Disclosure

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

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

John Vinson, Pharm.D., CEO
Arkansas Pharmacists Association
Objectives

• Analyze and Discuss recent and upcoming regulatory updates
• Discuss the importance and impact of legislation from the 2021 session for pharmacists related to their 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
Arkansas Drug Summit

• 2021 Arkansas Prescription Drug Abuse Prevention Summit
• Register today to join us on Tuesday, November 16th in Northwest Arkansas for the 10th annual Prescription Drug Abuse Prevention Summit. We will offer 5 breakout tracks: clinical, criminal justice, family, counseling/recovery and education/prevention. We will send you more information once the agenda is finalized.

• 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
So who has had a “slow” year?

- Prep Act Updates…
- Rule Suspensions
- Rule Suspensions ended 3/31/2021
- Legislative Session Changes
- Rule Updates in Process

- Okay folks, that was funny!
PREP Act

- HHS Expansion for Pharmacists and Pharmacy Interns to order and administer vaccines to children age 3 to 18 under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.
PREP Act Cont

- Age 3 to 18
- If you are not utilizing the current methods for the provision of vaccines/immunizations under an Arkansas Protocol and are instead utilizing the expanded authority under the PREP Act the following would apply:
  - You cannot use the prescriber of record from a statewide protocol unless actually using the protocol under current rules.
  - Billing may be an issue when using the PREP Act depending on how an individual insurance company may or may not accept billing under the pharmacist’s direct authority.
  - Administered vaccines must still be reported into the state’s repository.
  - PREP Act requires current CPR (does not say live or in person)
  - The Pharmacist or Intern does not necessarily need an endorsement on their license to administer medications but must have the required training as outlined by the Act.
COVID-19 Vaccine Authority Expanded

“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.”

The vaccine must be FDA-authorized or FDA-licensed.

The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.

SAME TRAINING REQUIREMENTS AS BEFORE

PREP Act Amendments
Arkansas Acts from 2021...

**THERE ARE A LOT!**

<table>
<thead>
<tr>
<th>Act 63</th>
<th>Act 665</th>
</tr>
</thead>
<tbody>
<tr>
<td>Act 406</td>
<td>Act 666</td>
</tr>
<tr>
<td>Act 407</td>
<td>Act 758</td>
</tr>
<tr>
<td>Act 408</td>
<td>Act 769</td>
</tr>
<tr>
<td>Act 412</td>
<td>Act 922</td>
</tr>
<tr>
<td>Act 462</td>
<td>Act 960</td>
</tr>
<tr>
<td>Act 503</td>
<td>Act 1053</td>
</tr>
<tr>
<td>Act 626</td>
<td>Act 1103</td>
</tr>
<tr>
<td>Act 651</td>
<td>Act 1104</td>
</tr>
</tbody>
</table>
Arkansas Act 63...

HB1174 – ACT 63 TO ELIMINATE THE NURSING HOME CONSULTANT PHARMACIST PERMIT AND THE DISEASE STATE MANAGEMENT CREDENTIAL.

- Removed Endorsement Requirements in the statute to act as a consultant pharmacist (LTC, Assisted Living Facilities, Prisons…)
- Removed Licensure fees to get the endorsement
- Removed Extra CE requirement for consultants

- Removed Endorsement Requirements in the statute to practice Disease State Management
Arkansas Act 406

HB1134 – ACT 406 TO ALLOW PHARMACISTS TO PRESCRIBE, ADMINISTER, DELIVER, DISTRIBUTE, OR DISPENSE VACCINES, IMMUNIZATIONS, AND MEDICATIONS TO TREAT ADVERSE REACTIONS TO ADMINISTERED VACCINES.

Pharmacist may prescribe, administer, deliver, distribute, or dispense medications for adverse reactions associated with the administration of vaccines and immunizations, vaccines, and immunizations to or for a person three (3) years of age or older.

3-6 has guidelines
Arkansas Act 406

Ages 3 to 6

- Participate in Federal Vaccines for Children Program
- Inform caregivers of the importance of well-child visit with pediatrician or other primary care provider. Recommend annual visits.
Arkansas Act 407

HB1135 – ACT 407 TO AUTHORIZE PHARMACY TECHNICIANS TO ADMINISTER VACCINES AND IMMUNIZATIONS.

