Arkansas Pharmacy Law Update

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Executive Director
Arkansas State Board of Pharmacy

Disclosure

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

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

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 Drug Summit

- Please plan to attend the **2019 Arkansas Prescription Drug Abuse Prevention Summit on November 14, 2019** at the Hot Springs Convention Center.
- We will offer four breakout tracks: **Clinical**, Criminal Justice, Education/Prevention and Counseling/Recovery.
- Early bird registration should open soon! Reserve your seat as space is limited.
- https://arkansasag.eventsmart.com/

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/

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State Board of Pharmacy

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

Board of Pharmacy Regulations

Statute Changes that will impact pharmacy practice in 2019 and beyond

ACT 173

AN ACT TO REMOVE OBSOLETE LANGUAGE REGARDING THE STAGGERING OF TERMS FOR A MEMBER OF THE ARKANSAS STATE BOARD OF PHARMACY; AND FOR OTHER PURPOSES.

Sponsored by Representative Marsh Davis and Senator Mathew Pitsch

ACT 174

AN ACT TO ABOLISH THE ADVISORY COMMITTEE TO THE ARKANSAS STATE BOARD OF PHARMACY; AND FOR OTHER PURPOSES.

Sponsored by Representative Marsh Davis and Senator Mathew Pitsch

Removed language outlining the 7 member committee to make recommendation to the board on the merit of all regulations dealing with medical equipment, legend devices, and medical gasses which are proposed to the Board before they are adopted by the Board.

ACT 175

AN ACT TO ABOLISH THE ADVISORY COMMITTEE FOR HOSPITAL PHARMACIES; AND FOR OTHER PURPOSES.

Sponsored by Representative Marsh Davis and Senator Mathew Pitsch

Removed language outlining the 5 member committee required to advise with the board concerning the rules, regulations, and standards to be promulgated by the board under this subchapter. No rule, regulation, or standard shall be promulgated by the board until it has consulted with the committee.

ACT 309

AN ACT TO REMOVE DUPLICATIVE LANGUAGE REGARDING THE PRESCRIPTIVE ABILITIES OF PHYSICIAN ASSISTANTS, OPTOMETRISTS, AND ADVANCED PRACTICE REGISTERED NURSES; TO PROVIDE THAT PHARMACISTS MAY FILL PRESCRIPTIONS FOR ALL HEALTHCARE PROFESSIONALS WITH PRESCRIPTIVE AUTHORITY TO THE EXTENT OF THE SCOPE OF PRACTICE FOR THAT HEALTHCARE PROFESSION; AND FOR OTHER PURPOSES.

Sponsored by Representatives Justin Boyd and Marsh Davis as well as Senator Mathew Pitsch

ACT 637

AN ACT TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL PRODUCT SUBSTITUTIONS; AND FOR OTHER PURPOSES.

Sponsored by Representative Magie

(d)(1) Within five (5) business days after dispensing an interchangeable biological product that has been substituted for a biological product, the dispensing pharmacist or his or her designee shall record the specific interchangeable biological product provided to the patient, including without limitation the name of the interchangeable biological product and the manufacturer of the interchangeable biological product.

(2) The record shall be electronically accessible to the prescriber through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(3) If requested by a prescriber, a pharmacist shall communicate to the prescriber within five (5) business days using facsimile, telephone, electronic transmission, or other prevailing means that an interchangeable biological product has been dispensed.

(4) A communication is not required when:

(A) An interchangeable biological product does not exist for the prescribed biological product; or

(B) A refill prescription for a biological product is not substituted with an interchangeable biological product on a subsequent filling of the prescription.

(5) The pharmacist or pharmacy shall maintain a record of *biological products dispensed for at least two (2) years.*

(6) Under subdivision (d)(2) of this section, the dispensing pharmacist or prescriber is not:

(A) Required to show proof that a prescriber has access to the record in any type of payment audit conducted by a payer or pharmacy benefit manager; or

(B) Subject to disciplinary action or civil penalties for failure to ensure that the record is accessible or for failure to access the record.

ACT 651

AN ACT TO AMEND THE DEFINITION OF "PRACTICE OF PHARMACY" TO AUTHORIZE A PHARMACIST TO INITIATE THERAPY AND ADMINISTER OR DISPENSE, OR BOTH, CERTAIN TYPES OF TOBACCO CESSATION; TO AUTHORIZE A PHYSICIAN TO ADMINISTER OR DISPENSE, OR BOTH, CERTAIN TYPES OF TOBACCO CESSATION; AND FOR OTHER PURPOSES.

