Clinical Track Regulatory Updates

John Clay Kirtley, Pharm.D.
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 and Discuss recent regulatory issues and challenges for healthcare providers related to controlled substances

So, anyone notice any changes?

- Recent Cases?
- Limits on purchases?
- Suspicious Order Reports?

Supreme Court Case

CNN politics The Biden Presidency Facts First US Elections

Supreme Court sides with doctors challeng convictions in opioids 'pill mill' case

By Ariane de Vogue and Chandelis Duster, CNN
Updated 1:42 PM ET, Mon June 27, 2022

(CNN) — The Supreme Court on Monday ruled in favor of two doctors who were convicted of prescribing dangerous opioids without valid medical justification in violation of federal law.

Lawyers for the doctors appealed their convictions, arguing that a jury should have been able to consider whether they reasonably believed that they were acting within professional boundaries. The government had argued such a standard was not necessary.

Related Article: Protests spread across the US after the Supreme Court overturns the constitutional right to abortion

The court ruling for the doctors was unanimous, but the justices differed 6-3 on the legal rationale.

Justice Stephen Breyer, writing for the majority, said that for the prosecution of the doctors to be successful, the government "must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner."

Interesting Case AR Supreme

- Kowalski v. Rose Drugs of Dardanelle, Inc.
- The Estate further asserted a wrongful-death action against Rose Drugs for its "failure to properly monitor and negligent filling of numerous medications without regard to the ramifications of the multiple prescriptions."
- "Its sole point on appeal is that the circuit court erred in concluding that Rose Drugs, as a pharmacy, had no general duty to warn, not to fill dangerous prescriptions, and to inquire of a prescribing physician."

- https://caselaw.findlaw.com/ar-supreme-court/1610636.html

Arkansas Indictments

TEXARKANA

DEA search Lansdell Family Clinics across southwest Arkansas

by: John Walton
Posted: May 18, 2021 / 11:42 AM CDT
Updated: May 18, 2021 / 04:44 PM CDT

STATE NEWS

8 indicted in federal opioid abuse investigation involving Arkansas clinics

Member of local law enf
Lockesburg, Arkansas. (

by: Carolyn Roy
Posted: Mar 8, 2022 / 01:27 PM CST
Updated: Mar 8, 2022 / 02:29 PM CST

SHARE

TEXARKANA, Ark. (KTAL/KMSS) – Three pharmacists and five nurse practitioners are due in federal court Wednesday following their indictments on federal charges in connection with ar opioid abuse investigation involving Lansdell clinics and pharmacies in Southwest Arkansas.

A grand jury from the Western District of Arkansas handed up the indictments on March 1, charging each of the defendants with conspiracy to distribute controlled substances without legitimate medical purpose.

Sebastian County Justice of the Peace, husband plead guilty to Social Security fraud

According to Jared Harper, assistant special agent in charge of the DEA Little Rock, the indictments stem from raids conducted by federal and Southwest Arkansas authorities in May 2021 at clinics in Texarkana, De Queen, Lockesburg, and Dierks.

The defendants' names have not yet been released, but they are expected to be revealed during their arraignments Wednesday morning in federal court in Texarkana.

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/

- Is it legal for a prescriber to write 6 separate C2 prescriptions – 1 for now then 5 for future fills?

Arkansas Act 651 of 2021

- 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.

COVID Confusion on Controls

We had lots of 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

COVID Confusion on Controls

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.

COVID Confusion on Controls

"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."