“A pharmacy technician may administer vaccines and immunizations to a person three (3) years of age or older if delegated to do so by a supervising pharmacist, but may not administer other medications.”
Arkansas Act 408

HB1069 – ACT 408 TO AMEND THE PROVISIONS OF THE ARKANSAS CODE CONCERNING THE PRACTICE OF PHARMACY; AND TO AUTHORIZE PHARMACISTS TO PROVIDE ACCESS TO AND ADMINISTRATION OF ORAL CONTRACEPTIVES.

****Training Program and Materials must be developed****
An Arkansas licensed pharmacist who is practicing within the state, may initiate therapy by administering or dispensing, or both, oral contraceptives to a patient who is eighteen (18) years of age or older under a statewide protocol under the following guidance:

1. Complete a training program related to oral contraceptives approved by the Board of Pharmacy,
2. Utilize and follow Board approved screening assessment procedures and questionnaires,
3. Screen patients to assess whether they have been seen by a primary care provider or women’s healthcare provider within the previous six (6) months. If the patient has not been seen within six (6) months the pharmacist shall:
   a. Provide a referral to a local primary care provider or women’s healthcare provider
   b. Not dispense more than a six-month supply of oral contraceptives or the equivalent number of refills to the patient until they have been seen by a local primary care provider or women’s healthcare provider
4. Shall not provide the patient with a referral to a licensed abortion provider.
5. Explain verbally to the patient the possible effects of an oral contraceptive, including without limitation the death of an unborn child and possible health complication or adverse reactions as printed by the United States Food and Drug Administration.
6. The patient and pharmacist shall sign an informed consent form that documents the explanation described above and place the form in the patient's medical record;
7. Report the following information to the Department of Health:
   a. The number of women who receive oral contraceptives without a prescription; and
   b. The age of the women who receive oral contraceptives without a prescription;
8. Provide a standardized information sheet about the oral contraceptive dispensed to the patient;
9. Write a summary of consultation to be maintained in the patient's medical record;
10. Notify the primary care provider of the patient of any drug or device furnished to the patient or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider;
11. Provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice, if the patient does not have a primary care provider; and
12. Make a standardized fact sheet available to the recipient of the drug or device. The standardized fact sheet shall include without limitation:
   a. The indications and contraindications for the use of the drug or device;
   b. The appropriate method for the use of the drug or device;
   c. The need for medical follow-up; and
   d. Other appropriate information.
Arkansas Act 412 (HB1258)

• TO AUTHORIZE FULL INDEPENDENT PRACTICE AUTHORITY FOR CERTIFIED NURSE PRACTITIONERS WHO MEET CERTAIN REQUIREMENTS; AND TO CREATE THE FULL INDEPENDENT PRACTICE CREDENTIALING COMMITTEE.
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

• **History: Arkansas § 20-16-304(1973) - Contraception**
  conscience clause for physicians, pharmacists, paramedical personnel, agent of, institution, or employee of
Arkansas Act 503

HB1246 – ACT 503 TO ALLOW PHARMACISTS TO TREAT CERTAIN HEALTH CONDITIONS; TO MODIFY PHYSICIAN DISPENSING; AND TO ALLOW DELEGATION OF PHYSICIAN DISPENSING.

Allows for Therapeutic Substitution which requires a change to Rule 7

ALSO REQUIRES:
Statewide Protocol for treatment of Influenza and Strep A as well as other health conditions adopted by rule in consultation with medical board
MUST ADOPT BY RULE:
Formulary and a written statewide protocol including age and medications that can be used
Arkansas Act 626

• AN ACT TO CREATE THE ARKANSAS SAVE ADOLESCENTS FROM EXPERIMENTATION (SAFE) ACT; AND FOR OTHER PURPOSES.

• 20-9-1502. Prohibition of gender transition procedures for minors.
  • (a) A physician or other healthcare professional shall not provide gender transition procedures to any individual under eighteen (18) years of age.
  • (b) A physician, or other healthcare professional shall not refer any individual under eighteen (18) years of age to any healthcare professional for gender transition procedures.
Arkansas Act 651

• SB505 – ACT 651 TO MANDATE THE COPRESRIPTION 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.
Arkansas Act 665

• TO AMEND THE ARKANSAS PHARMACY AUDIT BILL OF RIGHTS; AND TO AMEND THE ARKANSAS PHARMACY BENEFITS MANAGER LICENSURE ACT.