Sponsored by Representative Les Eaves

ACT 593

AN ACT TO AMEND THE PRESCRIPTIVE AUTHORITY OF AN ADVANCED PRACTICE REGISTERED NURSE; AND FOR OTHER PURPOSES.

Sponsored by Representative Justin Gonzales and Senator Kim Hammer

(B) An advanced practice registered nurse's prescriptive authority also extends to drugs listed in Schedule II if:

(i) The prescription is for an opioid and the prescription is only for a five-day period or less; or

(ii) The prescription is for a stimulant and meets the following criteria:

(a) The prescription was originally initiated by a physician;

(b) The physician has evaluated the patient within six (6) months before the advanced practice registered nurse issues a prescription; and

(c) The prescription by the advanced practice registered nurse is to treat the same condition as the original prescription.

Act 447 - 1/1/2021 or later

AN ACT TO REQUIRE MANDATORY ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES; AND FOR OTHER PURPOSES

Sponsored by Senator Hammer and Representative Boyd

(c) Except as provided in subsection (d) of this section, a practitioner shall not issue a prescription for a controlled substance included in Schedule II through Schedule VI unless the prescription is made by electronic prescription from the practitioner issuing the prescription to a pharmacy. (d) A practitioner may issue a prescription for a controlled substance included in Schedule II through Schedule VI by written, oral, or faxed method if issued: (1) By: (A) A veterinarian; or (B) A practitioner: (i) To be dispensed by a pharmacy located outside of the state…

Act 447 continued

Other exemptions then:

(2) In circumstances in which electronic prescribing is not available due to temporary technological or electrical failure; or

(3) When the practitioner and the dispenser are the same entity.

(e)(1) A pharmacist or pharmacy that receives a written, oral, or faxed prescription for a controlled substance included in Schedule I through Schedule VI is not required to verify that the prescription properly falls under one (1) of the exceptions listed in subsection (d) of this section.

(2) A pharmacist may continue to dispense a controlled substance from an otherwise valid written, oral, or faxed prescription that is consistent with state law or rules or federal law and regulations.

ACT 504

AN ACT CONCERNING HEMP-DERIVED CANNABIDIOL; AND FOR OTHER PURPOSES.

Sponsored by Representative Justin Boyd and Senator David Wallace

SECTION 1. Arkansas Code § 5-64-101(15)(B), concerning the definition of "marijuana" under the Uniform Controlled Substances Act, is amended to read as follows:

(B) “Marijuana” does not include:

ACT 504

(vi) Hemp-derived cannabidiol that:

(a) Contains not more than three-tenths of one percent (0.3%) of tetrahydrocannabinol (THC) on a dry weight basis as verified by a nationally accredited laboratory for quality, purity, and accuracy standards; and

(b) Is not approved by the United States Food and Drug Administration for marketing as a medication; or

CBD is it Legal

1st ? – Do you have a couple of hours?
Legal for what? Industrial use? Recreational Use? Health conditions? Seizures? For a pharmacy to sell? Once again for what?
Cautions: Read:

Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

CBD is it Legal 2

"In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases…

CBD is it Legal 3

Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities. The FDA has sent warning letters in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food…"

NC Dept of Agriculture

Please be advised of the following regarding CBD products in the marketplace:

- It is a prohibited act under section 301(ll) of the FD&C Act [21 U.S.C. 331(ll)] to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. 355] or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

- CBD is the active ingredient in the approved drug product Epidiolex, a drug product that has been approved under section 505 of the federal Food, Drug & Cosmetic Act ("FD&C Act"). Substantial clinical investigations have been instituted for CBD and the existence of such investigations have been made public.

- Since CBD is the active ingredient in the approved drug product Epidiolex, it is currently excluded from being a dietary supplement under section 201(ff)(3)(B)(i) and (ii) of the FD&C Act.

