Arkansas Pharmacy Law Update

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Executive Director
Arkansas State Board of Pharmacy

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Disclosure

- I do not have any financial interests or other disclosures of conflict for this program.

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Objectives

- Analyze recent changes in pharmacy regulations in Arkansas
- Discuss the reasoning behind changes to pharmacy regulations
- Describe recent pharmacy regulatory changes and challenges
- Identify three practice changes to protect your controlled substance inventory

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About the Board of Pharmacy

- The Board licenses:
  - Individuals
  - Businesses
- The Board tracks over 21 different license configurations / types
- We have a 3 member administrative team
- We are always busy
- Please remember to be patient and polite…
- Employment change notifications are *required*

Arkansas Prescription Drug Abuse Prevention Summit 2018

- Please plan to attend the **2017 Arkansas Prescription Drug Abuse Prevention Summit on November 1, 2018** at the Hot Springs Convention Center.
- We will offer four breakout tracks: **Clinical**, Criminal Justice, Education/Prevention and Counseling/Recovery.
- Early bird registration is open! Reserve your seat now as space is limited.
- https://arkansasag.eventsmart.com/

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Other CE Available

- AR-IMPACT is a weekly free interactive televideo program offering free CME credit. The first conference is scheduled for May 2 and will continue to be held each Wednesday, from 12 to 1 p.m. The interactive conferences will begin with a brief didactic presentation about an aspect of the care of these patients, followed by a case conference format where doctors can present their difficult cases for discussion with their peers and with our panel of subspecialists.
- https://arimpact.uams.edu/

UAMS AR IMPACT
IMPROVING MULTI-DISCIPLINARY PAIN CARE TREATMENT

New Staff

- Cindy Fain
- New Board Members?

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State Board of Pharmacy

pharmacyboard.arkansas.gov
www.arkansas.gov/asbp

- Board News & Events
- Licensee Information - Newsletters
- Forms & Instructions
- Pharmacy Lawbook – Regulation Changes
- Complete – Up-to-Date Lawbook

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Board of Pharmacy Regulations

Statutes that will impact pharmacy practice in 2017 and beyond

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ACT 284

AN ACT TO AMEND THE PROVISIONS OF ARKANSAS CODE CONCERNING THE PRACTICE OF PHARMACY; TO AUTHORIZE USE OF PHARMACISTS TO PROVIDE ACCESS TO AND ADMINISTRATION OF CERTAIN MEDICATIONS; TO AUTHORIZE DISPENSING OF CERTAIN MEDICATION BY PHYSICIANS; AND FOR OTHER PURPOSES

Sponsored by Senators Cecile Bledsoe and Lance Eads as well as Representative Justin Boyd

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ACT 284

- Erases the limited list of medications that a pharmacist can administer and instead points to the Board of Pharmacy to make rules on any limits. Previous language limited pharmacists to administering immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications.
- Added language to allow pharmacists to initiate therapy and administer or dispense or both Naloxone pursuant to a statewide protocol.
- Allows physicians to dispense Naloxone or contraceptives without a dispensing permit.

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ACT 477

AN ACT TO AMEND LAWS REGARDING THE PRACTICE OF PHARMACY AND THE ARKANSAS STATE BOARD OF PHARMACY; AND FOR OTHER PURPOSES

This act, sponsored by Representatives Jimmy Gazaway and Justin Boyd as well as Senator

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ACT 477

1. Clarify that our inspectors/investigators can seize products to test for sterility, potency and pyrogenicity when inspecting permitted facilities.

2. Delete the word gross from the terminology 'gross unprofessional conduct' as there is no differentiation for 'gross' and our rules only define unprofessional conduct.

3. Match our fining authority to other healthcare licensure boards at $1,000 per incident rather than $500. (the Board has seldom fined the maximum amount currently but there are times when it has been needed vs closing a business causing patient disruption)

4. Allow the Board to assess a monetary penalty in addition to revoking a permit when appropriate.

5. Allow the Board to recoup investigative costs incurred when preparing for and holding a disciplinary hearing.

6. Allow the Board to collect costs of inspections when we need to inspect an out of state facility permitted with our Board.

7. Update notification requirements so that they match our rules to give 5 days for certain notifications vs the 3 days reflected by previous statutes.

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ACT 139

AN ACT TO AMEND THE COMPREHENSIVE CRIMINAL RECORD SEALING ACT OF 2013 TO ALLOW A STATE AGENCY OR BOARD ENGAGED IN THE LICENSING OF MEDICAL PROFESSIONALS TO HAVE ACCESS TO AND USE OF EXPUNGED AND SEALED RECORDS OF CRIMINAL CONVICTIONS; AND FOR OTHER PURPOSES

This act, sponsored by Representative Justin Boyd and Senator Missy Irvin, clarifies that health licensure Boards have the ability to view and consider sealed convictions when considering licensing of applicants.

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ACT 401

AN ACT TO MAKE AN APPROPRIATION FOR PHARMACY STUDENT LOANS AND SCHOLARSHIPS FOR THE STATE BOARD OF PHARMACY FOR THE FISCAL YEAR ENDING JUNE 30, 2018; AND FOR OTHER PURPOSES

This act, sponsored by Representative Les Eaves, allows the Board of Pharmacy to establish a second Rural Loan / Scholarship program in Arkansas with funding of $275,000

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ACT 282

AN ACT TO MODIFY THE EMERGENCY REFILL OF PRESCRIPTION BY PHARMACISTS; AND FOR OTHER PURPOSES

This act, sponsored by Senator Lance Eads and Representative Clint Penzo, removes the restriction by statute which limits emergency prescription refills to a 72 hour supply. The Board of Pharmacy will discuss guidance for pharmacists during the June meeting of the Board to publish guidelines at a later date once the new statute is in place.

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ACT 820

AN ACT TO AMEND THE PRESCRIPTION DRUG MONITORING PROGRAM TO MANDATE PRESCRIBERS CHECK THE PRESCRIPTION DRUG MONITORING PROGRAM WHEN PRESCRIBING CERTAIN MEDICATIONS; AND FOR OTHER PURPOSES.

Sponsored by Senator Jeremy Hutchinson and Representative Kim Hammer

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ACT 820

- Defines when a practitioner must access the PDMP
  - When prescribing a schedule II or III Opioid
  - Benzodiazepine for the first time
  - Exempts –
    - Immediately before or during surgery
    - During surgery recovery in a healthcare facility
    - In a healthcare facility
    - Emergency situation at the scene of an emergency, in a licensed ground ambulance or air ambulance or the ICU of a licensed hospital
    - Palliative care or hospice patient
    - Resident in a licensed nursing home facility
    - Situations where the PDMP is not accessible due to technological or electrical failure
  - Licensed oncologist shall check on initial malignate episodic diagnosis and every three months following while continuing treatment

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ACT 820

- Allows Department of Health to send quarterly reports to prescribers and dispensers
- After 12 months if information still looks suspect, the Department of Health can report to the licensing boards
- Push for same day and even real time reporting
- Expanded the PDMP oversight board with a person from the Medical Board and the Dental Board
- Can allow for exemptions to the law through the Department of Health with legislative approval
- Allows licensure boards to adopt rules limiting the quantities of medications that can be prescribed or dispensed

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ACT 1024

AN ACT TO AMEND ARKANSAS CONSTITUTION, AMENDMENT 98, ALSO KNOWN AS THE "ARKANSAS MEDICAL MARIJUANA AMENDMENT OF 2016" TO REQUIRE A DISPENSARY TO MAKE VAPORIZERS AVAILABLE FOR SALE TO QUALIFYING PATIENTS AND TO APPOINT A PHARMACIST CONSULTANT; AND FOR OTHER PURPOSES

This act, sponsored by Representative Clint Penzo and Senator Missy Irvin specifically outlines a requirement for dispensaries to employ a Pharmacist Consultant.