(h) The Insurance Commissioner shall:
(1) Administer and enforce this subchapter; and
(2) Promulgate rules to implement the purposes and requirements of this subchapter.
Arkansas Act 666

• TO AMEND ARKANSAS CONSTITUTION, AMENDMENT 98, ALSO KNOWN AS THE "ARKANSAS MEDICAL MARIJUANA AMENDMENT OF 2016"; AND TO MODIFY REQUIREMENTS CONCERNING A PHARMACIST CONSULTANT.

(f) When a patient receives a written certification from a physician, the physician may require the patient to consult with a pharmacist consultant of a dispensary.

(3) A dispensary shall:

(A) Post signage at the check-in station of the dispensary notifying the qualifying patient of the availability of a pharmacist consultant;

(B) Provide to the new qualifying patient of the dispensary a card containing language about a consultation with a pharmacist consultant and the contact information of the pharmacist consultant; and

(C) Post information on the website of the dispensary regarding a consultation with a pharmacist consultant, the availability of the pharmacist consultant, and the contact information of the pharmacist consultant.

/s/Penzo
Arkansas Act 758

- HB1781 (ACT 758) - Representative Lee Johnson
- TO CLARIFY AND EXPAND THE PRESCRIPTION LIMITATIONS IN THE ARKANSAS MEDICAID PROGRAM.

- Removes the extension of benefits requirements for prescriptions medications for adult patients in the Fee for Service Medicaid program, and allow 6 prescriptions per month without an extension of benefits.
- Removes the existing restriction of expiration of all prescriptions at 6 months, to match federal and state law which is 12 months for regular prescription medications (blood pressure, cholesterol, inhalers) and 6 months for controlled substance prescriptions (DEA controlled substances)
Arkansas Medicaid prescription drug exempt list:

- **Prior to 2021**
  - contraception
  - smoking cessation
  - naloxone
  - Medication Assisted Treatment for opioid use disorder (addiction)

- **2021/2022 Additions consistent with Act 758**
  - blood pressure
  - cholesterol
  - asthma
  - COPD
  - blood thinners
  - diabetes
Arkansas Act 769


Increases option for Rural Loan/Scholarship program
Increases amount we can spend on education and professional contractual needs
Arkansas Act 922

- HB1852 – ACT 922 AN ACT TO SET STANDARDS FOR PRESCRIPTIONS DELIVERY; AND FOR OTHER PURPOSES.

(a) As used in this section, "home delivery services" means providing medications from a pharmacy licensed in this state to a patient through any means other than the patient picking up the medication at the physical pharmacy location, including shipping, mailing, or delivering in any manner a dispensed legend drug.

(b)(1) The Arkansas State Board of Pharmacy shall promulgate and maintain rules defining the standard of care for pharmacies and pharmacists that provide home delivery services in this state.

(2) If a pharmacy or pharmacist owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager affiliate, then the pharmacy, including any common ownership or controlling entities, or pharmacist, shall not require that a patient receive his or her prescriptions through home delivery services.

(c) A pharmacy or pharmacist is not prohibited from charging a nominal fee for any home delivery service if the nominal fee is charged to the patient with his or her express consent.

(d) The board may modify delivery standards to accommodate changes in technology and for other reasons.
Arkansas Act 960

• AN ACT TO SPECIFY A PROCESS OF REVIEW OF RULES REGARDING SCOPE OF PRACTICE OF HEALTHCARE PROFESSIONALS; AND FOR OTHER PURPOSES.

• Healthcare scope of practice rules must go through the Public Health Legislative Committees for approval.
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

Arkansas Act 1103 & 1104

• 1103 - AN ACT TO ESTABLISH THE 340B DRUG PRICING NONDISCRIMINATION ACT; AND FOR OTHER PURPOSES.

