

# Arkansas Pharmacy Board Update



John Clay Kirtley, Pharm.D.  
Executive Director  
Arkansas State Board of Pharmacy

# Disclosure

The background of the slide features a faded, sepia-toned photograph of a grand classical building. The building is characterized by a series of tall, fluted columns supporting a heavy entablature. The perspective is from a low angle, looking up at the structure, which creates a sense of scale and grandeur. The overall tone is historical and formal.

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

# Objectives

---

- Discuss recent and upcoming regulatory updates
- Discuss the importance and impact of recent legislative changes for practice



# Quick Thoughts in Healthcare

- Why do we fight each other?
  - Money, Bad information, Bad attitudes
- Why do we lack updated knowledge?
  - Often we fail to seek knowledge and have the attitude that it should be brought to us
- Why don't we help each other learn?
  - See Above
- What can we work together on?
  - Everything, Opioids, Scope
- How can we support each other?
  - Communication, Education

# So who has had a “slow” year?

- Supreme Court Case
- PBM Issues with the Board of Pharmacy
- Prep Act Updates...
- Rule Suspensions
- Deregulation
- Legislative Session Changes
- CONTROLLED SUBSTANCE ISSUES
- New Staff?

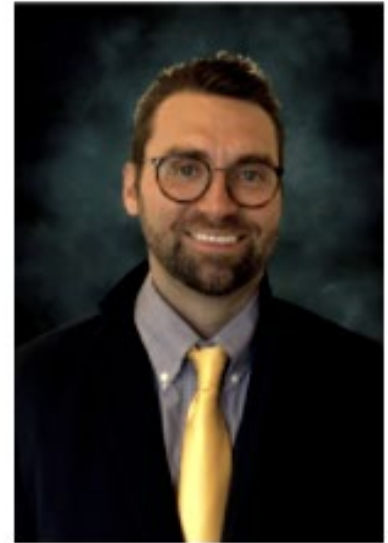
# Our Team of Inspectors



**Kevin Robertson,  
Pharm.D.**



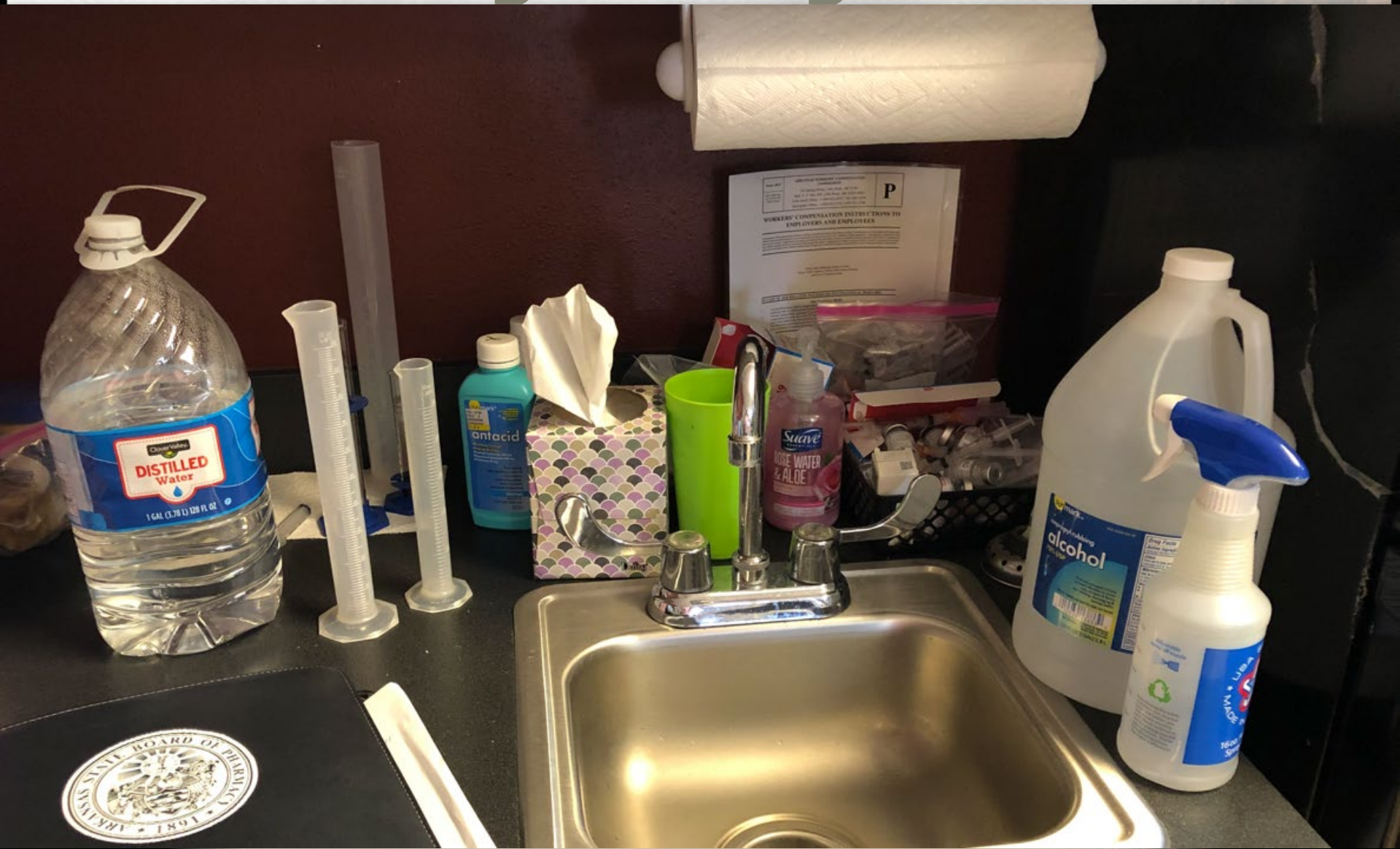
**Cindy Fain, P.D.**



**Brandon Holland,  
Pharm.D.**



# Something Wrong?



# PREP Act Amendments

- NOPE, NOT GOING OVER ALL THAT MADNESS – We would be here all day long.
- BUT a few points are in order:
- “This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.”
- MONOCLONAL ANTIBODY ordering and administration:
  - Already in the Pharmacist Scope in Arkansas as a Passive Immunization
  - IV administration usually a team approach with nursing
  - Subcutaneous Administration
  - MONOCLONAL ANTIBODY PLAYBOOK



# PREP Act Amendments Cont

- In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing