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ACT 411 of 2015

Act 411 of 2015 - TO CREATE THE SUBSTANCE ABUSE REPORTING ACT.

- By: Representatives Boyd, Bentley, G. Hodges, Scott, Baine, C. Fite, C. Douglas, Vaught, Senator Irvin
- Act 411 of 2015 would commonly be referred to as an Affirmative Duty to Report the Diversion, Misuse or Abuse of Prescription Drugs. This bill lays out language to require the following:

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ACT 411 of 2015

1) When a healthcare employer takes action against a healthcare professional employee or that employee voluntarily resigns with pending disciplinary action for the diversion, misuse or abuse of illicit drugs or controlled substances, this action must be reported to the appropriate licensing authority for the healthcare professional.
2) If the licensing authority determines after investigation and due process that the healthcare professional may have acted criminally by diverting controlled substances to a third party then this must be reported to the local DEA office.
3) Whenever a healthcare employer takes action against any other employee that is not a healthcare professional due to the diversion of controlled substances to a third party, this must be reported to the appropriate law enforcement agency.
4) Required reporters in this act shall not be liable to any person and are immune from civil liability for filing a required report.

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ACT 411 of 2015

- In essence, this will help to require reporting for healthcare professionals that are impaired while working so that licensure boards can ensure that they are safe to practice and help our licensure boards to help further protect the public health and welfare (many of the healthcare licensure boards have recovery programs that allow professionals to return to work with proven sobriety). Furthermore, this act also requires further reporting to law enforcement any time that drugs are diverted or stolen to be provided to a third party.
- This act targets drug abuse and addiction to get help and targets drug trafficking for potential criminal investigation.

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BOARD INTERPRETATIONS

- The Board of Pharmacy will also routinely discuss policy issues that do not require a change in Statutes or Regulations for clarification.
- 30 to 90 day prescriptions
- Multi Dose MOU
- Filling part of a Schedule 2 prescription
- Electronic Prescriptions for Controlled Substances

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90 Day Fill from a 30 Day Script

- The Board discussed this during the February 2017 Board of Pharmacy meeting and came up with the following interpretation: A pharmacist may fill an advanced days supply of a non-controlled maintenance medication for an amount not to exceed the total number approved with the original supply plus refills.
- In the instance of controlled substances, the pharmacist may only fill more than indicated on the initial prescription after consultation with and approval by the prescriber which should be noted on the prescription or in the pharmacy's software system for that prescription.

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Multi-Dose MOU

- The Board voted to allow a change the MOU for Multi-Dose Packaging including and up to a 93 day supply of medications to be packaged when requested and to allow for a patient or caregiver the ability to bring back packaged medications to the pharmacy for repackaging due to changes in the medication regimen for the patient. In these instances, the pharmacy/pharmacist would have to have policies and procedures of how they document what is repackaged and exactly what was changed and leave the date that was originally filled on the package as well as let the patient take any removed medications back or destroy it. These issues must be covered by their policies and procedures explaining how this will be done.

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (the "MOU") is between _____

("the Pharmacy") located at _____

licensed as license number _____ and the Arkansas State Board of Pharmacy ("the Board") and both parties acknowledge that the Pharmacy will be permitted to dispense in multi-dose packaging on the following terms and conditions:

Whereas, the Pharmacy is currently licensed in good standing by the Arkansas State Board of Pharmacy;

Whereas, Arkansas licensed pharmacies are permitted to dispense in multi-dose packaging if the dispensing protocol is approved by the Board;

Whereas, the Pharmacy and the Board acknowledge and agree that the Pharmacy will dispense in multi-dose packaging to Arkansas residents using the following protocol:

PRESCRIPTIONS – FILLING AND REFILLING

1. Prescriptions for medication may be written, electronically transmitted, faxed, or verbally called in to the pharmacy. Because they are less susceptible to error, written orders are preferable to verbal orders.
2. ALL PRESCRIPTIONS MUST BE SIGNED BY THE PHYSICIAN, NURSE PRACTITIONER, OR OTHER PRESCRIBER AUTHORIZED BY ARKANSAS LAW.
3. If verbally called in to the pharmacy, the person calling in the prescription must be the prescriber or the prescriber's authorized representative and must give the prescription directly to a pharmacist in the pharmacy.
4. The pharmacy should establish policy for how PRN, controlled medications, Short Term Therapy Medications (*prep meds, antibiotics…*), Do Not Crush meds and NTI medications (*warfarin, phenytoin, …*) will be handled if included in this packaging system. Most pharmacies will choose to have this packaged separately or should have specific cautionary labeling to warn of these medications if included in the multi-dose package. PRN medications must be packaged separately.
5. The pharmacy may accept and repackage multi-dose medications for the same patient when there are changes in the patient's medication regimen. In these instances, the pharmacy/pharmacist must have policies and procedures for the following:
   a. Document what is being repackaged and exactly what was changed in the packaging system,
   b. the package should reflect and retain original dating for packaging, and
   c. any removed medications should be returned to the patient or destroyed.

PRESCRIPTIONS – SCHEDULE FOR REFILLS

1. The pharmacy will fill all new prescription orders with a maximum of a 93 day supply of medication.
2. The Pharmacy will inform patients that any changes to existing medications should be reported immediately to the Pharmacy, so that the Pharmacy can instruct the patient on modifying the pill pouches already dispensed. The patients and/or caregivers will be responsible to ensure that any modifications or discontinuations made to prescriptions already dispensed are accurate.
3. The Pharmacy will also inform patients on how and when to dispose of unused or expired medication in conformity with state law.

This MOU will remain in effect unless and until the parties agree to a written modification. The Pharmacy agrees if its multi-dose dispensing protocol changes from that outlined in this MOU, it will cease all dispensing activity to Arkansas residents until a new MOU has been approved by the Board. This MOU shall not apply to medications dispensed in nursing homes.

By entering into this MOU, the Board is not accepting any responsibility or liability in connection with work performed or actions taken by the Pharmacy under this MOU.

Approved by: **Pharmacy** **Arkansas State Board of Pharmacy**

Signature, Title: Signature, Executive or Assistant Director

Date: Fax#: Date:

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Odd Questions

07-04-0002—PARTIAL FILLING OF A SCHEDULE II PRESCRIPTION

- The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).
- The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

NOTHING in state or federal guidelines says that a pharmacist **MUST** fill the entire quantity of a prescription. You can always give less than the total prescribed if that is what the patient wants. Even if it kills the rest of the prescription.

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New Regulation

Regulation 9 - Pharmaceutical Care/Patient Counseling

- Deleted language for the Medications Administration Advisory Committee.
- Removed the limitations on the list of medications that can be administered by pharmacists.
- Deleted a reference that CPR courses must be accredited by the American Heart Association

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Attempted Regulation

Regulation 7 – Drug Products/Prescriptions

- Proposed changes would have updated definitions to match FDA definitions and glossary terms to add terms for biological product, biosimilar, biosimilar product, drug, generic drug, and interchangeable biological product.
- Changes would have also clarified language regarding pharmacists' ability to substitute products that are either generically equivalent, interchangeable biological products or manufacturer authorized generics.
- Language would have been added to show that a pharmacist cannot dispense more of a schedule II narcotic medication than a prescriber can prescribe.