- CBD products marketed with claims to prevent, mitigate, diagnose, treat or cure serious diseases (aka "health claims") indicate that the products are intended for use as drugs under the FD&C Act [21 U.S.C. 321(g)(1)]. Section 201(p) of the FD&C Act [21 U.S.C. 321(p)] specifies that new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA. CBD in products other than the approved drug Epidiolex and which makes health claims would be a new drug that cannot legally be introduced into interstate commerce.

- North Carolina has routinely adopted by reference the federal Food, Drug & Cosmetic Act and implementing regulations. The violation of these federal laws and regulations would equally be a violation of state laws and regulations.

Warning Letters and Test Results for Cannabidiol-Related Products

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Over the past several years, FDA has issued several warning letters to firms that market unapproved new drugs that allegedly contain cannabidiol (CBD). As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware purchasing and using any such products.

Content current a

of:

04/02/2019

2019 Warning Letters

2018 Warning Letters

2017 Warning Letters

2016 Warning Letters

Firm	Product	State	Purchase Website	Product Size CBD Label Claim	Lab Results (mg/g)			Lab Results %(w/w)		
					CBD	Δ9-THC	Other Cannabinoids	CBD	Δ9-THC	Other Cannabinoids
Cali Stores	CBDy CBD Supplement Tincture	CA	calistores.com	1oz 200mg CBD	--	0.029	THCA: 0.16	--	0.0029%	THCA: 0.016%
Cali Stores	Hermosa Farm CannaHoney w/ CBD - 6oz	CA	calistores.com	6oz N/A CBD	--	--	THCA: <0.01	--	--	THCA: <0.001%

CBD is it Legal

ONCE AGAIN
Legal for what?
Industrial use?
For a pharmacy to sell?
For what reason?
Recreational Use?
Health conditions?
Seizures?
What if someone uses your product and tests positive for THC?
Loses their Job because of it?

“Medical Marijuana”

Safety-sensitive position is defined by the Arkansas Medical Marijuana Amendment of 2016 Amendment 98 as “any position involving a safety sensitive function pursuant to federal regulations governing drug and alcohol testing adopted by the United States Department of Transportation or any other rules, guidelines, or regulations adopted by any other federal or state agency. “Safety sensitive position" also means any position designated in writing by an employer as a safety sensitive position in which a person performing the position while under the influence of marijuana may constitute a threat to health or safety, including without limitation a position: that requires any of the following activities:

(a) Carrying a firearm;
(b) Performing life-threatening procedures;
(c) Working with confidential information or documents pertaining to criminal investigations; or
(d) Working with hazardous or flammable materials, controlled substances, food, or medicine; or
(ii) In which a lapse of attention could result in injury, illness, or death, including without limitation a position that includes the operating, repairing, maintaining, or monitoring of heavy equipment, machinery, aircraft, motorized watercraft, or motor vehicles as part of the job duties.”

“Medical Marijuana”

(3) (A) An employer shall not discriminate against an applicant or employee in hiring, termination, or any term or condition of employment, or otherwise penalize an applicant or employee, based upon the applicant’s or employee’s past or present status as a qualifying patient or designated caregiver.

(B) A cause of action shall not be established against an employer based upon, and an employer is not prohibited from, any of the following actions:

(i) Establishing and implementing a substance abuse or drug-free workplace policy that may include a drug testing program that complies with state or federal law and taking action with respect to an applicant or employee under the policy;

(ii) Acting on the employer's good faith belief that a qualifying patient;

(a) Possessed, smoked, ingested, or otherwise engaged in the use of marijuana while on the premises of the employer or during the hours of employment; or

(b) Was under the influence of marijuana while on the premises of the employer or during the hours of employment, provided that a positive test result for marijuana cannot provide the sole basis for the employer's good faith belief; or

(iii) Acting to exclude a qualifying patient from being employed in or performing a safety sensitive position based on the employer's good faith belief that the qualifying patient was engaged in the current use of marijuana.

(C) The authorized or protected actions of an employer under this subdivision (f)(3) include without limitation:

(i) Implementing, monitoring, or taking measures to assess, supervise, or control the job performance of an employee;

(ii) Reassigning an employee to a different position or job duties;

(iii) Placing an employee on paid or unpaid leave; (iv) Suspending or terminating an employee;

(v) Requiring an employee to successfully complete a substance abuse program before returning to work;

(vi) Refusing to hire an applicant; or

(vii) Any combination of the actions listed in subdivisions (f)(3)(C)(i) - (f)(3)(C)(vi) of this section.