# Elimination of Barriers

- Remove Endorsement Requirements to areas of practice
  - You have a doctoral level of education so why do you need an endorsement for:
    - MTM
    - Disease State Management
    - Nursing Home Consulting
    - Collaborative Practice Agreements with Physicians



# Elimination of Barriers Immunizations

- Restrictions of age for treatments and administration of ACIP indicated immunizations?
- Pharmacy Technicians able to administer immunizations
  - Old Discussion – techs should be able to give shots, nobody ever got hurt from a tech giving a shot.... (same authority as a pharmacist)
  - New Discussion – Pharmacists have autonomy to order and administer immunizations without the need for protocols, physician agreements, authority documents...
    - Pharmacists with independent authority to order and deliver can also DELEGATE the administration to a trained pharmacy technician

# COVID 19 Responses - CONT

The Board of Pharmacy has the ability on a case by case basis of need to review and consider approval for the following (if you have interest in pursuing this you need to contact the Board of Pharmacy office):

- Ability for a pharmacist to perform order entry, order verification, prescription input review and/or prescription processing off-site. This consideration does not mean that a pharmacy can operate without a pharmacist being present on site in the pharmacy to supervise activities and perform final checks on products in pharmacies. This also does not allow for pharmacy technicians to work off site. While currently available to hospital pharmacies, we can allow for retail permits as well by temporary waiver and can waive the required Board appearance for temporary approval.
  - 04-02-0012 – RETAIL PHARMACY OFF SITE ORDER ENTRY (currently limited between licensed retail pharmacies)
  - 04-05-0004 - OFF SITE ORDER ENTRY (hospital)



# COVID Treatment Off Label

Early on there were critical shortages Hydroxychloroquine and guidance largely focused on the fact that it was not recommended for use with COVID without involving an infectious disease physician.