DEA Prescribing Guidance

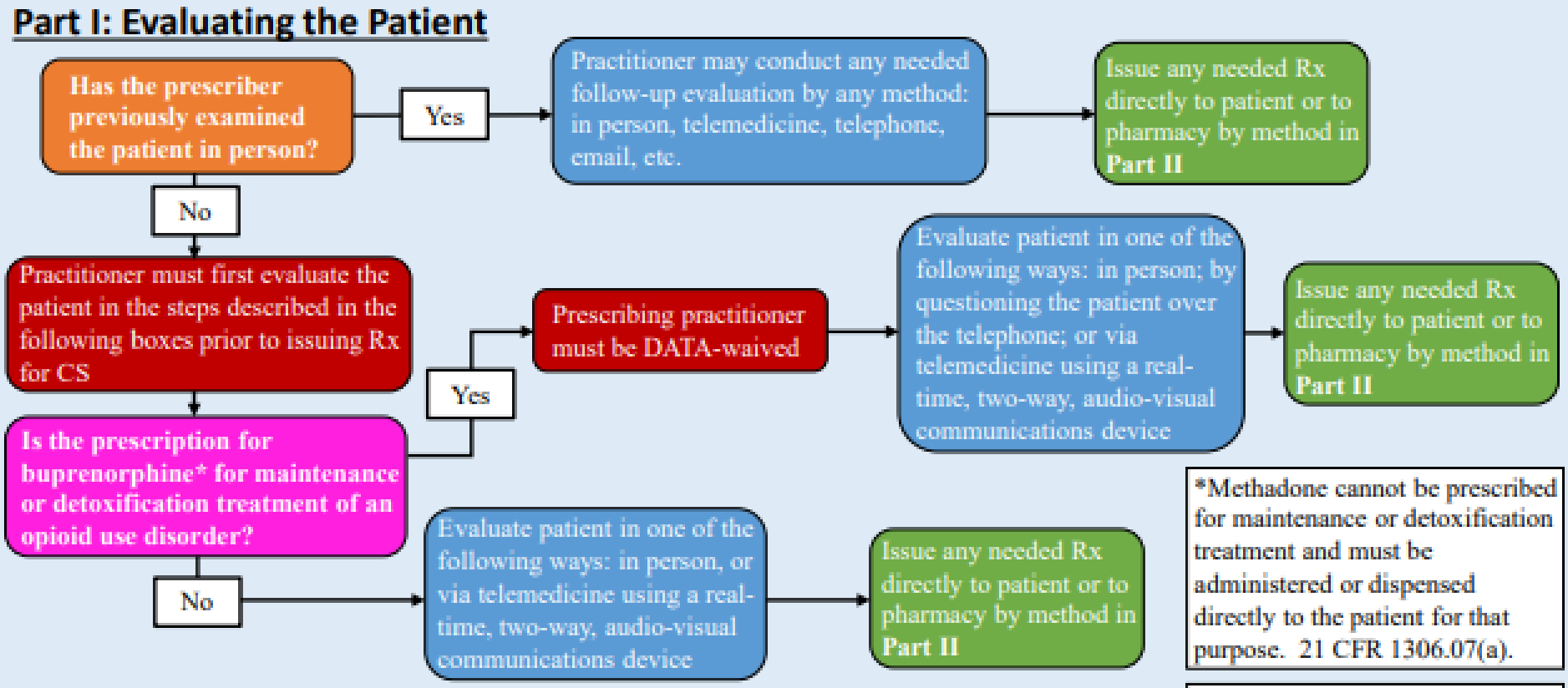
How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency