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"Authorized Generics"

What Is an Authorized Generic Drug?

- The term "authorized generic" drug is most commonly used to describe an approved, brand name drug that is marketed as a generic product without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. It may be marketed by the brand name drug company, or another company with the brand company's permission. In some cases, even though it is the same as the brand name product, the authorized generic may be sold at a lower cost than the brand name drug.

Long story short, 'authorized generics' may be automatically substituted for their branded counterparts

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New Proposed Regulations

- Public Hearing June 6, 2018
- REGULATION 5
  - LONG-TERM-CARE FACILITIES
- REGULATION 7
  - DRUG PRODUCTS/PRESCRIPTIONS
- REGULATION 8
  - WHOLESALE DISTRIBUTION

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REGULATION 5 – LONG-TERM-CARE FACILITIES

- Proposed changes will:
  - update language regarding destruction of unused drugs for long-term care facilities to remove outdated language,
  - update emergency kit guidelines for use in long-term care and
  - establish a list of emergency medications that can be used in Crisis Stabilization Units.

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(C) Non-controlled legend drugs.

(i) Drugs to be destroyed shall be handled in accordance with state and federal requirements. ~~The consultant pharmacist shall cause a designated nurse to record all discontinued and outdated non-controlled legend drugs in a bound and numbered drug destruction book when the drug is discontinued or becomes outdated. The consultant pharmacist(s) and a designated nurse shall jointly inventory and destroy the drugs and each shall sign the drug destruction book to document the destruction of these drugs.~~

(ii) Drugs to be donated. The consultant pharmacist shall cause all drugs that are designated for donation to charitable clinics licensed by the Board under Regulation 04-03-0004 and ACA § 17-92-1101 et seq., to be processed in accordance with Board Regulation 04-07-0006.

(D) Controlled drugs shall be handled in accordance with state and federal requirements. ~~All discontinued and outdated controlled drugs shall be signed out of narcotic inventory at the time of discontinuation or at the point of becoming outdated and shall be entered on the Arkansas Department of Health's *Report of Drugs Surrendered* form by a designated nurse and the director of nurses. Said outdated or discontinued drugs shall be secured in the office of the director of nurses pursuant to paragraph 3(A) of this section until sent to the Department of Health. The consultant pharmacist shall confirm the quantity of drugs segregated for shipment to the Arkansas Department of Health is accurately entered on the inventory of controlled substances recorded on the *Report of Drugs Surrendered* form.~~

(E) ~~The controlled drugs shall be sent to the Arkansas Department of Health by licensed facility personnel, to be designated by the administrator, at least quarterly. The Arkansas Department of Health's receipt of drugs destroyed shall be reconciled with the nurse/pharmacist inventory. The consultant pharmacist shall make recommendations ensuring that the facility conforms to the policies and procedures established by the Division of Pharmacy Services and Drug Control, Arkansas Department of Health.~~

05-00-0005—DRUG CATEGORIES FOR EMERGENCY KITS IN LONG-TERM CARE FACILITIES

The following is a list of categories of drugs which are acceptable in emergency kits in long-term-care facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. The Board shall set guidelines for specific quantities of approved medications which will be reviewed biennially or periodically as needed. The provision or presence of an emergency kit in long-term care facilities does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours. In every instance where injectables are indicated, only single-dose injectables are acceptable.

(a) Analgesics, controlled drugs
(b) Anti-Infectives
(c) Anticholinergics
(d) Anticoagulant
(e) Antidiarrheals
(f) Antihistamine Injectables
(g) Antinauseants
(h) Antipsychotic injectables
(i) Anti-hyperglycemics
(j) Anxiolytics
(k) Cardiac life support medications
(l) Coagulants
(m) Corticosteroids
(n) Hypoglycemics
(o) Seizure control medications
(p) Large volume parenterals
(q) Poison control
(r) Respiratory medications
(s) GI Medications
(t) Other medications as approved by the Board

05-00-0007—DRUG CATEGORIES FOR EMERGENCY KITS IN CRISIS STABILIZATION UNITS.

The following is a list of categories of drugs which are acceptable in emergency kits for facilities that are certified by the Arkansas Department of Human Services as a Crisis Stabilization Unit (CSU). The Board shall set guidelines for specific quantities of approved medications which will be reviewed periodically. The provision or presence of an emergency kit in a Crisis Stabilization Unit does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

(a) Analgesics, controlled drugs
(b) Antihistamine Injectables
(c) Antinauseants
(d) Antipsychotic Medications
(e) Anxiolytics
(f) Cardiac life support medications
(g) Injectable seizure control medications
(h) Anticholinergic medications
(i) Opioid antagonist
(j) Other medications as approved by the Board

REGULATION 7 – DRUG PRODUCTS/PRESCRIPTIONS

- Proposed changes will:
  - reduce regulatory burdens when transferring prescriptions between pharmacies and
  - add language to specify that a pharmacist cannot dispense more of a schedule II narcotic medication than a prescriber can prescribe.

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07-00-0002—PRESCRIPTION TRANSFERS

(a) The transfer of original prescription information for a legend drug or a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed or registered individuals where one of the two must be a pharmacists and the transferring individualpharmacist records the following information:

(A) Write the word "Void" on the face of the invalidated prescription.

(B) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(C) Record the date of the transfer and the name of the pharmacist, technician or intern transferring the information.

(b) The pharmacist receiving the transferred prescription information shall electronically record or reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(A) date of issuance of original prescription;

(B) original number of refills authorized on original prescription;

(C) date of original dispensing;

(D) number of valid refills remaining and date(s) and locations of previous refill(s);

(E) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(F) name of pharmacist who transferred the prescription.

(c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transfer.

(e) Pharmacies transferring prescriptions may utilize facsimile or other electronic means to communicate information for transfers with validation via phone to ensure receipt of all necessary information between both parties.

(f) Transfers of controlled substances must follow federal law and regulations and may only be completed by pharmacists and interns.

(Amended 5/31/2014)

07-04: CONTROLLED SUBSTANCES

07-04-0001—SCHEDULE II PRESCRIPTION DRUGS

(b) Licensees of the Arkansas State Board of Pharmacy may not dispense a quantity of a Schedule II Narcotic that exceeds the prescriber's authority to prescribe. (Amended 2018)

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REGULATION 8 – WHOLESALE DISTRIBUTION

- Proposed changes will clarify language in Regulation 8 to match statutory language in 17-92-108 and will also allow an outsourcing facility to operate under a single permit if they do not provide medications directly to patients.

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Define Outsourcing Facilities

08-00: WHOLESALE DRUG DISTRIBUTORS OF LEGEND/CONTROLLED SUBSTANCES

08-00-0001—DEFINITIONS

As used in this regulation, unless the context otherwise requires.

(n) "Outsourcing Facility" means a facility at one geographic location or address that:

(1) Is engaged in the Compounding of sterile drugs for human use;

(2) Is registered as an Outsourcing Facility with the FDA; and

(3) Complies with all of the requirements of Section 503B of the Federal FD&C Act.