Other Acts

Act 319 – Collective Rule Making

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act319.pdf

Act 426 – Temporary and Expedited Licenses

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act426.pdf

Act 516 – Prohibition of Microchipping of Employees

Act 517 – Deadline to File Rules

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act517.pdf

Act 600 – Red Tape Reduction Sunrise and Sunset Act

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act600.pdf

Act 820 – Occupational Licensure for Active Members of the Military

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act820.pdf

Act 893 – Exception to APA to change "Regulation" to "Rule"

Act 910 – Transformation 2047 Pages 1539-1542

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act910.pdf

Act 990 – Criminal Background Checks – Delete language referring to Moral Turpitude

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act990.pdf

Act 1028 – Requirement to have the ability to provide audio or video record of all public meetings

http://www.arkleg.state.ar.us/assembly/2019/2019R/Acts/Act1028.pdf

ACT 820 of 2017

- 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

ACT 820 of 2017

- 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

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

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.

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.

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:

“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

2015 Prescription Drugs Dispensed

Drug	# of RX	Quantity	Average Per RX
Hydrocodone	1,714,600	111,987,967	65.31
Tramadol	762,766	58,672,813	76.92
Alprazolam	689,292	44,543,911	64.62
Oxycodone (all)	646,333	50,244,192	77.74
Zolpidem	568,550	17,718,692	31.16

2016 Prescription Drugs Dispensed

Drug	# of RX	Quantity	Average Per RX
Hydrocodone	1,691,895	108,648,138	64.22
Tramadol	770,322	59,400,035	77.11
Alprazolam	690,386	43,493,832	63.00
Oxycodone (all)	652,912	49,716,481	76.15
Zolpidem	552,912	17,402,324	31.47

2017 Prescription Drugs Dispensed *Arkansas Residents Only

Drug	# of RX	Quantity	Average Per RX
Hydrocodone	1,521,564	94,033,249	61.8
Tramadol	712,349	54,156,328	76.0
Alprazolam	631,709	39,355,560	62.3
Oxycodone (all)	588,911	43,597,818	74.0
Zolpidem	510,214	16,178,026	31. 7

2018 Prescription Drugs Dispensed *Arkansas Residents Only

Drug	# of RX	Quantity	Average Per RX
Hydrocodone	1,369,322	76,613,992	55.95
Tramadol	702,668	45,130,539	64.23
Morphine	116,847	5,542,745	47.44
Oxycodone (all)	534,590	34,659,919	64.83
Codeine	192,613	7,734,391	40.16

Total Morphine Milligram Equivalents Dispensed* in Arkansas per Year

Year	Total Morphine Milligram Equivalents
2014	3,038,577,510
2015	3,103,113,931
2016	2,966,072,413
2017	2,672,992,851
2018	2,189,807,406

The percent decrease in total MME from the year 2014 to 2018 is **28%.**

***Note: Filled by AR residents**

Source: Arkansas Prescription Drug Monitoring Program

Top-Selling* Prescription Drugs by Class in Arkansas in 2018

Rank	Drug Type	Pills Sold	Number of Prescriptions
1	Opioid	186,424,459	3,283,428
2	Benzo	86,029,755	1,739,022
3	Stimulant	26,846,338	762,057
4	Zolpidem	14,236,720	499,592
5	Muscle Relaxant	5,869,053	93,071
Total		319,406,325	6,377,170

***Note: Filled by AR residents**
Source: Arkansas Prescription Drug Monitoring Program

PDMP ISSUES of CONCERN

HOW GOOD IS THE SYSTEM

- Only as good as the information you feed into it.
- PROBLEMS! problems!
- FAKE DEA NUMBERS Such as AA1111119 and AA1234563 should never be used to report a controlled substance into the system. This is an immediate indication of a prescription with incorrect information on it showing that a prescription has likely been filled incorrectly.
- INCORRECT prescriber attributed to prescriptions
  - Must have the correct prescriber and DEA number attached to each prescription. If this is reported to you it should be fixed immediately. Both the Arkansas Department of Health and Board of Pharmacy get calls on these and will expect it to be fixed.