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.**

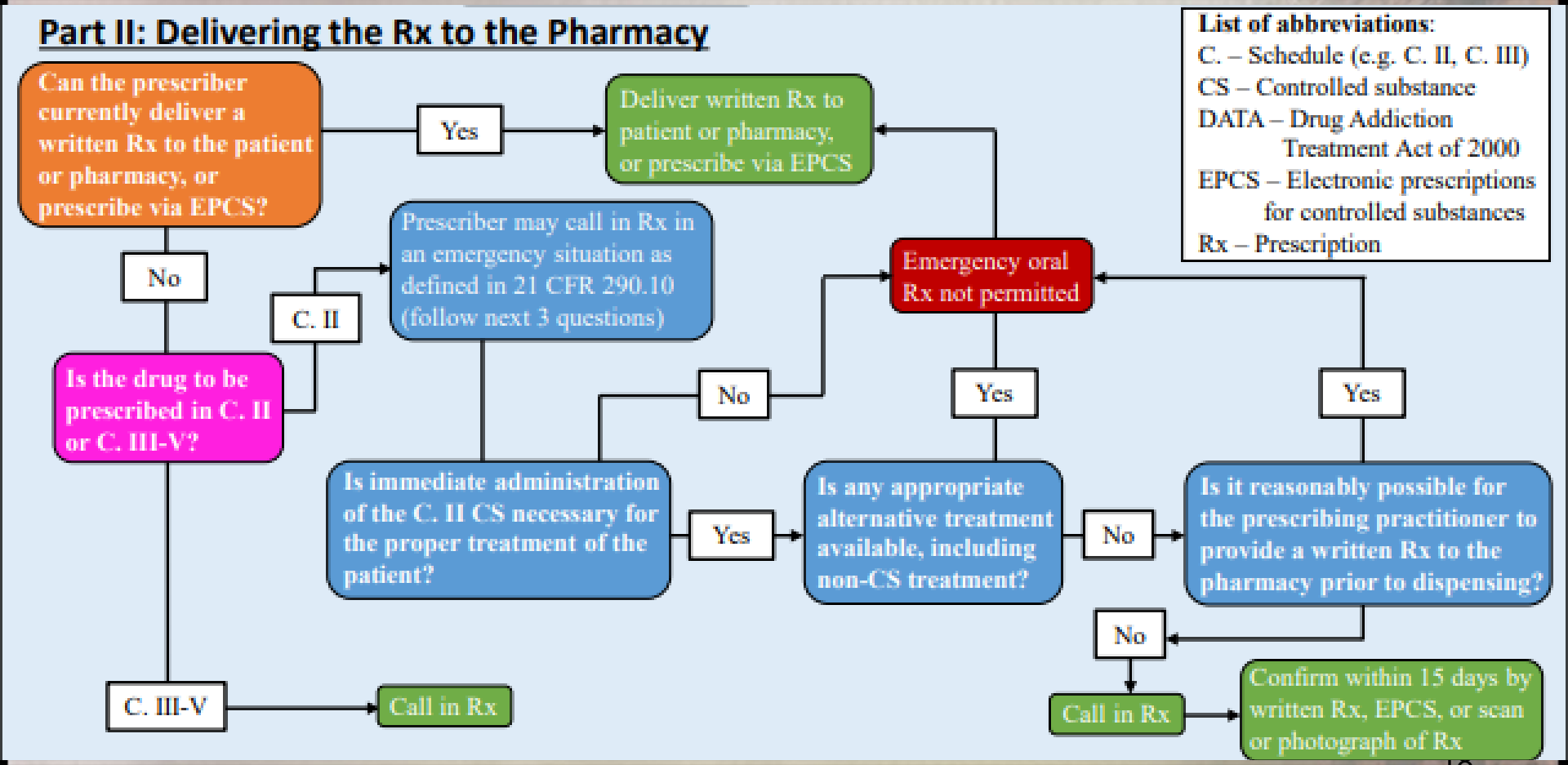
This decision tree merely summarizes the policies for quick reference and does not provide a complete description of all requirements. Full details are on DEA's COVID-19 website (https://www.deadiversion.usdoj.gov/coronavirus.html), and codified in relevant law and regulations.

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 2: Delivering the RX



DEA Prescribing Guidance

- “electronic signatures” for fax or paper?
- A paper prescription must be written in ink or indelible pencil or typewritten, or printed on a computer printer, and must be manually signed by the practitioner on the date when issued. 21 CFR 1306.05(d). An individual (i.e., secretary or nurse) may prepare prescriptions for the practitioner’s signature. 21 CFR 1306.05(f). The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state. 21 CFR 1306.05(f).

Changes to Prescriptions DEA

- In 2022 we have faced some real confusion on what changes can be made to controlled substance prescriptions.
- Largely arose from 2019 (as I am told) guidance for federal agencies to place guidance documents in central locations.
- See FDA guidance as an example.
- History….

Latest updates first?

NACDS Policy Council,

Late last night, NACDS received the email communication, *below*, from the Deputy Assistant Administrator/Diversion Control Division of the DEA providing an update on DEA policy on pharmacist annotation of C-II prescriptions. It can best be described as a retraction of its earlier policy reversal, with modification. In what it is calling an "interim measure," the DEA is now saying that it will permit pharmacist annotation of C-II prescriptions as permitted under state law, in consultation with the prescriber. (This DEA consultation requirement is an addition to the prior DEA policy regarding C-IIs but appears to align it with similar policy related to drugs on other schedules). Some states laws may already have this consultation requirement. We have asked the DEA how/when it plans to inform stakeholders of this "interim measure," but have no response as of yet. We will keep you informed of any further developments.