Some supply avenues also limited the use of the donated or supplied HCQ to RA and Lupus

Our office received calls daily asking us to:

A: Ban all use of these products other than for RA and Lupus patients

B: Force pharmacies to fill any prescriptions for these products from a prescriber no matter the indication

Lots of calls from out of state pharmacies and even compounders wanting waivers to ship in critical need medications without any proof of a critical need.

# Hydroxychloroquine CONT

TO BE CLEAR, THE ADH GUIDANCE IS NOT A “BAN” OR PROHIBITION ON THE OFF-LABEL USE OF CHLOROQUINE (CQ) AND HYDROXYCHLOROQUINE (HCQ) TO TREAT COVID-19

Furthermore, the Arkansas State Board of Pharmacy has never issued a ban on the dispensing of these products for off-label usage. We would remind you that any new prescriptions must be counseled on which would include potential side effects or cautions.

This was a hotly discussed topic on 8/31/2020 at the Capitol. The health-related boards underneath the ADH umbrella published the ADH statement that was released. Many individuals and healthcare providers took the ADH statements as outright BAN on the use of these medications for COVID.



# IVERMECTIN ???

- Dewormer
- Everyone has done their “research”
- Board of Pharmacy perspective is that pharmacists can use their professional judgement when choosing to fill these prescriptions.
- We recognize that this medication is also in short supply at this time.
- PLEASE DO NOT RECOMMEND LARGE ANIMAL MEDS FROM THE FEED STORE<sup>15</sup>

# Hurricane Impacts



Welcome to 2021 and Hurricane Season again

Louisiana got hit hard and there seem to be 2 major disruptions

- Electrical loss

- Physical damage

Unlike previous issues we have seen along the lines of Katrina, this has displaced some individuals and shut down some pharmacies but not to the levels seen with previous emergencies.

Non controlled vs Controlled substances



# Arkansas Drug Summit

- Please plan to attend the **2021 Arkansas Prescription Drug Abuse Prevention Summit on November 16, 2021** in Rogers, AR.
- We will offer breakout tracks: **Clinical**, Criminal Justice, Education/Prevention and Counseling/Recovery.
- Put it on your calendar and GET YOUR LIVE CE.

CE requirements have **NOT** changed and you have until 12/31/2021 to get your CE as a pharmacist.

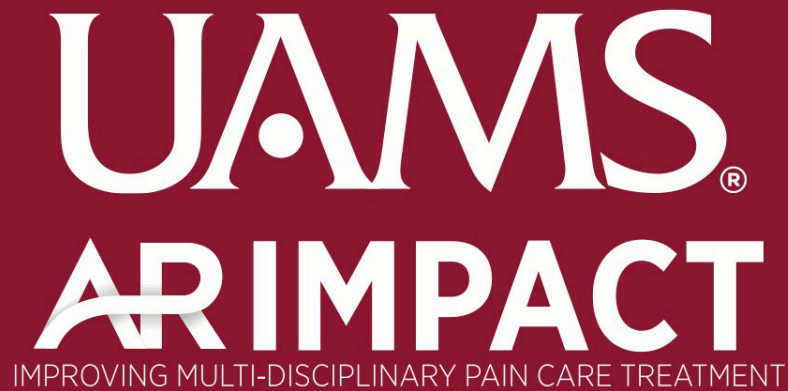
30 hours total

12 live hours

12 ACPE Accredited hours

# Other CE Available

- AR-IMPACT is a weekly free interactive televideo program offering free CME credit held each Wednesday, from 12 to 1 p.m. <https://arimpact.uams.edu/>
- APA has had offerings through AAHP for members of AAHP
- Tons of Free, Live CE if you look around





# Protocols on Board Website

## NALOXONE Protocol Updated:

The prescriber of record for any pharmacy related paperwork may be listed as Dr. Appathurai Balamurugan (Dr. BALA) with ADH or the deciding pharmacist so that any questions back on this would be directed to the pharmacy and pharmacist using this protocol.