20-7-604 (c)

(c) Each dispenser required to report under subsection (b) of this section shall submit to the department by electronic means information that shall include without limitation:

(1) The dispenser's identification number;

(2) The date the prescription was filled;

(3) The prescription number;

(4) Whether the prescription is new or is a refill;

(5) The National Drug Code for the controlled substance that is dispensed;

(6) The quantity of the controlled substance dispensed;

(7) The number of days' supply dispensed;

(8) The number of refills ordered;

(9) (A) A patient identifier.

(B) A patient identifier shall not be a Social Security number or a driver's license number;

(10) The patient's name;

(11) The patient's address;

(12) The patient's date of birth;

(13) The patient's gender;

(14) The prescriber's identification number;

(15) The date the prescription was issued by the prescriber; and

(16) The source of the payment for the prescription.

Exempt CV Cough Syrup

Watch for further guidance but in short:

Both federal and state regulations require you to document these in:

"A bound record book (which must be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04) for dispensing of controlled substances is maintained by the pharmacist, which contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser;"

Additionally, Arkansas code section 20-7-604 (b) requires:

(1) Each dispenser shall submit to the department information regarding each controlled substance dispensed.

(2) A dispenser located outside Arkansas and licensed and registered by the Arkansas State Board of Pharmacy shall submit to the department information regarding each controlled substance prescription dispensed to an ultimate user whose address is within Arkansas.

(3) The State Board of Health shall create a controlled substances database for the Prescription Drug Monitoring Program.

Exempt CV Continued

What to do?

Put it in the Bound Log Book to meet regulatory requirement set #1 then also put it in the prescription system for your pharmacy to be reported into the PDMP for issue #2.

Pharmacy can be recorded as the prescriber and this should be able to match up to the paper bound log book for other requirements. This will also help with any tracking to be sure that people are not shopping this system to obtain more than they should of the exempt cough syrup.

OR JUST DO NOT SELL IT

New Regulations

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

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.

(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.

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 pharmacist~~s~~ and the transferring individual~~pharmacist~~ records the following information:

(A) ~~Write the word "Void" on the face of the invalidated~~ Void the transferred 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~~ individual receiving the prescription information.

(C) Record the date of the transfer and the name of the ~~pharmacist~~ individual transferring the information.

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

(1) ~~Write the word "transfer" on the face of the~~ Record that the prescription is a 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~~ individual 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.

(f) Transfers of controlled substances must follow federal law and regulations.

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.

(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)

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

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- 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.

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.

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.

CURRENT PROBLEMS WE SEE

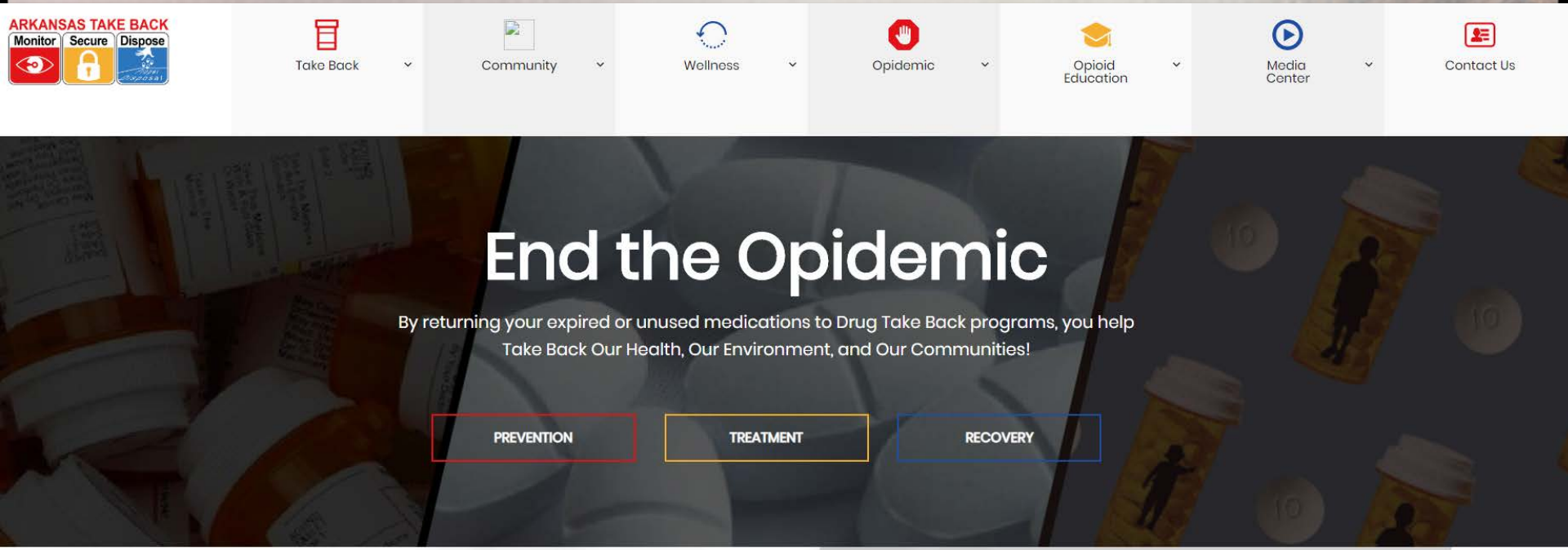
- CE TOMORROW!
- Compounding Inspections…
  - Compounding clean rooms
  - Certifications?
- Transfer of controlled substances on “Hold”
- 222 forms – MUST BE COMPLETED
- PDMP Login – Individual not Group
- CSOS Login – Individual not Group
- EMERGENCY SERVICES

