct involvement in furnishing cannabis and its various components for medical and recreational use.
>
> IPhA supports the development and promotion of healthcare provider education related to the clinical efficacy, safety, and management of patients using cannabis and its various components.
>
> IPhA supports that pharmacists should provide cannabis-related pharmacist-delivered patient care services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process.
>
> IPhA supports legislative and regulatory changes to further facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components.

According to the Agency for Healthcare Research and Quality (AHRQ), each year 700,000 people are taken to the emergency room for adverse drug events and among those 100,000 end up being hospitalized.[1] The Food and Drug Administration (FDA) states that about 7,000 people die to an adverse drug event each year.[2] Pharmacists are healthcare providers that receive specialty training in the science and management of medications. Pharmacists provide medications, educate patients, and

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ensure their proper usage. In addition, pharmacists are expertly positioned to review a patient's medication regimen and examine for possible interactions with other medicinal agents such as vitamins, dietary supplements, and herbal supplements including cannabis. As part of a patient-centered approach, a pharmacist makes medication recommendations and advises a patient's healthcare team to ensure optimal health and medication outcomes.[3]

According to Americans for Safe Access, over 5.1 million patients are using medical cannabis in 48 states, the District of Columbia, and territories.[4] Many of these patients are utilizing additional medications. Most patients are taking at least five medications for their health conditions.[1] Cannabis, like other herbal supplements, have drug-drug interaction and adverse effect profiles. Cannabis primary pharmaceutical components are cannabidiol (CBD) and tetrahydrocannabinol (THC) and their derivatives. Cannabis is metabolized in the liver by cytochrome P450. There are various enzymes of the cytochrome system that metabolize CBD and THC specifically including cytochrome 3A4, 2C9, and 2C19 (CBD only).[5] Many common medications are also metabolized by these enzymes. When medications interact through this pathway, a medication effect may be increased or decreased. This can cause a medication to be less effect or increase to toxic levels. Pharmacists can properly engage to reduce adverse drug events and interactions, so patients can confidently utilize cannabis along with other medications.

If cannabis is rescheduled to Schedule III, pharmacists are best positioned to assist in medication management and especially in the expanding sphere of cannabis as a healthcare treatment option and in improved clinical research. Pharmacists can educate on the safe and effective usage and with decreasing stigma among patients, the community, and healthcare providers.

IPhA recognizes there will remain Federal and State laws and regulations that may continue to cause barriers for patients to fully concern or utilize cannabis as a healthcare treatment option, but the proposed steps enable pharmacists to be more engaged in the process to ensure patient safety.

Any questions please contact me at greynolds@ipha.org or 217-522-7300. Thank you for opportunity to provide comment.

Sincerely,

Garth K. Reynolds, BSPharm, RPh, MBA, FAPhA
Executive Director

Sources:
1) https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events
2) https://www.fda.gov/drugs/drug-interactions-labeling/preventable-adverse-drug-reactions-focus-drug-interactions
3) https://jcpp.net/patient-care-process/
4) https://www.safeaccessnow.org/sos
5) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7055953/pdf/192e206.pdf

Electronic Transfer of CII-V Prescriptions for Initial Fill

- Change: The DEA now allows electronic transfer of Schedule II-V prescriptions between pharmacies for the first fill.
- Pharmacist Considerations:
  - Verification of transfer legitimacy.
  - Documentation and audit trail maintenance.
  - Coordination with state-specific e-prescribing laws.
- Not yet ready for primetime:
  - NCPDP/Surescript in development of security/data protocols.
- Illinois Pharmacy Practice Act Rules amended to meet new requirements:
  - 68 IAC 1330.720 b): "A prescription for Schedule II, III, IV and V drugs may be transferred only from the original pharmacy and only one time for the purpose of original fill."

Reference: https://www.deadiversion.usdoj.gov/ecomm/ecomm.html

MATE Act: X-Waiver & MAT Training

- Medication Access and Training Expansion (MATE) Act passed Dec 2022.
- Key Change:
  - X-waiver requirement for prescribing buprenorphine has been eliminated. (April 2023) | "X" DEA Number
- New Training Requirement:
  - All DEA-registered prescribers must complete 8 hours of training on medication-assisted treatment (MAT) for opioid use disorder.
- Pharmacist's Role:
  - Understanding expanded access to MAT.
  - Buprenorphine prescriptions with just prescriber's DEA number.

Reference: https://www.samhsa.gov/substance-use/treatment/statutes-regulations-guidelines/mate-act

Expiration of COVID-19 Telemedicine Exemptions

- New Telemedicine Policy:
  - Pre-COVID rules: Controlled substances require an in-person visit before prescribing. (*Ryan Haight Act*)
  - Temporary Waivers: Allowed prescribing without an in-person evaluation.
  - Upcoming Change: Waivers set to expire unless a new federal rule is enacted.
- Pharmacy Considerations:
  - How to verify legitimate telemedicine prescriptions.
  - Increased rejection of non-compliant prescriptions.
  - Potential need for pharmacist-prescriber collaboration.
- Temporary Rules extended until 12/31/2025.