FYI on the other Naloxone programs with Drug Director and CJI we have over 1,100 saves so far!

NICOTINE REPLACEMENT THERAPY STATEWIDE PROTOCOL

Developed with APA

# NICOTINE Replacement Therapy

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



# Arkansas Act 651

- SB505 – ACT 651 TO MANDATE THE COPRESCRIPTION OF AN OPIOID ANTAGONIST UNDER CERTAIN CONDITIONS; AND TO AMEND THE NALOXONE ACCESS ACT.
- <https://www.arkleg.state.ar.us/Bills/Detail?id=sb505&ddBienniumSession=2021%2F2021R&Search=>

# Arkansas Act 651

## Act 651 Current Policy Draft Option

1. Except as provided below, a healthcare professional shall coprescribe an opioid antagonist to a patient who does not have an existing prescription for an opioid antagonist when prescribing or dispensing an opioid if:
  - i. The opioid dosage prescribed or dispensed is equal to or in excess of fifty morphine milligram equivalents (50 MME) per day for 5 days or longer;
  - ii. A benzodiazepine has been prescribed or dispensed for the patient in the past year or will be prescribed or dispensed at the same time as the opioid; or
  - iii. The patient has a history of opioid use disorder, substance use disorder or drug overdose.
2. If a healthcare professional does not believe that it is in the best interest of a patient to coprescribe an opioid antagonist, the healthcare professional shall make documentation to that effect as provided in the guidance or rules of the appropriate licensing entity.
3. A healthcare professional who coprescribes an opioid antagonist as required shall provide counseling and patient education to a patient, or a patient's parent or guardian if the patient is less than eighteen (18) years of age, as provided in the guidance or rules of the appropriate licensing entity.
4. A healthcare professional who fails to coprescribe an opioid antagonist as required under this guidance and Arkansas Statutes may be referred to the appropriate licensing board for administrative sanctions or disciplinary action.
5. This guidance does not apply to a patient receiving hospice or other end-of-life care.

# What about other oddities

- Do you require written consent of a patient for transfers?
- Does a pharmacy have to disclose conflicts of interest or ownership interest with clinics or other health facilities?
- Is there a prohibition on data mining for clinics or hospitals that own pharmacies?



# Arkansas Act 1053

- TO REQUIRE WRITTEN CONSENT OF A PATIENT TO TRANSFER A PRESCRIPTION FROM A PHARMACY; TO REQUIRE CERTAIN DISCLOSURES OF OWNERSHIP INTEREST OR POSSIBLE CONFLICTS OF INTEREST; AND TO PROHIBIT DATA MINING OF PATIENT INFORMATION
- <https://www.arkleg.state.ar.us/Acts/FTPDocument?path=%2FACTS%2F2021R%2FPublic%2F&file=1053.pdf&ddBienniumSession=2021%2F2021R>.

# Arkansas Act 1053

- A pharmacy, pharmacist, employee of a pharmacy, or entity who owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, health clinic, rural health center, federally qualified health center, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager affiliate shall not request or solicit:

(1) Refill requests for prescription medications from a prescriber for a patient who has not previously filled prescriptions with the pharmacy without express written consent for each individual prescription requested; or

(2) New prescription medications from a prescriber for a patient who has not previously filled prescriptions with the pharmacy without express written consent for each individual prescription requested.