Take BACK

APRIL 2019 Take BACK

28,073 Pounds

www.artakeback.org



Medication-Assisted Treatment

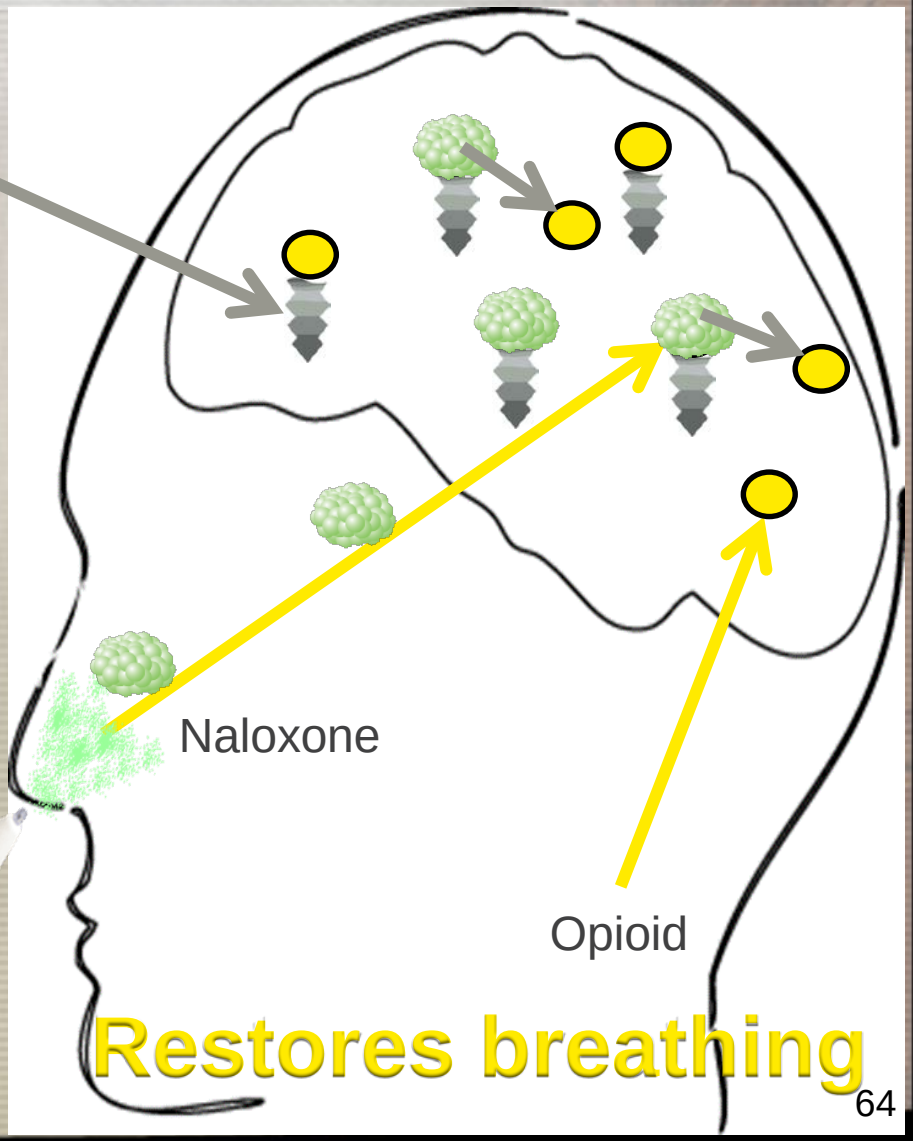
- Medication-Assisted Treatment (MAT) is the use of medications, **in combination with counseling and behavioral therapies**, to provide a “whole-patient” approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can help some people struggling 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/