In the past few months, DEA has received an increasing number of questions concerning pharmacists' ability to add or modify information—like a patient's address—on paper prescriptions. To address these questions, DEA has been reviewing the relevant regulations and working to draft new regulations to address this issue. ***As an interim measure, pharmacists are permitted to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber.*** *(Emphasis added).*

- 8/20/22 at 3:16PM – ASBP received about 5th hand 8/22/22 at 7:40 AM

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veterans Administration facility, exempted from registration under § 1301.24(c) shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in § 1301.24 (c), in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under § 1301.25 shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18733, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1306.06 Persons entitled to fill prescriptions.

A prescription for controlled stances may only be filled by a pl macist acting in the usual course his professional practice and eit registered individually or employe a registered pharmacy or registered stitutional practitioner.

§ 1306.07 Administering or dispensing narcotic drugs.

(a) The administering or dispen directly (but not prescribing) of cotic drugs listed in any schedule narcotic drug dependent person "detoxification treatment" or "mai nance treatment" as defined in sec 102 of the Act (21 U.S.C. 802) shal deemed to be within the meanin the term "in the course of his pro sional practice or research" in sec 308(e) and section 102(20) of the (21 U.S.C. 828 (e)): *Provided*, That practitioner is separately regist with the Attorney General as requ by section 303(g) of the Act (21 U. 823(g)) and then thereafter com with the regulatory standards imp relative to treatment qualification, curity, records and unsupervised of drugs pursuant to such Act.

(b) Nothing in this section shall hibit a physician who is not specifi ly registered to conduct a narc treatment program from adminis ing (but not prescribing) narc drugs to a person for the purpos relieving acute withdrawal sympt when necessary while arrangem are being made for referral for tr ment. Not more than one day's m cation may be administered to person or for the person's use at time. Such emergency treatment be carried out for not more than t days and may not be renewed or tended.

(c) This section is not intended impose any limitations on a physi or authorized hospital staff to ad ister or dispense narcotic drugs hospital to maintain or detoxif person as an incidental adjunct medical or surgical treatment of co

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e) of this chapter.

(c) Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.

(d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

(e) Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.

(h) An official exempted from registration under § 1301.23(a) of this chapter must include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each paper prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

[75 FR 16307, Mar. 31, 2010]

Deja Vu?

- 2007 DEA Preamble to Rulemaking on the Issuance of Multiple Prescriptions for Controlled Substances Stated changes could not be made to C2 prescriptions for additions.

December 2008

Arkansas State Board of Pharmacy

From DEA Diversion Control Q & A

Question: What changes may a pharmacist make to a prescription written for a controlled substance?

Answer: The pharmacist may add the patient's address or change the patient's address upon verification. The pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted on the prescription as well as the patient's medical record. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of

Continued on page 4

Continued from page 1

these changes to controlled substance prescriptions. The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address; such additions should be verified.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Where did we get Clarification?

NEWS
February 2009
Arkansas State Board of Pharmacy

From DEA Diversion Control Q & A

Following a number of questions and the article from our last *Newsletters* the Board is including a copy of Drug Enforcement Administration's (DEA) Office of Diversion Control, General Questions and Answers. This list has been updated since our last *Newsletter* was sent for publication and comments from the Arkansas State Board of Pharmacy are included below.

Question: **Is it permissible to dispense a prescription for a quantity less than the face amount prescribed resulting in the actual number of dispensings being greater than the number of refills indicated on the prescription?**

Answer: Yes. Partial refills of Schedule III and IV controlled substance prescriptions are permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (ie, date refilled, amount dispensed, initials of dispensing pharmacist, etc.), the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and no dispensing occurs after six months past the date of issue.

Question: **What changes may a pharmacist make to a prescription written for a controlled substance in Schedules III through V?**

Answer: The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

Question: **What changes may a pharmacist make to a prescription written for a controlled substance in Schedule II?**

Answer: On November 19, 2007, DEA published in the Federal Register (FR) the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [Schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) . . . may not be modified orally."