Reference: https://www.dea.gov/press-releases/2025/01/16/dea-announces-three-new-telemedicine-rules-continue-open-access

Medicare Part D Electronic Prescribing Mandate

- New Requirement:
  - All prescriptions for Medicare Part D patients must be electronically prescribed.
- Pharmacy Impact:
  - Mandatory compliance with e-prescribing laws.
  - Integration of eRx platforms.
  - Handling exceptions for paper prescriptions.
- CMS requirement begins 01/01/2028.

Reference: https://www.cms.gov/medicare/regulations-guidance/electronic-prescribing/adopted-standard-and-transactions

Legal Updates: Illinois

E-Prescribing Requirements for Controlled Substances

- Illinois mandates that all Schedule II-V prescriptions be electronically prescribed unless exempted.
- Pharmacist Considerations:
  - Handling exceptions (e.g., system outages, rural access issues).
  - Compliance with documentation and audit requirements.

Reference: https://www.cms.gov/medicare/regulations-guidance/electronic-prescribing/adopted-standard-and-transactions

E-Prescriptions | Public Acts 102-0490 / 102-1109

- Representative Dagmara Avelar
- Effective 01/01/2023
- Require all controlled substances prescription to be submitted via electronic prescription (e-Rx)
- All Schedules
- Effective 01/01/2023…

Reference: https://ilga.gov/legislation/publicacts/102/PDF/102-1109.pdf

E-Prescriptions | Public Acts 102-0490 / 102-1109

- During 2022 Veto Session, IPhA worked with ISDS and ISMS to delay implementation until 01/01/2024.
- Also work on additional legislation to determine exemptions to the e-Rx mandate.
- More to come later…

Reference: https://www.cms.gov/medicare/regulations-guidance/electronic-prescribing/adopted-standard-and-transactions

HB2077 | E-Prescriptions

- Representative Dave Vella / Senator Steve McClure
- Effective 01/01/2024 – PA 103-0425
- Exemptions
  - 150 prescriptions through 2028, then 50 prescriptions in 2029.
  - Hardship waiver for prescriber
  - Temporary technology or electrical failure
  - Prescriber determines it would be impractical to obtain prescription via electronic means
  - Prescription for a patient in: LTC, Hospice/Palliative Care, Outpatient renal dialysis, VA, incarcerated, under a research protocol, dispensed under a standing order or public health emergency
  - Prescriber and dispenser are the same entity
  - Prescription is for a compound

Reference: https://ilga.gov/legislation/billstatus.asp?DocNum=2077&GAID=17&GA=103&DocTypeID=HB&LegID=145480&SessionID=112

HB2077 | E-Prescriptions

- A pharmacist is not required to ensure or responsible for ensuring the prescriber's compliance.
- …nor may any other entity or organization require a pharmacist to ensure the prescriber's compliance.
- It shall be a violation of this Section for any prescriber or dispenser to adopt a policy contrary to this Section.

Reference: https://ilga.gov/legislation/billstatus.asp?DocNum=2077&GAID=17&GA=103&DocTypeID=HB&LegID=145480&SessionID=112

HB4874 | Control Sub-Opioids-Compliance

- Representative Dagmara Avelar | Senator Suzy Glowiak-Hilton

➢ Amends the Illinois Control Substances Act [*720 ILCS 570/311.6 (b-5)*].

➢ Adds language to the new e-Rx provisions that went into effective 1/1/24.

➢ (e) Any pharmacist who dispenses in good faith based upon a valid prescription that is not prescribed electronically may be exempt from any disciplinary action. A pharmacist is not required to ensure or responsible for ensuring the prescriber's compliance under subsection (b), nor may any other entity or organization require a pharmacist to ensure the prescriber's compliance with that subsection. A pharmacist may not refuse to fill a valid prescription solely because it is not prescribed electronically.

➢ (g) A compliance action with respect to this Section initiated by the Department of Financial and Professional Regulation prior to December 31, 2030 is limited to a non-disciplinary warning letter or citation, unless the prescriber or dispenser fails to abide by the initial non-disciplinary warning letter or citation, has acted in bad faith, or a pattern of practice in violation of this Section occurs.

➢ STATUS: Public Act 103-0732 | Effective Date: 08/02/2024

Reference: https://www.cms.gov/medicare/regulations-guidance/electronic-prescribing/adopted-standard-and-transactions

Electronic Prescriptions for Controlled Substances

Public Act 103-0425 signed on August 4, 2023 and effective January 1, 2024 amends Section 311.6 of the Illinois Controlled Substances Act. The new language provides guidelines for when an electronic prescription is required for controlled substances and exemptions.

A prescription for a substance classified in Schedule II, III, IV, or V must be sent electronically.

From January 1, 2024 until December 31, 2028, a prescriber shall not be required to issue prescriptions electronically if they certify to the Department of Financial and Professional Regulation (DFPR) that they will not issue more than 150 prescriptions during a 12-month period. Prescriptions in both oral and written form included in determining whether the limit of 150 prescriptions was reached.