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



www.artakeback.org

- Updated Website with New Info

Resources/News

Make sure you check out the resources section of our website for helpful and educational information about the growing problem in our state.

FAQ's

Our FAQ section of the website has answers to common questions you may have. Keep checking back, we update them regularly!

Myths & Facts

What are some of the common disposal myths? Find out the facts here.

Partners

Businesses and Organizations that have partnered with us on this initiative.

Helpful Links

Helpful links to other websites and information. Keep checking back, we are adding more links on a regular basis.

Media & Videos

Commercials, PSA's, and more about the Take-Back can be found here.

Latest from the ARTake back

Take-Back this Saturday

24-Apr-2013

Arkansas's next prescription drug take back will be held Saturday, April 27, 2013, from 10 AM until 2 PM.

We have a problem in Arkansas

24-Apr-2013

Our teenagers are dying from recreational prescription drug abuse

Old Stuff Worth Repeating

Audit and Shrink Reports

TOOLS?

Board of Pharmacy Site

FAQs

Shrink Report Tool

https://pharmacyboard.arkansas.gov/faqs12

DEA 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
2018				

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

Reporting

Reports to professional licensing boards

Arkansas Dept. of Health

DEA Notification (Form 106)

Consideration of theft/criminal prosecution

Involvement of local law enforcement

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.

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

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

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

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]

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/

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

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
				0

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	452	485	546	484	664	6256	
Credits	credits Line here or subtract from Purchases	500												500	
Montly Totals		459	-651	490	1609	2579	4460	2429	4048	5515	4454	3016	2336	30744	Ordered more than dispensed or - dispensed 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	credits Line here or subtract from Purchases	500												500	
Montly Totals		-541	-651	-510	109	79	-1440	-571	548	515	454	-984	-1464	-4456	Ordered more than dispensed or - dispensed 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	credits Line here or subtract from Purchases													0	
Montly Totals		959	-651	490	1609	2579	4460	0	0	0	0	0	0	9446	Ordered more than dispensed or - dispensed 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	

Full Audit Sheet

AUDIT DATE: _____ PHARMACY: _____

ADDRESS: _____

1	2	3	4	5	6	7	8	
DRUG & STRENGTH	Starting Inventory	Total Purchases	Total Accountable For:	Closing Inventory	Should Have Disposition Records For	Have Disposition Records For:	Number (+) Over or (-) Short:	% Different
	Date:		*(2+3)*	*Date:*	*(4-5)*		*(6-7)*	*(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!

Loss Prevention Tools

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

Technician Duties

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

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

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

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.

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.

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

- 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

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

Upcoming Meetings

Board of Pharmacy Meeting

June 11-13, 2019

11th will be streamed on AETN ARCAN (Arkansas Citizens Access Network)

The Arkansas Educational Television Network and Gov. Asa Hutchinson announced today the launch of AR-CAN – the Arkansas Citizens Access Network, aetn.org/arcan – a web-based network that will provide Arkansans with livestreaming coverage of legislative proceedings, board and commission meetings, and other government hearings and activities.

Other Important Contacts

Arkansas Dept. of Health

Pharmacy Services/Drug Control

501-661-2325

PDMP

501-683-3960

http://www.arkansaspmp.com/

Arkansas DEA

Diversion Investigators

501-217-6500

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.

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.

Post Test Questions

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

A. True

B. False

Post Test Questions

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

A. True

B. False

Post Test Questions

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

A. True

B. False

Future Questions?

Arkansas State Board of Pharmacy

ar.pharmacy

pharmacyboard.arkansas.gov

www.arkansas.gov/asbp

(501) 682 - 0190