The instructions contained in the rule's preamble are in opposition to DEA's previous policy, which permitted the same changes a pharmacist may make to Schedules III through V controlled substance prescriptions after oral consultation with the prescriber. DEA recognizes the resultant confusion regarding this conflict and plans to resolve this matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

Arkansas State Board of Pharmacy Reflection on the above statement and answer: The Arkansas State Board of Pharmacy continues to allow the changes to a Schedule II prescription as had been previously published in this *Newsletter* after consultation with the prescribing physician including: the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address, and such additions should be verified. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

AUG 2 4 2011

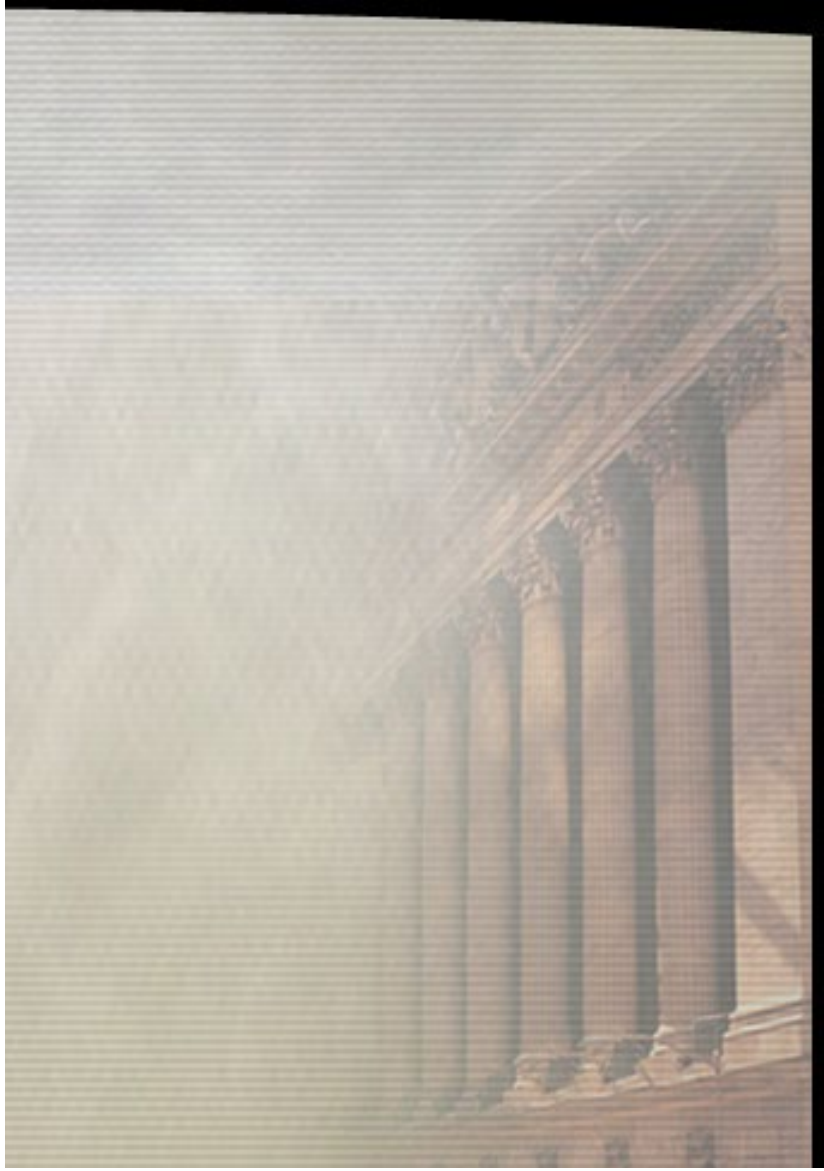
Mr. Carmen Catizone, M.S., R.Ph., D.Ph.
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, Illinois 60056

Dear Dr. Catizone:

This correspondence is in response to your letter dated July 26, 2011, to the Drug Enforcement Administration (DEA) seeking clarification on DEA's policy regarding information a pharmacist may provide when it is missing from a prescription for a schedule II controlled substance. Thank you for contacting DEA on this issue.

DEA is aware that pharmacists are sometimes presented with prescriptions for schedule II controlled substances that are missing information required for a valid prescription under state or federal law. In accordance with DEA regulations, pharmacists have a corresponding responsibility with practitioners for the proper prescribing and dispensing of controlled substances and must ensure that prescriptions for controlled substances conform in all essential respects to the law and regulations. 21 C.F.R. §§ 1306.04(a) and 1306.05(f). In particular, DEA regulations require that all prescriptions for controlled substances be dated as of, and signed on, the day when issued and bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. 21 C.F.R. § 1306.05(a). Whether it is appropriate for a pharmacist to make changes to the prescription, such as adding the practitioner's DEA number to the prescription or correcting the patient's name or address, varies case-by-case based on the facts present. Consequently, DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.