Beginning January 1, 2029, a prescriber shall not be required to issue prescriptions electronically if they certify to DFPR that they will not issue more than 50 prescriptions during a 12-month period. Both oral and written prescriptions included in determining whether the limit of 50 prescriptions was reached.

Here is a link to IDFPR's FAQ on the hardship waiver.

A prescriber shall not be required to issue prescriptions electronically under the following circumstances:

- prior to January 1, 2026, the prescriber demonstrates financial difficulties in buying or managing an electronic prescription option;
- on and after January 1, 2026, the prescriber provides proof of a waiver from CMS for the Electronic Prescribing for Controlled Substances Program due to demonstrated economic hardship for the previous compliance year;
- there is a temporary technological or electrical failure that prevents an electronic prescription from being issued;
- the prescription is for a drug that the practitioner reasonably determines would be impractical for the patient to obtain in a timely manner if prescribed by an electronic data transmission prescription and the delay would adversely impact the patient's medical condition;
- the prescription is for an individual who:
  - resides in a nursing or assisted living facility;
  - is receiving hospice or palliative care;
  - is receiving care at an outpatient renal dialysis facility and the prescription is related to the care provided;
  - is receiving care through the United States Department of Veterans Affairs; or
  - is incarcerated in a state, detained, or confined in a correctional facility;
- the prescription prescribes a drug under a research protocol;
- the prescription is a non-patient specific prescription dispensed under a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, or in response to a public health emergency or other circumstance in which the practitioner may issue a non-patient specific prescription;
- the prescription is issued when the prescriber and dispenser are the same entity;
- the prescription is issued for a compound prescription containing 2 or more compounds; or
- the prescription is issued by a licensed veterinarian within 2 years after January 1, 2024.

DFPR may adopt rules for the administration of Section 311.6 to the requirements under this Section that DFPR may deem appropriate.

Any prescriber who makes a good faith effort to prescribe electronically, but for reasons not within the prescriber's control is unable to prescribe electronically, may be exempt from any disciplinary action.

Any pharmacist who dispenses in good faith based upon a valid prescription that is not prescribed electronically may be exempt from any disciplinary action. A pharmacist is not required to ensure or responsible for ensuring the prescriber's compliance, nor may any other entity or organization require a pharmacist to ensure the prescriber's compliance with that subsection.

It shall be a violation of this Section for any prescriber or dispenser to adopt a policy contrary to Section 311.6.

Language has been edited to make for easier reading. Intent and context were not altered.

Prescription Monitoring Program (PMP) & NABP Interconnect

- PMP Review for Controlled Substances
    - Best practice recommendations to check the PMP before dispensing opioids and other controlled substances.
    - The goal is to prevent doctor/pharmacy shopping, opioid misuse, and excessive prescribing.
- PMP Reporting & Data Submission Compliance
    - Pharmacies must submit dispensing data for all Schedule II-V controlled substances to the PMP within one business day.
    - Non-compliance with data submission rules can result in fines, audits, and potential DEA/ILBOP scrutiny.
- Use of NABP InterConnect for Multi-State Monitoring | PMPnow Dashboard
    - Illinois participates in the NABP InterConnect, allowing pharmacists to access prescription histories across state lines.
    - Pharmacists should integrate PMP checks into their workflow and document concerns to ensure compliance and patient safety.

Reference: https://www.ilpmp.org

Naloxone Standing Order & Opioid Counseling Requirements

- Naloxone Standing Order:
  - Pharmacists may dispense naloxone without a prescription to at-risk individuals.
- Opioid Counseling:
  - Mandatory opioid risk counseling for patients receiving first-time opioid prescriptions.
  - Pharmacists must document compliance with counseling requirements.

Illinois Opioid Overdose Reversal Agent
Standardized Procedure

This updated Opioid Overdose Reversal Agent Standardized Procedure (formerly limited to Naloxone only) outlines for health care and other trained personnel how entities, including schools, may become authorized to obtain, dispense, and administer naloxone or nalmefene for the purpose of reversing an opioid overdose This procedure also presents the educational requirements for obtaining the Illinois Opioid Overdose Reversal Agents Standing Order and the technique for administering these reversal agents.

Introduction

In September 2015, Illinois added Section 85/19.1 to the Illinois Pharmacy Practice Act, 225 ILCS 85/19.1, expanding access to the opioid antagonist, naloxone. Naloxone may be used to reverse opioid overdoses, including those caused by heroin, fentanyl, and certain prescription pain medications. This statute authorizes personnel trained to dispense and/or administer reversal agents as an opioid antagonist intervention, per the instructions below.

In May 2023, the FDA also approved nalmefene as an opioid reversal agent, similar in mechanism to naloxone, and is therefore included in this update.

In January 2024, this standing order was expanded to include Illinois schools as a naloxone entity due to the need to have emergency procedures in place should persons exhibit signs of opioid overdose while on school premises. See Illinois School Code, 105 ILCS 5/22-30(e-10), (f), (f-5) and (g).