• 1104 - AN ACT TO PROVIDE GUIDELINES ON HOW REBATES ARE OFFERED BY A PHARMACEUTICAL MANUFACTURER THAT SELLS INSULIN IN THIS STATE; AND FOR OTHER PURPOSES.
Some Barriers are Unique

Emergency Rule Suspensions due to COVID 19

- Remove requirements for an endorsement on a pharmacist or intern license to administer medications Rule 09-00-0002
- Remove requirements for current CPR to administer medications Rule 09-00-0002
- Remove requirements for an endorsement to act as a Consultant Pharmacist 17-92-412. Nursing home consultant permit
- Remove requirements for an endorsement to provide Disease State Management via written protocols Rule 09-01-0001
- Intern ratio limitation of 1 intern working per pharmacist is waived during this time period. (already waived for educational experiences) It is important to note that this does not waive the pharmacy technician to pharmacist ratio which remains at 3:1. 02-01-0004 (h) 4.
- Therapeutic substitution if a medication is not available and there is a therapeutically equivalent medication available during the emergency the pharmacist can discuss with the patient and substitute with a notice sent to the prescriber of the substitution due to emergency when the prescriber is unavailable. – Albuterol Inhaler were agreed to initially


COVID Confusion on Controls

We had several calls from pharmacies where prescribers seemed to think that any C2 can be called or faxed in due to COVID 19. I have heard everything from the DEA has suspended all rules (not true) to the president announced we can do this to the Governor said we could. It appears to be necessary to explain that there is a big difference in Telemedicine giving the ability to prescribe vs the actual issuance of a prescriptions. Being able to prescribe via Telemedicine without an in-person medical evaluation has been allowed by DEA as outlined in the linked site below. The next part of actual issuance of a prescription was not changed by DEA according to the reading of this as well as discussions with DEA.

https://www.deadiversion.usdoj.gov/coronavirus.html
“Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for schedules II-V) or by calling in an emergency schedule II prescription to the pharmacy, or by calling in a schedule III-V prescription to the pharmacy.”

While DEA allows for “emergency” prescriptions the state pharmacy board has a long term rule that limits emergency supplies on a C2 to a 72 hour supply as is consistent with most other states. That rule has not been suspended.
"The Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., states that a pharmacist may not dispense a schedule II controlled substance without a written prescription of a practitioner, “except that in emergency situations… such drug may be dispensed upon oral prescription….” 21 U.S.C. 829(a). The criteria for identifying an emergency situation are found in a Food and Drug Administration (FDA) regulation, 21 CFR 290.10, which provides that an emergency situation is one in which the prescribing practitioner determines that immediate administration of the schedule II controlled substance is necessary for the proper treatment of the intended user, that no appropriate alternative treatment is available, and that it is not reasonably possible for the prescribing practitioner to provide a written prescription to the pharmacy prior to dispensing the substance. Whether an emergency situation exists is a determination made by a practitioner based on the individual facts of a particular medical situation. Thus, an emergency situation does not necessarily exist with regard to every prescription of a schedule II controlled substance issued during the Public Health Emergency: this determination must still be made by practitioners on a case-by-case basis. DEA acknowledges, however, that the Public Health Emergency is likely creating emergency situations, as defined by 21 CFR 290.10, in some cases."
(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...
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.
WILL IT BE DELAYED?

• Federal Government

• 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.
How to Prescribe Controlled Substances to Patients
During the COVID-19 Public Health Emergency

In response to the COVID-19 public health emergency declared by the Secretary of Health and Human Services, the Drug Enforcement Administration (DEA) has adopted policies to allow DEA-registered practitioners to prescribe controlled substances without having to interact in-person with their patients. This chart only addresses prescribing controlled substances and does not address administering or direct dispensing of controlled substances, including by narcotic treatment programs (OTPs) or hospitals. These policies are effective beginning March 31, 2020, and will remain in effect for the duration of the public health emergency, unless DEA specifies an earlier date.

This decision tree merely summarizes the policies for quick reference and does not provide a complete description of all requirements. Full details are on DEA’s COVID-19 website (https://www.deadiversion.usdoj.gov/coronavirus.html), and codified in relevant law and regulations.

Under federal law, all controlled substance prescriptions must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. 21 CFR 1306.04(a). In all circumstances when prescribing a controlled substance, including those summarized below, the practitioner must use his/her sound judgment to determine that s/he has sufficient information to conclude that the issuance of the prescription is for a bona fide medical purpose. Practitioners must also comply with applicable state law.
Part 1: Evaluating the Patient

Part I: Evaluating the Patient

Has the prescriber previously examined the patient in person?
- Yes
  - Practitioner may conduct any needed follow-up evaluation by any method: in person, telemedicine, telephone, email, etc.
  - Issue any needed Rx directly to patient or to pharmacy by method in Part II

- No
  - Practitioner must first evaluate the patient in the steps described in the following boxes prior to issuing Rx for CS