(4) Shall be a licensed under the Wholesale Distribution regulations as a 503B Outsourcer,

(5) Shall have an Arkansas licensed Pharmacist in Charge on staff a minimum of 32 hours per week,

(6) All Compounding shall be done under the supervision of a licensed Pharmacist and comply with Federal requirements applicable to Outsourcing Facilities,

(7) Does not provide patient specific prescription products unless also licensed as a pharmacy and does not provide any products that are prohibited under the FDA guidelines of a 503B

Clarify Licensure Requirement

08-00-0003—WHOLESALE DISTRIBUTORS THIRD-PARTY LOGISTICS PROVIDERS, MANUFACTURERS AND OUTSOURCING FACILITIES—PERMIT REQUIRED.

(a) Every wholesale distributor, third-party logistics provider, manufacturer and outsourcing facility who shall engage in the ~~wholesale~~ distribution of prescription drugs, to include without limitation, manufacturing in this state, shipping into this state or selling or offering to sell in this state, shall register with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the Board and accompanied by a fee as defined in regulation 01-00-0007. The Board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

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CURRENT PROBLEMS WE SEE

- Compounding Inspections…
  - Compounding clean rooms
  - Certifications?
- Transfer of controlled substances on "Hold"
- 222 forms – MUST BE COMPLETED
- PDMP Login – Individual not Group
- CSOS Login – Individual not Group
- DEA Inspections
- EMERGENCY SERVICES

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COMMON SCARY TOPIC

- Jurisprudence Exam Failures
- NAPLEX Failures

- As of November 1, 2016, the NAPLEX waiting period is 45 days between a failed attempt on the NAPLEX and the next scheduled appointment to test. Some jurisdictions have a waiting period stated in rules or regulations that exceeds the NAPLEX 45-day waiting period. Candidates shall be required to comply with the jurisdiction's stated waiting period in such cases.
- To retake the NAPLEX, candidates must complete the online registration and submit the fees. Eligibility must be reconfirmed by a board of pharmacy and candidates must adhere to the 45-day waiting period. The waiting period policy includes a provision that there shall be no more than three attempts to pass the NAPLEX in a 12-month period. If a candidate fails the NAPLEX three times in a 12-month period, the candidate shall be subject to eligibility approval by the board of pharmacy (or designated authority) and will not receive an authorization to test until the 12-month time frame has passed.

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COMMON SCARY TOPIC

- Jurisprudence Exam Failures
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- As of November 1, 2016, the NAPLEX waiting period is 45 days between a failed attempt on the NAPLEX and the next scheduled appointment to test. Some jurisdictions have a waiting period stated in rules or regulations that exceeds the NAPLEX 45-day waiting period. Candidates shall be required to comply with the jurisdiction's stated waiting period in such cases.
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Take BACK

October 2017 Take BACK

28,035 Pounds

APRIL 2018 Take BACK

28,020 Pounds

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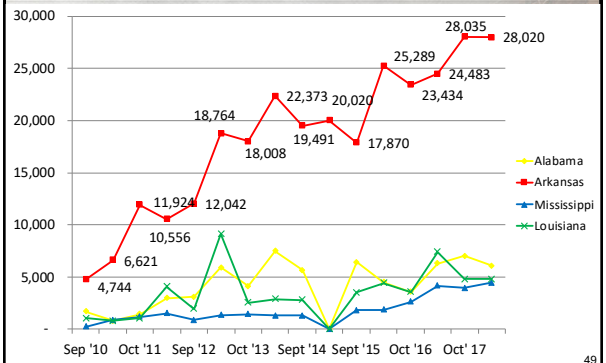
Drug Take Back – Quantity in Pounds?



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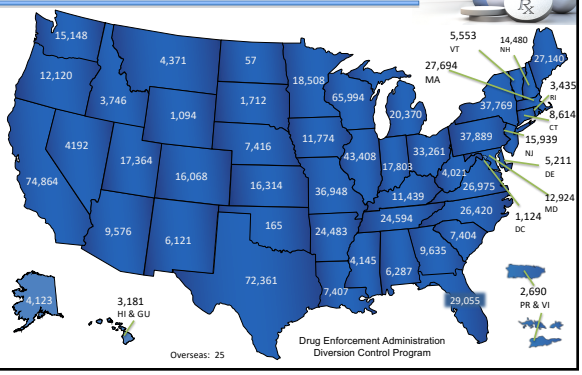
13th National Take Back Day: April 29, 2017

Total Weight Collected (pounds): 900,386 lbs. (450 Tons)



Monitor, Secure and Dispose

Patients should

- Know what they are taking and how much they have
- Secure their prescription medications
- Properly dispose of prescription drugs
  - www.smarxtdisposal.net
  - www.ioit2me.com
  - www.artakeback.org

What Else are We Doing?

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AMA Sees Progress in Declining Opioid Prescriptions, Urges Continued Focus on Evidence-Based Treatment

"A 22-percent decrease in opioid prescriptions nationally between 2013 and 2017 reflects the fact that physicians and other health care professionals are increasingly judicious when prescribing opioids. It is notable that every state has experienced a decrease, but this is tempered by the fact that deaths related to heroin and illicit fentanyl are increasing at a staggering rate, and deaths related to prescription opioids also continue to rise…"

- Patrice A. Harris, MD, MA, chair of the AMA Opioid Task Force

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State and National Totals of Retail Filled Prescriptions: All Opioid Analgesics, 2013-2017

State	2013	2014	2015	2016	2017	Cumulative % change 2013-2017	Percent change 2016-2017
Alabama	6,814,305	6,393,791	5,840,754	5,638,226	5,226,453	-23.3%	-7.3%
Alaska	468,266	457,730	420,617	406,210	371,330	-20.7%	-8.6%
Arizona	5,050,348	5,038,497	4,813,236	4,549,927	4,146,719	-17.9%	-8.9%
Arkansas	3,477,289	3,523,762	3,312,715	3,240,776	3,031,816	-12.8%	-6.4%
California	21,047,372	20,561,933	18,666,608	17,441,819	15,935,858	-24.3%	-8.6%
Colorado	3,678,624	3,637,189	3,471,691	3,191,200	2,903,238	-21.1%	-9.0%
Connecticut	2,512,161	2,476,310	2,297,397	2,050,162	1,825,478	-27.3%	-11.0%
Delaware	823,522	814,682	768,974	717,686	636,103	-22.8%	-11.4%
District of Columbia	530,757	520,817	462,789	424,773	396,380	-25.3%	-6.7%
Florida	13,636,391	13,413,544	12,708,441	12,750,684	12,161,370	-10.8%	-4.6%
Georgia	8,643,869	8,305,929	7,880,524	7,856,894	7,403,647	-14.3%	-5.8%
Hawaii	717,220	694,579	645,508	612,090	566,039	-21.1%	-7.5%
Idaho	1,361,009	1,348,590	1,263,510	1,211,463	1,127,967	-17.1%	-6.9%
Illinois	8,800,796	8,518,837	8,003,978	7,665,040	7,012,770	-20.3%	-8.5%
Indiana	6,924,241	6,307,577	5,837,382	5,527,092	5,114,530	-26.1%	-7.5%
Iowa	2,274,401	2,246,454	2,121,545	1,983,098	1,787,157	-21.4%	-9.9%
Kansas	2,751,590	2,677,203	2,504,956	2,399,365	2,233,674	-18.8%	-6.9%
Kentucky	4,997,389	4,900,964	4,471,521	4,178,616	3,835,758	-23.2%	-8.2%
Louisiana	5,497,900	5,248,487	4,818,945	4,714,697	4,390,626	-20.1%	-6.9%
Maine	1,105,502	1,060,604	985,562	867,776	752,128	-32.0%	-13.3%
Maryland	4,229,380	4,181,855	3,941,165	3,664,825	3,321,383	-21.5%	-9.4%
Massachusetts	4,584,487	4,431,390	4,066,743	3,551,098	3,108,589	-32.2%	-12.5%
Michigan	10,482,299	10,315,827	9,528,806	8,858,912	8,018,969	-23.5%	-9.5%
Minnesota	3,330,832	3,250,152	2,975,420	2,688,110	2,395,469	-28.1%	-10.9%
Mississippi	3,514,236	3,407,069	3,212,366	3,087,482	2,797,901	-20.4%	-9.4%