To this end, pharmacists and other practitioners must be mindful of what dispensing-related activities violate the Controlled Substance Act (CSA). For instance, it is unlawful to knowingly or intentionally furnish false or fraudulent material information in, or omit any material information from any application, report, record, or other document required to be made, kept, or filed under the CSA; to dispense a controlled substance in violation of 21 U.S.C. 829, which includes requirements for a schedule II controlled substance prescription; or to knowingly or intentionally use in the course of dispensing of a controlled substance a registration number that is fictitious, revoked, suspended, expired, or issued to another person. See e.g., 21 U.S.C. §§ 842(a)(1), (2), and (5), and 843(a)(2), (3), and (4)(A).



I would like to thank you again for your willingness to work with DEA and I look forward to our continued cooperation.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 17, 2022

Fellow Patient Care Stakeholder:

Re: DEA Policy Reversal on Allowed Prescription Annotations for Schedule II Prescriptions

The National Association of Chain Drug Stores (NACDS) writes to share information regarding recent communications NACDS has had with the federal Drug Enforcement Administration (DEA) concerning DEA's policy reversal on the annotations that a pharmacist may make to a prescription for a Schedule II controlled substance.

During a May 2, 2022 telephone discussion among DEA officials and NACDS staff, DEA officials indicated that, despite its historical guidance permitting pharmacist annotations to Schedule II controlled substance prescriptions and established state law permitting the same, Schedule II controlled substance prescriptions now must arrive at the pharmacy with all elements required by 21 C.F.R. 1306.05(a)[1] in final form.

The implication of this DEA policy reversal is that if any of the elements required by 21 C.F.R. 1306.05(a) are missing or in need of alteration (such as the current address of the patient) then a pharmacist cannot add or change any of them, and the prescriber must instead issue a new prescription.

Considering the likely negative impact of this DEA policy reversal on patients' ability to receive timely their critical medications, in response to hearing this information from DEA, NACDS requested from DEA the following:

1. That DEA reconsider its policy reversal on annotation of controlled substance prescriptions without delay; or,
2. In the alternative, that DEA consider temporarily suspending that reversal pending formal rulemaking on the issue.
3. Absent either of the above, NACDS asked for DEA's prompt written confirmation of this long-standing policy reversal.

Since, as of the time of this writing, DEA has failed to respond to the above-mentioned requests, NACDS feels compelled to share this information with you because it appears to NACDS that DEA has not publicly announced this policy reversal. For additional information, we would suggest that you contact the DEA Office of Diversion Control, Liaison and Policy Section, at 571-362-3260 or ODLP@dea.gov.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

[1] "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner." 21 C.F.R. 1306.05(a)

1776 Wilson Blvd., Suite 200, Arlington, VA 22209 • P: 703.549.3001 • F: 703.836.4869 • NACDS.org

Recent Letter In DEA

Dear DPMs, GSs, and DIs,

The following information is being provided to you regarding, **What a Pharmacist Can Add to a Prescription.** If you receive questions from pharmacists, or state and local counterparts please feel free to provide them with this information.

Title 21 CFR 1306.05(a) clearly states what information is required to be on a prescription when it is prepared by the practitioner, "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

Further, The Administrative Procedure Act (APA) (Pub. L. 79-404, 1946) places certain procedural requirements on guidance or interpretations, applicable to multiple entities, issued by the Drug Enforcement Administration (DEA) and other federal agencies. Any statement of policy or interpretation of law or regulations that the DEA provides concerning your inquiry will be published on DEA's website, so as to provide notice simultaneously to all members of the public. Some guidance interpretations may be accomplished through the regulatory drafting process as the APA directs. Guidance documents are posted to the DEA website or via notice and comment rulemaking published in the Federal Register. Further information can be found by accessing the Question and Answer (Q&A) section of the DEA Diversion website. The Q&As offer information on DEA requirements in a plain language format. Further guidance information may be found by accessing the DEA Guidance Portal. Please contact the DEA Policy Section by email if we may provide additional assistance at ODLP@dea.gov.

DEA is currently reviewing the relevant regulations found under 21 CFR part 1300 to end, and working to draft regulations to address **what, if any, information a pharmacist can add to a prescription**. DEA encourages you to monitor the website www.regulations.gov for any new Notices of Proposed Rulemaking. See also the Office of Management and Budget, Unified Agenda of Regulatory and Deregulatory Actions at www.reginfo.gov for status updates on any pending regulations.