Is the prescription for buprenorphine* for maintenance or detoxification treatment of an opioid use disorder?
- Yes
  - Prescribing practitioner must be DATA-waived
  - Evaluate patient in one of the following ways: in person; by questioning the patient over the telephone; or via telemedicine using a real-time, two-way, audio-visual communications device
  - Issue any needed Rx directly to patient or to pharmacy by method in Part II

- No
  - Evaluate patient in one of the following ways: in person, or via telemedicine using a real-time, two-way, audio-visual communications device

*Methadone cannot be prescribed for maintenance or detoxification treatment and must be administered or dispensed directly to the patient for that purpose. 21 CFR 1306.07(a).
Part 2: Delivering the RX

Part II: Delivering the Rx to the Pharmacy

Can the prescriber currently deliver a written Rx to the patient or pharmacy, or prescribe via EPCS?

- Yes: Deliver written Rx to patient or pharmacy, or prescribe via EPCS
- No:
  - C. II: Prescriber may call in Rx in an emergency situation as defined in 21 CFR 290.10 (follow next 3 questions)
  - C. III-V: Call in Rx

Is the drug to be prescribed in C. II or C. III-V?

- Yes: Is immediate administration of the C. II CS necessary for the proper treatment of the patient?
- No: Is any appropriate alternative treatment available, including non-CS treatment?
  - Yes: Is it reasonably possible for the prescribing practitioner to provide a written Rx to the pharmacy prior to dispensing?
  - No: Confirm within 15 days by written Rx, EPCS, or scan or photograph of Rx
  - Emergency oral Rx not permitted

List of abbreviations:
- C. – Schedule (e.g. C. II, C. III)
- CS – Controlled substance
- EPCS – Electronic prescriptions for controlled substances
- Rx – Prescription
PDMP ISSUES of CONCERN

HOW GOOD IS THE SYSTEM

• Only as good as the information you feed into it.
• Only as good as how you check it.
• 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.
PDMP ISSUES of CONCERN

Login Security
• Login is only for the individual that it is issued for.
• There is no such thing as a clinic or pharmacy login
• Do NOT share your login

Delegate Authority
• Allows prescribers and pharmacists to delegate authority to support staff
  – Delegate MUST have their OWN login which is under the authority of the prescriber or pharmacist.
  – The supervising individual is responsible for whatever their delegates are looking up
PDMP ISSUES of CONCERN

Dear Pharmacist/Pharmacist’s Delegate,

The Arkansas Prescription Drug Monitoring Program (AR PDMP) is emailing you to provide some best practices to pharmacy reporting of controlled substance dispensations to the AR PDMP. Here are some common reporting errors that can be prevented.

- For Schedule V Exempt narcotics, (ie, guaifenesin/codeine syrup), dispensations should be reported to the AR PDMP using the pharmacy name, DEA number and address as the prescriber.
- Verify the prescriber DEA number the prescription is being reported under matches the DEA number on the prescription. Avoid using “fake” or “dummy” DEA’s such as AA111119 or AA1234563.
- If your pharmacy corrects a prescription error on a dispensation that has already been reported to the AR PDMP, it is the pharmacy’s responsibility to ensure that update is reported to the AR PDMP. Sometimes this will take a manual edit to the dispensation that can be completed in the PMP AWARE system.

The Arkansas PDMP team hopes that you find this information helpful in your practice. If you have questions, please contact our Arkansas PDMP support team at 501-683-3960.

Sincerely,

Arkansas Department of Health
Prescription Drug Monitoring Program
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.
Early on there were critical shortages of this medication 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.
Current Guidance from the Arkansas Department of Health states the following: “GUIDANCE FOR THE USE HYDROXYCHLOROQUINE AND CHLOROQUINE FOR THE TREATMENT OF COVID-19