Pursuant to the Substance Use Disorder Act, 20 ILCS 301/, the Pharmacy Practice Act, and the School Code, the Illinois Department of Financial and Professional Regulation (IDFPR) – in consultation with the Illinois Department of Public Health (IDPH) and Illinois Department of Human Services (IDHS) – has issued a standardized procedure for appropriately trained professionals to obtain, dispense, or administer naloxone and nalmefene to persons suspected of drug overdose.

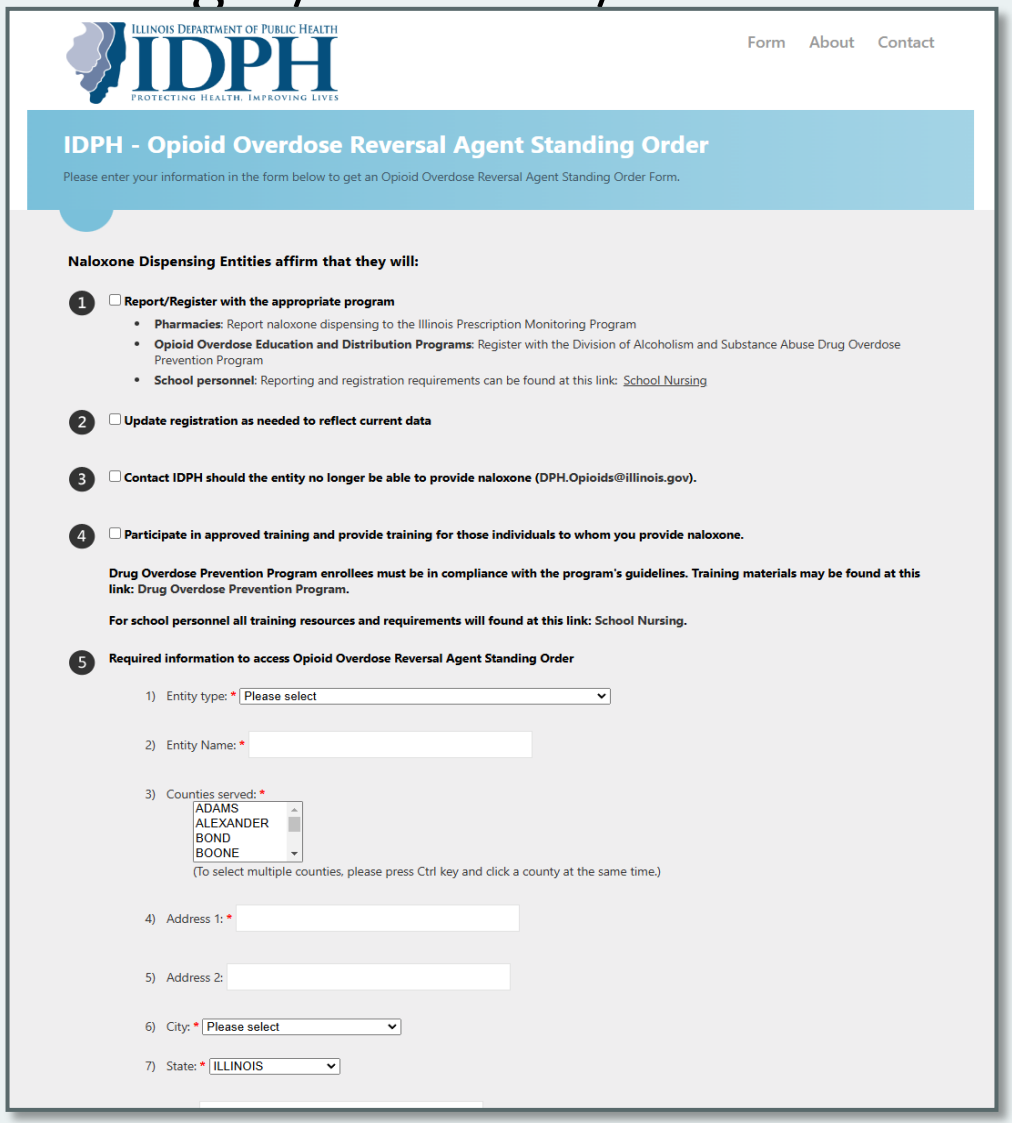
Naloxone Entity

Naloxone entities may dispense either naloxone or nalmefene, and include pharmacies, pharmacists, or opioid overdose education and naloxone distribution (OEND) programs, as discussed below:

- Participating pharmacies and pharmacists must be licensed under the Illinois Pharmacy Practice Act (225 ILCS 85) and have knowledge of the Illinois Naloxone Standardized Procedure. Pharmacies/pharmacists shall report naloxone and nalmefene dispensing to the Illinois Prescription Monitoring Program at https://www.ilpmp.org/.

Illinois Statewide Standing Order

https://idph.illinois.gov/Naloxone/



ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

Form About Contact

IDPH - Opioid Overdose Reversal Agent Standing Order

Please enter your information in the form below to get an Opioid Overdose Reversal Agent Standing Order Form.