Missouri	5,755,659	5,602,998	5,217,577	4,955,781	4,568,443	-20.6%	-7.8%
Montana	798,887	776,545	722,011	686,115	616,656	-22.8%	-10.1%
Nebraska	1,497,183	1,470,605	1,378,816	1,325,382	1,229,836	-17.9%	-7.2%
Nevada	2,436,691	2,467,414	2,393,881	2,276,188	2,144,804	-12.0%	-5.8%
New Hampshire	970,834	937,024	886,243	764,009	648,791	-33.2%	-15.1%
New Jersey	5,160,965	5,082,090	4,917,404	4,593,494	3,971,549	-23.0%	-13.5%
New Mexico	1,422,434	1,436,906	1,409,482	1,299,762	1,154,945	-18.8%	-11.1%
New York	10,957,729	10,450,786	10,164,060	9,534,858	8,731,689	-20.3%	-8.4%
North Carolina	9,482,526	9,232,258	8,717,746	8,276,712	7,475,119	-21.2%	-9.7%
North Dakota	505,227	495,555	466,131	441,930	397,286	-21.4%	-10.1%
Ohio	11,261,528	10,794,842	9,955,858	9,057,498	7,884,784	-30.0%	-12.9%
Oklahoma	4,666,575	4,242,737	3,972,838	3,765,604	3,508,003	-24.8%	-6.8%
Oregon	3,456,129	3,389,575	3,145,023	2,897,444	2,573,451	-25.5%	-11.2%
Pennsylvania	11,330,259	11,031,159	10,394,466	9,496,052	8,163,730	-27.9%	-14.0%
Rhode Island	871,892	823,219	732,367	655,736	578,919	-33.6%	-11.7%
South Carolina	4,866,458	4,797,342	4,490,916	4,296,073	3,982,951	-18.2%	-7.3%
South Dakota	570,917	585,432	581,534	554,246	514,472	-9.9%	-7.2%
Tennessee	8,525,017	8,239,110	7,800,947	7,366,191	6,709,154	-21.3%	-8.9%
Texas	18,569,734	17,959,748	15,903,061	15,444,180	14,551,496	-21.6%	-5.8%
Utah	2,364,661	2,308,830	2,186,792	2,107,481	1,975,493	-16.5%	-6.3%
Vermont	418,161	415,687	388,108	348,511	307,528	-26.5%	-11.8%
Virginia	6,346,359	6,047,580	5,608,460	5,240,314	4,526,212	-28.7%	-13.6%
Washington	5,163,236	5,121,469	4,881,633	4,607,428	4,209,000	-18.5%	-8.6%
West Virginia	2,420,990	2,389,802	2,076,883	1,752,690	1,510,207	-37.6%	-13.8%
Wisconsin	4,326,863	4,224,458	3,984,693	3,655,386	3,216,311	-25.7%	-12.0%
Wyoming	413,701	405,626	382,837	374,192	349,111	-15.6%	-6.7%
All States	**251,814,801**	**244,462,569**	**227,780,920**	**215,051,279**	**196,001,292**	**-22.2%**	**-8.9%**

Sources: *Xponent* , IQVIA , Danbury, CT, Accessed March 2017
PayerTrak , IQVIA, Danbury, CT, Accessed March 2018

IMS Health & Quintiles are now IQVIA™

Medication-Assisted Treatment

- Medication-Assisted Treatment (MAT) is the use of medications, **in combination with counseling and behavioral therapies**, to provide a "whole-patient" approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can help some people struggling with addiction sustain recovery.
- Treatment should include access to the medication-assisted treatment (MAT) options of methadone, buprenorphine, or extended-release naltrexone, which are effective for both prescription opioid and heroin addiction. https://takebackday.dea.gov/

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What is Next? **Labels Save Lives**

artakeback.org
PROTECT OUR CHILDREN.
DISPOSE OF YOUR MEDS SAFELY.

October 27, 2018
Drug Takeback Day

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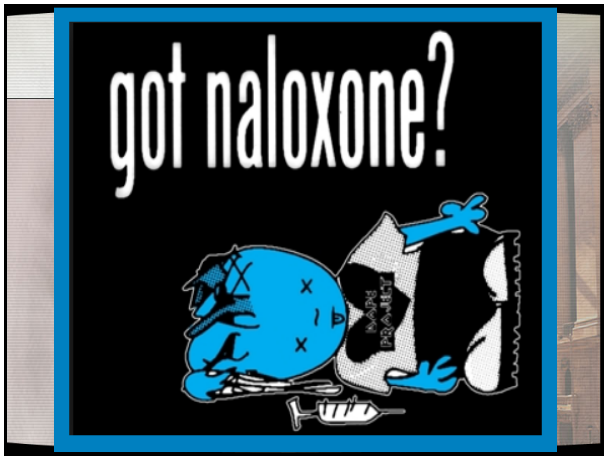
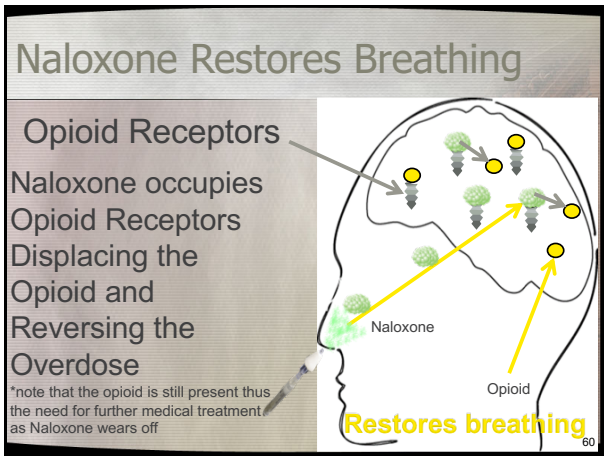
SIGNS OF OVERDOSE
PERSON IS NOT MOVING
BREATHING WILL BE SLOW OR ABSENT
PERSON MAY BE CHOKING
YOU CAN HEAR GURGLING OR SNORING SOUNDS
SKIN FEELS COLD AND CLAMMY
PUPILS ARE TINY
LIPS AND NAILS ARE BLUE
PERSON CAN'T BE WOKEN UP
NARCAN NASAL SPRAY
4 mg
58


got naloxone?