On June 15, 2020 the Food and Drug Administration (FDA) revoked the Emergency Use Authorization (EUA) for the use of chloroquine (CQ) and hydroxychloroquine (HCQ) to treat COVID-19 after concluding it was “no longer reasonable to believe that oral formulations of HCQ and CQ may be effective in treating COVID-19, nor is it reasonable to believe that the known and potential benefits of these products outweigh their known and potential risks”. The latter included serious cardiac adverse events. Based on this information, the Arkansas Department of Health (ADH) updated its guidance related to HCQ and CQ indicating that their use for treatment of COVID-19 should be avoided in both outpatient and hospitalized settings.”
“CQ and HCQ can continue to be administered, prescribed, and dispensed for FDA approved medical conditions under supervision of a patient’s healthcare provider. Unapproved use (i.e. “off label use”) of these medications is left to the discretion of individual clinicians and their patients. However, the ADH wants clinicians to be aware that coadministration of HCQ or CQ with remdesivir, an FDA EUA approved medication for treatment of COVID-19, is not recommended based on data showing an antagonistic effect of these medications on the antiviral activity of remdesivir.”
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.
"There is urgent need for widespread and early education of the medical profession, legislators, administrative authorities and laity into the facts of addiction-disease. Until narcotic addiction is widely appreciated and taught as a definite disease, and facilities are provided for clinical demonstration and instruction and for laboratory experimentation, we cannot hope for intelligent handling of the narcotic addict, nor for solution of the national drug problem."

Where is the blame for their continued addiction? Certainly not because of lack of effort on their part. Addicted for years they have tried one after another of the various and diverse treatments and so-called "cures" without success or ultimate relief. Is the blame theirs for lack of success and cure, or has there been something wrong in our treatment and handling of them? Did we know enough about addiction-disease to treat them intelligently and to exercise upon their cases the same professional skill and technical ability that we have been educated and trained to apply to other diseases? In the light of available clinical information and study and in the light of competent laboratory research we are forced as a profession to admit that we have not treated our addiction sufferers with sympathetic understanding and clinical competency and that the blame for the past failure to control the narcotic drug problem rests largely upon the educational inadequacy of our medical profession, and institutions of scientific and public health education."
NARCOTIC DRUG ADDICTION: A PUBLIC HEALTH PROBLEM.

ERNEST S. BISHOP, M. D., F. A. C. P.
Clinical Professor of Medicine, New York Polyclinic Medical School and Hospital, etc., etc., New York City.

Read before Public Health Administration Section, American Public Health Association, at Chicago, Ill., December 11, 1918.
Take BACK

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.

artakeback.org
PROTECT OUR CHILDREN.
DISPOSE OF YOUR MEDS SAFELY.
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 993 saves so far!

COPREScribing OF NALOXONE

NICOTINE REPLACEMENT THERAPY STATEWIDE PROTOCOL

Developed with APA
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/](https://arimpact.uams.edu/)
- APA has had offerings through AAHP for members of AAHP
- Tons of Free, Live CE if you look around
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
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.

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.

<table>
<thead>
<tr>
<th>Prescriber Type</th>
<th>MD/DO Licensed Physicians</th>
<th>Optometrist</th>
<th>Physician Assistant</th>
<th>Advanced Practice Registered Nurse</th>
<th>Dentists</th>
<th>Podiatrists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescriptive Authority in Arkansas</td>
<td>Yes</td>
<td>Yes within scope</td>
<td>Yes with Collaborative Practice Agreement</td>
<td>Yes with Collaborative Practice Agreement (CPA) (CNM). A Certified Nurse Practitioner (CNP) may have CPA or certificate of full practice authority which would not require a CPA. A Certified Nurse Midwife (CNM) not required to have a CPA unless prescribe Sch II. All will be issued a prescriptive authority certificate from the Board of Nursing so they can obtain a DEA</td>
<td>Yes within scope</td>
<td>Yes within scope</td>
</tr>
<tr>
<td>Non Controls</td>
<td>Yes</td>
<td>Yes within scope</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>C3-S</td>
<td>Yes with appropriate DEA registration</td>
<td>Yes within scope</td>
<td>Yes with appropriate DEA registration</td>
<td>Yes with appropriate DEA registration</td>
<td>Yes within scope</td>
<td>Yes within scope</td>
</tr>
<tr>
<td>Hydrocodone Combination Products</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other C2 (DEA must include schedule 2 for Narcotics and 2n for non-narcotics)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes, Limit of 5 days for Acute Pain, No defined limit on non-acute pain. All advanced practice registered nurse’s prescriptive authority also extends to drugs listed in Schedule II, (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</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

---

59
DEA Actions

• Criminal Cases against Doctors from DEA
• Registrant Actions – Administrative Actions Against Registrants
  – If you read through these you see that there is generally a long process to resolve these cases and publish them in the DEA resources database.
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

www.arkansas.gov/asbp

(501) 682 - 0190