Naloxone Dispensing Entities affirm that they will:

1. ☐ **Report/Register with the appropriate program**
   - **Pharmacies**: Report naloxone dispensing to the Illinois Prescription Monitoring Program
   - **Opioid Overdose Education and Distribution Programs**: Register with the Division of Alcoholism and Substance Abuse Drug Overdose Prevention Program
   - **School personnel**: Reporting and registration requirements can be found at this link: School Nursing
2. ☐ **Update registration as needed to reflect current data**
3. ☐ **Contact IDPH should the entity no longer be able to provide naloxone (DPH.Opioids@illinois.gov).**
4. ☐ **Participate in approved training and provide training for those individuals to whom you provide naloxone.**

Drug Overdose Prevention Program enrollees must be in compliance with the program's guidelines. Training materials may be found at this link: Drug Overdose Prevention Program.

For school personnel all training resources and requirements will found at this link: School Nursing.

5. **Required information to access Opioid Overdose Reversal Agent Standing Order**

1) Entity type: * Please select
2) Entity Name: *
3) Counties served: *
   ADAMS
   ALEXANDER
   BOND
   BOONE
   (To select multiple counties, please press Ctrl key and click a county at the same time.)
4) Address 1: *
5) Address 2:
6) City: * Please select
7) State: * ILLINOIS

SCAN ME

Illinois Law - Naloxone

- Pharmacy Practice Act – 225 ILCS 85/19.1
  - Sec. 19.1. Dispensing opioid antagonists.
  - (a) Due to the recent rise in opioid-related deaths in Illinois and the existence of an opioid antagonist that can reverse the deadly effects of overdose, the General Assembly finds that in order to avoid further loss where possible, it is responsible to allow greater access of such an antagonist to those populations at risk of overdose.
  - (b) Notwithstanding any general or special law to the contrary, a licensed pharmacist shall dispense an opioid antagonist in accordance with written, standardized procedures or protocols developed by the Department with the Department of Public Health and the Department of Human Services and filed at the pharmacy before implementation and are available to the Department upon request.
  - (c) Before dispensing an opioid a pharmacist shall inform patients that opioids are addictive and offer to dispense an opioid antagonist.
  - (d) For the purpose of this Section, "opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting and equally safe drug approved by the U.S. Food and Drug Administration for the treatment of drug overdose.

Reference: https://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapterID=24

Written & Numeric Quantity Changes for C-II Prescriptions

- 720 ILCS 570/309 | 01/01/2024 amended
  - "All prescriptions issued for Schedule II controlled substances shall include the quantity prescribed."
  - "All nonelectronic prescriptions issued for Schedule II controlled substances shall include both a written and numerical notation of quantity on the face of the prescription."

Reference: https://ilga.gov/legislation/ilcs/ilcs4.asp?DocName=072005700HArt%2E+III&ActID=1941&ChapterID=53&SeqStart=2700000&SeqEnd=5400000

Common Violations

Federal Violations (DEA, CSA, and CFR Violations)

1. **Failure to Maintain Accurate Inventory** – Not properly recording Schedule II-V controlled substances inventory as required.
2. **Dispensing Controlled Substances Without a Valid Prescription** – Filling prescriptions that are not issued for a legitimate medical purpose.
3. **Failure to Verify Prescriber DEA Registration** – Dispensing medications based on prescriptions from unauthorized prescribers.
4. **Forged or Fraudulent Prescriptions** – Filling altered, fraudulent, or forged prescriptions.
5. **Failure to Conduct a Required Drug Utilization Review (DUR)** – Ignoring signs of overprescribing, drug interactions, or potential abuse.
6. **Lack of Adequate Security for Controlled Substances** – Failure to properly secure controlled substances, leading to diversion.
7. **Failure to Report Theft or Significant Loss** – Not submitting DEA Form 106 within the required timeframe.

Federal Violations (DEA, CSA, and CFR Violations)

8. **Improper Disposal of Controlled Substances** – Failing to follow DEA regulations for disposing of expired or unused controlled substances.
9. **Refilling Schedule II Prescriptions** – Federal law prohibits refilling Schedule II medications.
10. **Exceeding Emergency Supply Limitations** – Dispensing more than allowed under emergency dispensing rules.
11. **Failing to Verify Patient Identity** – Dispensing controlled substances without verifying ID for new patients or high-risk prescriptions.
12. **Failure to Keep Controlled Substance Records for 2 Years** – Not maintaining accurate dispensing records.
13. **Altering Prescription Information Without Prescriber Approval** – Changing drug strength, dosage, or other critical details without authorization.
14. **Failure to Report Suspicious Orders to the DEA** – Not reporting excessive or unusual orders from prescribers.
15. **Dispensing Opioids Beyond Legal Supply Limits** – Violating federal regulations regarding opioid prescribing limits.

Illinois Violations (IL CSA, IL Phcy Prac Act, PMP Violations)

1. **Failure to Comply with Illinois Prescription Monitoring Program (PMP) Requirements** – Not reviewing PMP data before dispensing high-risk medications.
2. **Failure to Submit Controlled Substance Dispensing Data to the PMP** – Required by law for all Schedule II-V prescriptions.
3. **Unauthorized Access to the PMP** – Allowing unlicensed individuals to access the PMP database.
4. **Failure to Conduct an Annual Controlled Substances Inventory** – Not performing or maintaining annual inventory logs.
5. **Dispensing Expired Controlled Substances** – Dispensing controlled drugs beyond their expiration date.