Naloxone Restores Breathing
Opioid Receptors
Naloxone occupies Opioid Receptors Displacing the Opioid and Reversing the Overdose
*note that the opioid is still present thus the need for further medical treatment as Naloxone wears off
Naloxone
Opioid
Restores breathing
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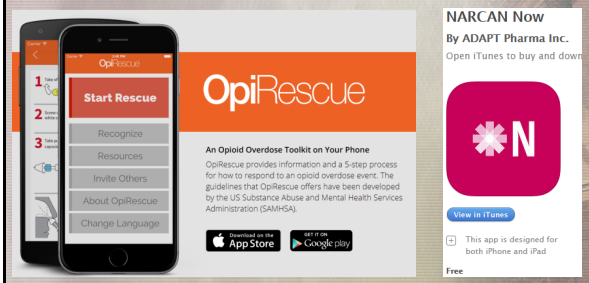
There's an App for that



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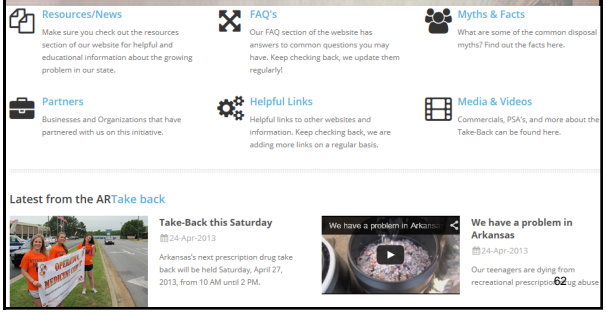
www.artakeback.org

- Updated Website with New Info



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Old Stuff Worth Repeating

Audit and Shrink Reports

TOOLS?

Board of Pharmacy Site

FAQs

Shrink Report Tool

http://pharmacyboard.arkansas.gov/faqs/Pages/default.aspx

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Pharmacy Prescription Drug Losses 106 Totals for Arkansas

	Alprazolam	Hydrocodone	Oxycodone	Codeine
2010	73,633	459,276	16,538	4,005
2011	42,953	213,639	32,422	8,878
2012	9,844	103,988	18,448	3,726
2013	8,323	128,864	28,336	44,878
2014	24,935	196,027	65,163	16,345
2015	29,986	131,870	74,555	7,485
2016	12,253	243,577	108,639	4,358
2017	28,383	133,887	109,788	24,919

How to Track Inventory Effectively

- Check on hand quantities
- Store controls correctly
  Lock up all controls, only CII's or disperse in inventory
- Limit access to controlled substances
  Interviewing potential employees – Verify Licensure
- Perpetual inventory -- Must be checked to actually work
- Invest or buy?
  Security systems – Return on Investment

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Reporting

Reports to professional licensing boards

Arkansas Dept. of Health

DEA Notification (Form 106)

Consideration of theft/criminal prosecution

Involvement of local law enforcement

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Upon Discovery of Theft

- Arkansas State Board of Pharmacy Regulation 07-04-0006 requires that any holder of a pharmacy permit that suffers a theft or loss of controlled substances shall:
- (a) Notify Arkansas Department of Health Division of Pharmacy Services and Drug Control, the nearest Drug Enforcement Administration Diversion Field Office, and the Arkansas State Board of Pharmacy immediately upon discovery by phone or fax, and
- (b) Deliver a completed DEA Form-106 to each of the agencies listed in (a) within 7 days of the occurrence of said loss or the discovery of said loss.

*According to 21 CFR part 1301 Sec. 1301.74 (c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. This written notice should be faxed to 501-217-6597.

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Upon Discovery of Theft

- Arkansas State Board of Pharmacy
  322 South Main Street, Ste 600
  Little Rock, AR 72201
  Phone: (501) 682-0190
  Fax: 501-682-0195
- Arkansas Department of Health
  Pharmacy Services and Drug Control
  4815 W. Markham
  Slot #H-25
  Little Rock, AR 72205-3867
  501-661-2325 fax 501-661-2769
- DEA – Submit online
  501-217-6500 fax 501-217-6597
  - For additional information, please see regulation 07-04-0006

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What is Missing?

- Do a Controlled Substance inventory!
- Count everything
- Be sure you are up to date on your biennial inventory
- Get a police record of the theft
- Notify authorities if you notice something else is missing

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DEA 106 Forms

- Must be filled out completely & correctly
- Must be sent within 7 days
- Must be signed
- www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html
- www.pharmacyboard.arkansas.gov → FAQ

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140 CHARGED IN ARKANSAS AS PART OF NATIONAL PRESCRIPTION DRUG INITIATIVE

"OPERATION PILLUTED" CULMINATES WITH ANNOUNCEMENT OF TWO FEDERAL PRESCRIPTION DRUG DISTRIBUTION INDICTMENTS CHARGING 46 DEFENDANTS IN REGIONAL OPERATION

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May 20, 2015

LITTLE ROCK – Christopher R. Thyer, United States Attorney for the Eastern District of Arkansas, and David Downing, Assistant Special Agent in Charge of the Little Rock District Office of the Drug Enforcement Administration (DEA), were joined today by DEA New Orleans Division Special Agent in Charge Keith Brown in announcing the charging and arrests of multiple individuals in several federal indictments presented as part of a DEA national initiative.

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Charges for Pharmacists

- Conspiracy to Distribute Schedule II, III and IV controlled substances
- Possession with Intent to Distribute and Distribution of Hydrocodone/Oxycodone
- Conspiracy to Obtain Prescription Narcotics by Fraud, and Obtaining Prescription Narcotics by Fraud
- Drug User/Addict in Possession of a Firearm
- Misprision of a Felony
- Healthcare Fraud

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STATUTORY SENTENCES

- Conspiracy to Possess with Intent to Distribute a Schedule II controlled substance is punishable by not more than 20 years' incarceration in the Bureau of Prisons with a possible fine of up to $1,000,000, and not less than 3 years supervised release.
- Conspiracy to Possess with Intent to Distribute a Schedule III controlled substance is punishable by not more than 10 years' incarceration in the Bureau of Prisons with a possible fine of up to $250,000, and 2 years supervised release.
- Conspiracy to Possess with Intent to Distribute a Schedule IV controlled substance is punishable by not more than 5 years' incarceration in the Bureau of Prisons with a possible fine of up to $250,000, and 1 year supervised release.
- Possession with Intent to Distribute and Distribution of Hydrocodone and Oxycodone, Schedule II controlled substances, is punishable by not more than 20 years' incarceration in the Bureau of Prisons with a possible fine of up to $1,000,000, and not less than 3 years supervised release.
- Possession with Intent to Distribute and Distribution of Hydrocodone, a Schedule III controlled substance is punishable by not more than 10 years' incarceration in the Bureau of Prisons with a possible fine of up to $250,000, and 2 years supervised release.
- Conspiracy to Obtain a Controlled Substance by Fraud and Obtaining a Controlled Substance by Fraud are punishable by not more than 4 years' incarceration in the Bureau of Prisons with a possible fine of up to $250,000, and not more than 3 years supervised release.
- Felon or Drug User/Addict in Possession of a Firearm are punishable by not more than 10 years' incarceration in the Bureau of Prisons with a possible file of up to $250,000, and not more than 3 years supervised release.
- Misprision of a Felony is punishable by not more than 3 years' incarceration in the Bureau of Prisons with a possible file of up to $250,000, and not more than 1 year supervised release.
- Health Care Fraud is punishable by not more than 10 years' incarceration in the Bureau of Prisons with a possible file of up to $250,000, and not more than 1 year supervised release.

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Corresponding Responsibility

21 C.F.R. § 1306.04

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.

- [36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005]

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Corresponding Responsibility

Discussions of common red flags can be found in Final Orders issued by the DEA in administrative proceedings and in presentations given by the Agency in public forums. Red flags may include:

- "Pattern prescribing" – prescriptions for the same drugs and the same quantities coming from the same doctor;
- Prescribing combinations or "cocktails" of frequently abused controlled substances;
- Geographic anomalies;
- Shared addresses by customers presenting on the same day;
- The prescribing of controlled substances in general;
- Quantity and strength;
- Paying cash;
- Customers with the same diagnosis code from the same doctor;
- Prescriptions written by doctors for infirmaries not consistent with their area of specialty;
- Fraudulent prescriptions.

http://deachronicles.quarles.com/2013/08/a-pharmacists-obligation-corresponding-responsibility-and-red-flags-of-diversion/

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Where are the Defendants getting these drugs?