# Arkansas Act 1053

- Section regarding Out of State Pharmacies that must obtain express consent to provide pharmacist services before any prescription medication being processed, filled, mailed, or delivered to a patient...
- Required disclosure of conflicts of interest
- Cannot access and utilize patient information including medical information in patient charts or billing claims information to market or contact patients in order to solicit the transfer of the patient to a particular pharmacy.



# Arkansas Act 462 Conscience Clause

- **SB289 (ACT462)**
- **AN ACT TO CREATE THE MEDICAL ETHICS AND DIVERSITY ACT**
- **Sponsored by Senator Kim Hammer and Representative Brandt Smith**
- "Conscience" means the religious, moral, or ethical beliefs or principles of a medical practitioner, healthcare institution, or healthcare payer.
- Right of Conscience - A medical practitioner, healthcare institution, or healthcare payer has the right not to participate in a healthcare service that violates his, her, or its conscience
- Pharmacist, pharmacy technician and pharmacy all named in the legislation in addition to a comprehensive list of health care workers
- **Historic Context: Arkansas § 20-16-304(1973)** - Contraception conscience clause for physicians, pharmacists, paramedical personnel, agent of, institution, or employee of

# EPCS Required Federally?

- Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies;...Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan;
- In the CY2021 [Medicare physician fee schedule proposed rule](#) from summer of 2020, CMS contemplated delaying EPCS requirements until January 1, 2022 due to COVID.
- **Instead they kept the effective date of 1/1/2021 but delayed enforcement of the rule until 1/1/2022. Oddly, although it is a rule there is no enforcement currently.**
- “(5) On or after January 1, 2022, prescribers must, except in circumstances in which the Secretary waives the requirement, conduct all prescribing for all Schedule II, III, IV, and V controlled substances electronically using the applicable standards in paragraph (b) of this section.”
- <https://www.federalregister.gov/documents/2020/08/17/2020-17127/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part>



# 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<sub>30</sub>

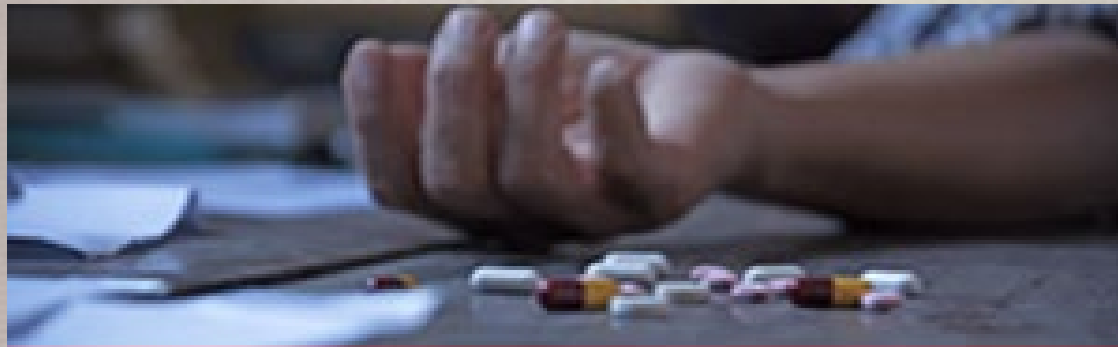
# PDMP ISSUES of CONCERN

## 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.
  - As a reminder, the DEA number used must be that of the actual prescriber not the supervising physician for a PA or APRN. Even if they don't have a provider contract for a specific insurance payor, the prescriber of record must be the actual prescriber.

# Take BACK

October 23, 2021



If you witness an overdose,

**DON'T RUN. CALL 911.**



Download the **NARCANSAS App** for life-saving information and resources, including how to save a life with naloxone.



# 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.



# 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.



# Future Questions?

Arkansas State Board of  
Pharmacy

[pharmacyboard.arkansas.gov](http://pharmacyboard.arkansas.gov)

[www.arkansas.gov/asbp](http://www.arkansas.gov/asbp)

(501) 682 - 0190