Illinois Violations (IL CSA, IL Phcy Prac Act, PMP Violations)

6. **Failing to Identify Potential "Doctor Shopping"** – Dispensing to patients receiving multiple controlled substances from different prescribers.
7. **Failure to Follow Naloxone Dispensing Protocols** – Illinois law requires pharmacists to follow specific protocols when dispensing naloxone.
8. **Dispensing Controlled Substances Without a Valid Illinois Controlled Substance License** – A separate license from the state is required.
9. **Unsupervised Student Pharmacist Dispensing of Controlled Substances** – Allowing student pharmacists to dispense without proper oversight.
10. **Failure to Comply with Electronic Prescribing Mandates** – Illinois requires electronic prescriptions for controlled substances.

Case Studies

Case Study 1: Invalid Prescription

- A pharmacist receives a handwritten prescription for oxycodone 30 mg from a new prescriber in town. The prescription lacks a diagnosis code, and the patient has a history of multiple opioid prescriptions from different providers. The Illinois Prescription Monitoring Program (PMP) reveals several opioid prescriptions filled in the past two weeks.
- What are the red flags in this prescription?
- What steps should the pharmacist take to validate the prescription?
- If the prescription is deemed invalid, how should the pharmacist handle the situation?
- What legal consequences could result from dispensing the prescription without verification?

Case Study 1: Invalid Prescription

- **Verification of Prescriptions:** 21 C.F.R. §1306.04(a) requires that controlled substance prescriptions be issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.
- **Illinois PMP Compliance:** 720 ILCS 570/316 requires pharmacists to review PMP data before dispensing opioids.
- **Recognizing "Doctor Shopping":** Multiple recent opioid prescriptions from different providers is a red flag.
- **Pharmacist's Role:** Evaluate the prescriber's legitimacy, confirm necessity with additional documentation, and possibly refuse to fill if concerns persist.

Case Study 2: Inventory Discrepancy

- During a routine controlled substance inventory, a health-system pharmacist notices that 20 fentanyl 100 mcg tablets are missing. Upon reviewing the logs, there is no waste documentation or any prescription records for these doses.
- What should be the pharmacist's first step in addressing the discrepancy?
- Who should be notified about the missing fentanyl?
- What are the potential consequences of failing to report missing controlled substances?
- What policies should hospitals implement to prevent controlled substance diversion?

Case Study 2: Inventory Discrepancy

- **Inventory Requirements**: 21 U.S.C. §827 and 21 C.F.R. §1304.11 require accurate record-keeping of all controlled substances.
- **Reporting Theft and Loss**: DEA Form 106 must be filed per 21 C.F.R. §1301.76.
- **Diversion Prevention**: Ensure access controls, regular audits, and staff training on theft prevention.
- **Institutional Responsibility**: The pharmacy must establish procedures to detect and prevent drug diversion.

Case Study 3: Fake Patient Call

- A pharmacy technician receives a phone call from a person claiming to be a physician’s assistant, requesting an early refill on Adderall 30 mg for a "patient" who is out of town.
- What verification steps should the pharmacy take?
- How should pharmacy staff respond to suspected fraud?
- What security measures should be implemented to prevent fraudulent calls?

Case Study 3: Fake Patient Call

- Fraudulent Prescription Prevention: 21 C.F.R. §1306.04(a) mandates that prescriptions be valid and issued for a legitimate medical purpose.
- Verification of Telephonic Orders: Pharmacists should contact the prescribing physician directly.
- Legal Obligations: If fraud is suspected, the pharmacist should refuse to fill and notify local authorities if necessary.
- Red Flags: Unusual refill requests, out-of-town patients, and urgent demands are common signs of fraud.

Case Study 4: Telemedicine Dilemma

- A pharmacist receives an electronic prescription for alprazolam (Xanax) 2 mg from a telemedicine provider. The patient has never been seen in person by this provider, and the prescription was issued without any documented evaluation.
- What legal requirements must a telemedicine provider meet when prescribing controlled substances?
- What steps should the pharmacist take before filling the prescription?
- How can pharmacists identify fraudulent or unethical telemedicine providers?
- What are the risks of filling controlled substance prescriptions from online-only providers?

Case Study 4: Telemedicine Dilemma

- Telemedicine Regulations: 21 C.F.R. §1306.09 outlines restrictions on prescribing controlled substances without an in-person evaluation.
- Legitimate Prescribing Practices: The pharmacist should verify whether the prescriber complies with federal and state telemedicine laws.
- DEA and Telemedicine Guidelines: Some COVID-era exemptions are expiring, requiring providers to have at least one in-person visit before prescribing controlled substances.
- Action Plan: Contact the prescriber for additional documentation; if concerns persist, refuse to fill and document the reason.