Pharmacy Robberies
Pharmacy Burglaries
Pharmacy Employee Diversion
Doctor Shopping
Fraud

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Burglaries / Robberies in Arkansas?

- 2017 – 12 Break Ins (5/31/17)
- 2016 – 6 Robberies, 68 Break Ins
- 2015 – 5 Robberies, 56 Break Ins
- 2014 – 5 Robberies, 33 Break Ins
- 2013 – 7 Robberies, 48 Break Ins
- 2012 – 8 Robberies, 38 Break Ins
- 2011 – 6 Robberies, 39 Break Ins
- 2010 – 9 Robberies, 44 Break Ins
- 2009 – 3 Robberies, 59 Break Ins
- 61 Break Ins in 2006
- TALK TO YOUR STAFF ABOUT THIS

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Burglaries / Robberies in Arkansas?

- TALK TO YOUR STAFF ABOUT THIS
- HAVE A DISCUSSION
- HAVE A PLAN
- Give them what they want
- Don't ask to see the weapon
- Don't go anywhere with the criminal

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Audit and Shrink Reports

Who already does this?

In and Out Reports
Shrink Reports
Monthly Review
Inventory Management

157 Notifications in 2015
56 Burglaries
5 Armed Robberies

How difficult is it?
How easy is it?
How long does it take?
What special tools do I need?

80

Shrink Report Tool

Drug	Time Period	Ordered	Dispensed	Over Bought (On Shelf)
EXAMPLE ONLY Hydro 10/650	Feb-13	3000	2815	185
Example Only Oxy 30mg IR	2/1/12 - 1/31/13	28500	22153	6347
Example Negative Hydro 10/325	2/1/12 - 1/31/13	11500	14300	-2800
				0
		1200	500	700
		7800	1200	6600
		75000	14530	60470
		14000	25000	-11000
				0
				0
				0
				0
				0
				0
				0
				0
				0
				0
				0
				0
				0
				0

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Shrink Report Tool Monthly

Drug Example 1		January	February	March	April	May	June	July	August	September	October	November	December	TOTAL FOR SHEET	
Purchased	Example Alprazolam 2mg	1500	0	1000	2000	3000	5000	3000	4500	6000	5000	3500	3000	37500	
Dispensed	Example Alprazolam 2mg	541	651	510	391	421	540	571	432	485	546	484	664	6236	
	credits Line here or subtract														
Credits	from Purchases	500												500	
															Ordered more than dispensed or - dispensed
Montly Totals		459	-651	490	1609	2579	4460	2429	4048	5515	4454	3016	2336	30744	more than ordered

Drug Example 2		January	February	March	April	May	June	July	August	September	October	November	December	TOTAL FOR SHEET	
Purchased	Example Hydrocodone 10/650	1500	1000	1000	1500	500	100	1000	2000	2000	2000	500	200	13300	
Dispensed	Example Hydrocodone 10/650	1541	1651	1510	1391	421	1540	1571	1452	1485	1546	1484	1664	17256	
	credits Line here or subtract														
Credits	from Purchases	500												500	
															Ordered more than dispensed or - dispensed
Montly Totals		-541	-651	-510	109	79	-1440	-571	548	515	454	-984	-1464	-4456	more than ordered

Drug Example 3		January	February	March	April	May	June	July	August	September	October	November	December	TOTAL FOR SHEET	
Purchased	Example Hydrocodone 10/325	1500	0	1000	2000	3000	5000	0	0	0	0	0	0	12500	
Dispensed	Example Hydrocodone 10/325	541	651	510	391	421	540	0	0	0	0	0	0	3054	
	credits Line here or subtract														
Credits	from Purchases													0	
															Ordered more than dispensed or - dispensed
Montly Totals		959	-651	490	1609	2579	4460	0	0	0	0	0	0	9446	more than ordered

Drug #	METHADONE 10	January	February	March	April	May	June	July	August	September	October	November	December	TOTAL FOR SHEET
Purchased	Drug Bought	2300	2200	1800	2600	2300								11200
Dispensed	Drug Sold	3035	1970	1880	2320	2388								11593
Credits	credits													0
Montly Totals		-735	230	-80	280	-88	0	0	0	0	0	0	0	-393

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Full Audit Sheet

AUDIT DATE: _____ PHARMACY: _____

ADDRESS: _____

1 DRUG & STRENGTH	2 Starting Inventory Date:	3 Total Purchases	4 Total Accountable For: (2+3)	5 Closing Inventory Date:	6 Should Have Disposition Records For (4-5)	7 Have Disposition Records For:	8 Number (+) Over or (-) Short: (6-7)	% Different (8/6)
Example Drug	123	5000	5123	149	4974	1587	-3387	-68%
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!
			0		0		0	#DIV/0!

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Arkansas Pharmacy Loss

- Totals reported on a SINGLE DEA 106

Hydrocodone/APAP 7.5/650	101,212 tablets
Hydrocodone/APAP 10/650	128,743 tablets
Alprazolam 2 mg	32,485 tablets
Total	262,440 tablets

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Dispensed _____ Ordered _____

	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10
Alprazolam 2mg	480	60	631	663	636	421	721	541	651	510	391	421	540	571	452	485	546	484	664
Alprazolam 2mg	500	1000	500	500	1000	500	500	1500	0	1000	2000	3000	5000	3000	4500	6000	5000	3500	3000
credits	-4500																		
Drug and Strength																			
Hydrocodone 10/650	8181	7966	7851	7644	9491	7610	10048	7321	8050	10152	9348	8596	9345	9601	8929	9426	8992	8846	9636
Hydrocodone 10/650	6000	5000	7500	12000	5000	5000	7500	6000	9000	7000	16000	23000	31000	25500	24000	32000	18000	28500	30000
Hyrdocodone 7.5/650	1228	2166	2041	74	2215	2082	2548	2418	2524	344	2200	2066	2391	2380	2064	2104	1916	2070	2083
Hydrocodone 7.5/650	0	0	0	5000	0	5000	0	4000	6000	0	6000	17500	21000	18000	15000	10000	10000	17000	15000

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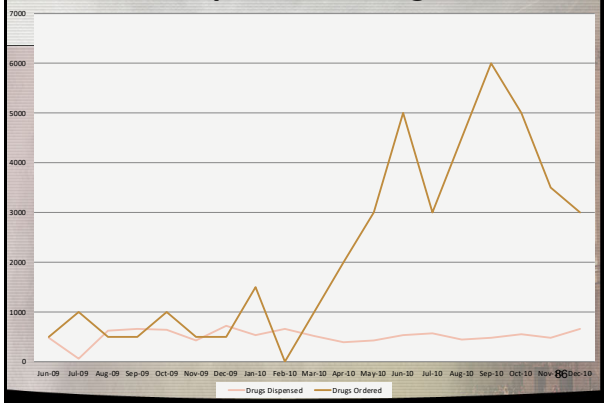
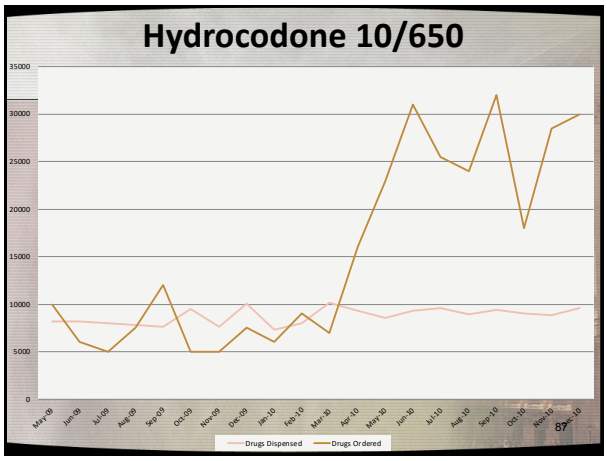
Alprazolam 2mg