Case Study 5: Medication Theft in a Long-Term Care Facility

- A pharmacist at a long-term care (LTC) facility notices a pattern of missing hydrocodone tablets from a single nursing unit. The same nurse has signed out the medication each time it was dispensed.
- What steps should the pharmacist take to investigate the missing medications?
- How should the pharmacist work with facility management to address potential diversion?
- When and how should DEA Form 106 be submitted?
- What measures can be implemented to prevent future controlled substance diversion?

Case Study 5: Medication Theft in a Long-Term Care Facility

- Drug Diversion in LTC Settings: 21 C.F.R. §1301.76 requires institutions to have safeguards against diversion.
- DEA Reporting Requirements: Theft must be reported via DEA Form 106.
- Internal Policies for Controlled Substance Tracking: Implementing secure medication storage, surveillance, and regular audits.
- Ethical and Legal Responsibilities: The pharmacy should work with facility management and law enforcement if diversion is suspected.

Case Study 6: Unsupervised Student Pharmacist

- A busy retail pharmacy has a student pharmacist working under the supervision of the pharmacist-in-charge. During a lunch break, the student pharmacist fills and dispenses a Schedule II prescription for oxycodone while the pharmacist is briefly out of the pharmacy.
- Was it legal for the student pharmacist to dispense the controlled substance?
- What are the potential legal consequences for the pharmacy and pharmacist?
- How can pharmacies prevent situations where students dispense without supervision?
- What should the supervising pharmacist do after discovering this error?

Case Study 6: Unsupervised Student Pharmacist

- Supervision of Student Pharmacists: 68 Ill. Adm. Code 1330.500 mandates that interns must be supervised when handling controlled substances.
- DEA Regulations on Dispensing: Only licensed pharmacists may dispense Schedule II substances.
- Liability for Improper Dispensing: The pharmacy and supervising pharmacist could face legal action.
- Preventative Measures: Establish clear policies prohibiting interns from dispensing controlled substances unsupervised.

Case Study 7: Lost DEA Number

- A compounding pharmacy receives a prescription with an invalid DEA number for a controlled substance. When staff call the clinic to verify, they receive conflicting information about the prescriber.
- How should the pharmacy verify a prescriber’s DEA registration?
- What steps should the pharmacy take if they cannot confirm the prescriber’s identity?
- What are the potential risks of filling a prescription from an unverified prescriber?
- When should the DEA be notified about possible fraudulent activity?

Case Study 7: Lost DEA Number

- DEA Verification Requirements: 21 C.F.R. §1306.03 mandates checking DEA registration validity.
- Handling Suspicious Prescriptions: Pharmacists must confirm prescriber credentials before dispensing.
- Steps for Verification: Cross-check the DEA database and contact the regulatory authorities if necessary.

Case Study 8: Medication Shortage in a Health-System Setting

- A hospital pharmacist notices an increase in patients being prescribed a high-demand controlled substance, raising concerns about stock shortages and diversion risks.
- What are the warning signs of excessive opioid prescribing?
- What actions should the pharmacist take in this situation?
- What role does the Illinois PMP play in preventing overprescribing?
- When should a pharmacist report a prescriber to the DEA or state board?

Case Study 8: Medication Shortage in a Health-System Setting

- Managing Controlled Substance Inventory: Compliance with DEA stock limits.
- Recognizing Unusual Prescribing Patterns: Identifying excessive orders.
- Prevention Measures: Implementing additional security controls.

Case Study 9: Suspicious Prescription

- A patient presents a prescription that appears altered, with a changed quantity for a Schedule II medication.
- What are the legal and ethical implications of altering a controlled substance prescription?
- What steps should a pharmacist take when encountering a prescription that appears altered?
- How should pharmacists document and report suspected fraudulent prescriptions?
- What role does the Illinois PMP play in identifying potential prescription fraud?

Case Study 9: Suspicious Prescription

- Altering Prescriptions Without Authorization: 21 C.F.R. §1306.05 prohibits unauthorized changes.
- Fraudulent Prescription Prevention: Ensuring authenticity through prescriber verification.
- Pharmacist's Role: Contact prescriber and document concerns.

Case Study 10: Overprescribing Physician

- A pharmacy notices a single physician issuing an abnormally high volume of opioid prescriptions.
- How can pharmacists identify and differentiate between high-prescribing patterns and potential overprescribing?
- What legal obligations do pharmacists have when they suspect a physician is overprescribing opioids?
- What steps should be taken before reporting a prescriber to the DEA or state medical board?
- How can pharmacists work collaboratively with prescribers to ensure compliance with controlled substance regulations?

Case Study 10: Overprescribing Physician

- **Reporting Suspicious Prescribing**: 21 C.F.R. §1301.74(b) requires reporting questionable orders.
- **Collaborating with Authorities**: Informing the DEA and medical board if needed.
- **Ethical Responsibility**: Protecting public health by intervening in cases of potential abuse.

Seeking Legal Advice

When a Pharmacist or Pharmacy Technician Should Seek Legal Advice

- **Suspicious or Illegitimate Prescriptions**
  - When encountering forged, altered, or fraudulent prescriptions for controlled substances.
  - If a prescription does not meet legal requirements and the prescriber is unresponsive to verification attempts.
- **Prescriber Red Flags and Overprescribing Concerns**
  - When noticing a prescriber issuing high volumes of controlled substances without appropriate medical documentation.
  - If a pattern of excessive prescribing raises concerns about potential legal or regulatory violations.
- **Pharmacy Compliance and DEA Investigations**
  - When the pharmacy is subject to a DEA audit or investigation regarding controlled substances.
  - If the pharmacy receives notice of non-compliance from regulatory bodies or law enforcement.
- **Controlled Substance Inventory Discrepancies and Losses**
  - When controlled substance inventory counts do not align with pharmacy records.
  - If a significant loss or theft occurs, requiring DEA Form 106 submission.

When a Pharmacist or Pharmacy Technician Should Seek Legal Advice

- **Pharmacist's Right to Refuse to Fill a Prescription**
  - If a pharmacist determines that filling a prescription violates professional judgment, ethics, or legal standards.
  - When facing retaliation or pressure from management or prescribers for refusing to dispense controlled substances.
- **Liability in Cases of Diversion or Misuse**
  - If a pharmacist or technician suspects an employee or coworker of diverting controlled substances.
  - When an employer's policies conflict with federal or state regulations, creating a legal gray area.
- **Conflicts Between Federal and State Laws**
  - When state and federal laws differ regarding controlled substance dispensing, requiring clarification on compliance.
  - If a state mandate contradicts DEA guidelines, requiring professional legal interpretation.
- **Patient Privacy and Prescription Monitoring Program (PMP) Use**
  - If a patient challenges the pharmacist's use of PMP data or requests that their prescription history not be reviewed.
  - When unsure about confidentiality obligations related to controlled substance records.

What to Look for in Attorney Representation

- **Expertise in Pharmacy Law**
  - Ensure the attorney has experience in DEA regulations, controlled substances laws, and state pharmacy board rules.
  - Look for a legal professional with a background in healthcare law, administrative law, or criminal defense related to pharmacy practice.
- **Experience Handling DEA and Board of Pharmacy Cases**
  - The attorney should have a proven track record in defending pharmacists and pharmacy technicians against audits, investigations, and compliance violations.
  - Prior experience negotiating settlements, fines, and disciplinary actions is crucial.
- **Understanding of Federal and State Laws**
  - Legal counsel should be well-versed in both federal controlled substance regulations (21 CFR, CSA) and Illinois-specific pharmacy laws.
  - Ability to provide guidance when state and federal regulations conflict.
- **Strong Reputation and References**
  - Seek out attorneys with positive client reviews, industry recommendations, or prior successful case outcomes.
  - Membership in pharmacy law associations or bar committees on healthcare law is a plus.

What to Look for in Attorney Representation

- **Accessibility and Communication**
  - Choose an attorney who is readily available to answer urgent legal questions and can provide ongoing legal support.
  - Ensure they are skilled in explaining complex legal matters in a way that pharmacists and technicians can understand.
- **Litigation vs. Preventative Legal Strategy**
  - A good pharmacy attorney should not only be able to defend against investigations but also help develop preventative compliance strategies.
  - Look for someone who offers policy reviews, risk assessments, and training for pharmacy staff.
- **Fee Structure Transparency**
  - Ensure clarity on legal fees, retainer agreements, and additional costs for expert witnesses or court filings.
  - Consider whether the attorney offers flat-rate services for compliance consultations or only hourly billing.

Questions

Post-Test Question 1

Which of the following best describes the pharmacist’s responsibility when reviewing new controlled substance laws and regulations?

A) Only review federal law changes, as state laws are always consistent.

B) Implement and comply with both federal and state law updates.

C) Rely on prescribers to stay updated on controlled substance regulations.

D) Follow only the pharmacy’s internal policies without verifying external requirements.

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Post-Test Question 2

A pharmacist receives a prescription for a controlled substance that does not meet legal documentation requirements. What should the pharmacist do first?

A) Contact the prescriber for clarification or necessary corrections.

B) Dispense the medication as long as the patient provides verbal verification.

C) Modify the prescription details without prescriber authorization. \

D) Refuse to fill the prescription and report the prescriber immediately.

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Post-Test Question 3

When reviewing a patient's history in the Illinois Prescription Monitoring Program (PMP), what is the pharmacist's primary obligation?

A) Verify past controlled substance prescriptions for potential misuse or doctor shopping.

B) Only check PMP records when required by the patient's insurance provider.

C) Document PMP reviews only for patients with a prior history of opioid use.

D) Rely solely on the prescriber's judgment regarding controlled substance appropriateness.

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Post-Test Question 4

Which of the following situations would require a pharmacist to seek legal counsel regarding controlled substances?

A) A prescriber consistently issues high doses of opioids without documentation.

B) A patient requests an early refill due to an upcoming vacation.

C) A pharmacy technician miscounts inventory but corrects the error immediately.

D) A patient complains about side effects from a prescribed controlled substance.

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