86

Hydrocodone 10/650



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Loss Prevention Tools

- Perpetual Inventory
- Visibility (camera systems, inventory systems)
- Witnesses
- Assistance
- Investigative Experience
- Background Checks
- Audit and Shrink Reports

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Audit and Shrink Reports

- Contact wholesaler-request report by NDC of purchases (can be sent in excel format for specific date range or printed at store from wholesaler system and saved in excel format)
- Run a drug usage report from pharmacy system for same date range as above (save in excel format)
- Copy and paste to a new spreadsheet with purchases minus dispensed quantity—should be very close to 1 or 2 bottles of whatever package size you carry
- Check shelves for any drugs that the report indicates you should have a large quantity on hand
- Do an additional report using biennial inventory to compare those drugs that look suspicious (on hand on date of biennial plus drugs ordered from biennial date to date of audit minus drugs dispensed=what you should have on hand)
- Verify on hand quantity on shelf
- Report any losses

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Pharmacy Board Applications

- Review applications with employees
- Criminal Background Checks
- Board of Pharmacy Website →
  - Forms and Instructions
- http://pharmacyboard.arkansas.gov/licenseeInfo/Documents/formsInstructions/PharmacyTechnicianApplicationWeb2016.pdf
- When can you perform defined duties?
  - When you have a permit issued and it is posted in a conspicuous place in a pharmacy you have notified the Board of Pharmacy you are working

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Technician Duties

- Scanning Prescriptions
- Counting Prescriptions
- Labeling Prescriptions
- Inputting Prescriptions
- Pulling stock to fill prescriptions
- Preparing patient bingo cards

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Performing Duties without a Permit?

- Pharmacist can face action
- Pharmacy can face action
- Prospective tech can face action
- Criminal action can also be pursued against the individual performing technician duties

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Board Issues

- Violations of Controlled Substance Laws
  - Diversion for Personal Use
  - Diversion for Distribution
  - Chemical Addictions
- Arkansas Pharmacy Support Group
  - The Arkansas Pharmacy Support Group helps pharmacy professionals who are fighting addiction. We know how to help, because we've been there. If you or someone you know has a problem, call:
  - The Arkansas Pharmacy Support Group HELP LINE (870) 636-0923 or http://www.arpsg.org/

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Case Studies

- Case studies
  - How quickly does diversion happen
  - How long does a break-in take
  - 'Trust' in your employees
  - Review of faulty procedures resulting in loss
- Top Diverted Drugs in Arkansas
  - Hydrocodone Products
  - Benzodiazepines
  - Promethazine with Codeine

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DRUG DIVERSION:

"Any criminal act involving a prescription drug"

DEA

The diverting of legitimate controlled substances (or chemicals) into the Black Market

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Street Values

Alprazolam (Xanax) - $1.00 to $20.00
Zolpidem (Ambien) - $2.00 to $15.00
Promethazine with Codeine Syrup – 1 pint - $200.00 to $400.00 to $1000
Hydromorphone (Dilaudid) - $25.00 to $50.00
Fentanyl Patch - $20.00 to $70.00
Hydrocodone - $.75 to $25.00
Methadone - $8.00 to $50.00
Morphine - $30.00 to $50.00
Oxycodone - $10.00 to $80.00
Tussionex - $5.00 to $40.00

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How do you perform an inventory?

DEA Pharmacist's Manual
SECTION VII – INVENTORY REQUIREMENTS

An "inventory" is a **complete and accurate list** of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an **estimated count or measure** of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

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Inventory Requirements

The C.F.R. requires that the inventory include:
1. The date of the inventory,
2. Whether the inventory was taken at the beginning or close of business,
3. The name of each controlled substance inventoried,
4. The finished form of each of the substances (e.g., 10 milligram tablet),
5. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle),
6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
7. A count of the substance - if the substance is listed in schedule II, an exact count or measure of the contents or if the substance is listed in schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.

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Idiocy and Idiosyncrasies

The Permit Holder and PIC will share responsibility for any inventory and resultant inconsistencies with the inventory.

> "DEA recommends, but does not require, an inventory record include the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory."

DO NOT SPREAD THIS OVER SEVERAL DAYS! Must be done in one day!
KEEP A SECOND COPY OR SCAN – You must be able to produce a copy of this inventory

MUST INCLUDE OUT OF DATE DRUGS OR ANY OTHER DRUGS PULLED FROM INVENTORY

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- Expired or unused drugs returned to pharmacy NO CONTROLS!
- In Clinical Settings – On site waste with minimum of two licensed witnesses – MUST BE WITNESSED – NOT IN RETAIL
- Use of Reverse Distributor (DEA 222)
- Are returns actually checked for potential tampering? If not, how do you know your documentation is accurate?
- Random audit of returns

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Employees

- Clear policy on diversion/impairment
- Drug testing policy
  - Screen on hire?
  - For cause?
  - Random?
- Background checks
- Controlled Access to Pharmacy
- Establish an audit process for controlled substance transactions
- Monthly Audit and Shrink Reports for control and accountability

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"Red Flags"

- Changes in work habits, behavior, physical appearance
- Major change or chaos in personal life
- Change in Controlled Substance usage patterns
- Unexplained absences on a regular basis during work
- Excessive "accidents" broken vials, spills etc.
- Patient's complaints due to being consistently short on tablets
- Personnel "in the wrong place" without good reasons
- Personnel at work early or stays late on a regular basis

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Last Points

Prescription Drugs are Worth More Once they are Stolen or Diverted

Circle of Addiction shows that as we do a better job with Prescription Drug Abuse, Issues with Heroin will increase

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Questions?

Please do not hesitate to call us with regulatory or practice questions. If you are a licensed pharmacist in Arkansas, you should be asking us what our regulations mean and how to follow appropriate procedures to maintain your license.

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Post Test Questions

1. What are potential steps you can take to protect your controlled substance inventory?
   - A. Limit Access to Controls by Authorized Personnel only
   - B. Limit Access to Inventory Adjustments and Ordering for Controlled Substances
   - C. Do Shrink Reports for Controlled Substances
   - D. Perpetual Inventory
   - E. Surveillance systems with a Public View Monitor
   - F. All of the Above plus several other steps.

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Post Test Questions

2. Naloxone can only be purchased in Arkansas with a prescription from your physician?

A. True
B. False

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Post Test Questions

3. Prescribers are required to check the PDMP whenever they are prescribing schedule 2 opioids after surgery?

A. True
B. False

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Post Test Questions

4. "Authorized Generics" may automatically be substituted by a pharmacist?

A. True
B. False

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Future Questions?

Arkansas State Board of Pharmacy

pharmacyboard.arkansas.gov

www.arkansas.gov/asbp

(501) 682 - 0190

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