In addition, some states might have rules or regulations that differ from what is outlined under the Controlled Substances Act. Under 21 CFR 1307.02, nothing in [21 CFR Part 1300 to end] shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

This email was approved for dissemination by Section Chief Noreen S. Valentine.

So, What Has Changed?

- Federal Regulation
  - NOTHING – Current version since 2010
- Interpretation
  - ? Possibly 180 degrees then back again
- Enforcement
  - No Clue –
- FUTURE RULE MAKING should happen

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.

https://www.arkleg.state.ar.us/Acts/FTPDocument?path=%2FACTS%2F2019R%2FPublic%2F&file=447.pdf&ddBienniumSession=2019%2F2019R

Act 447 continued

- Federal Government
- In the CY2021 Medicare physician fee schedule proposed rule from summer of 2020, CMS contemplates delaying EPCS requirements until January 1, 2022 due to COVID. We expect the final rule before the end of the year, so should have an answer then:

•Conversation about EPCS starts on page 535, with the below excerpt on page 543:

"We also recognize the importance of EPCS and the statutory mandate. We believe that requiring EPCS by January 1, 2022 strikes the balance between not providing too large of a burden on providers and helping ensure that the benefits of EPCS are leveraged expeditiously. Furthermore, requiring EPCS by January 1, 2022 would allow time to solicit and consider important feedback from the previously discussed Request for Information that is necessary for implementation of the EPCS requirements for waivers from the requirements and penalties."

EPCS Required Federally?

- In the fall of 2018, Congress passed the SUPPORT for Patients and Communities Act, which requires Medicare Part D program participants to use e-prescribing of controlled substances (EPCS) beginning January 1, 2021. In a final rule issued in late 2020, the Centers for Medicare & Medicaid Services (CMS) called for implementing the mandate but delayed enforcement until January 1, 2022. CMS is now proposing to delay enforcement for yet another year, until January 1, 2023.
  - https://surescripts.com/news-center/intelligence-in-action/opioids/cms-should-proceed-with-epcs-requirement-without-another-delay

•Throughout 2021, CMS solicited input on appropriate actions for non-compliance and how any penalties will be imposed. Comments were submitted and the Calendar Year (CY) 2022 Medicare Physician Fee Schedule Final Rule was released and is accessible at cms.gov as of November 2nd, 2021. As of November 2021, CMS compliance actions "will consist of sending letters to prescribers that we believe are violating the EPCS requirement during that period of time. These letters will consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver." However, between now and the enforcement deadline in 2023, CMS will re-evaluate whether further compliance actions and penalties are necessary.

•What Does The Enforcement Delay Mean For Your Practice?

•**While enforcement and CMS "compliance action" has been delayed, the mandate is currently in effect**

- https://www.rxnt.com/cms-delays-epcs-compliance-enforcement-again-2023/

Legal Education

- Pharmacy Law Course
- Pharmacy Jurisprudence Exam
- Physicians?
- Nurses?
- Dentists?

Scope of Practice – Controls

- APRN
- Act 412 of 2021 established the Full Independent Practice Credentialing Committee
- Through application the committee can grant full independent practice for an APRN after showing 6,240 hours of practice under a Collaborative Practice Agreement

PA Scope Expansion

- Act 634 of 2021
- Added a PA to the Medical Board
- (2) A physician assistant's prescriptive authority extends to drugs listed in Schedule II only if the prescription is for:

(A) An opioid, if the prescription is only for a five-day period or less; or

(B) A stimulant, if the prescription meets the following criteria:

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

(ii) The physician has evaluated the patient within six (6) months before the physician assistant issues a prescription; and

(iii) The prescription by the physician assistant is to treat the same condition as the original prescription.

"Prescriptions written by a physician assistant must contain the name of the supervising physician on the prescription. "

ADOPTED RULES Approved and Active September 2022

Controlled Substance Distribution

- Manufacturers – Limited Quotas for Production (overproduction 25%)
- Distributors – Suspicious Orders (prevention and reporting), Diversion Prevention
- Pharmacies – Volume Considerations
- Pharmacists – Corresponding Responsibility

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/

Prescriber Type	MD/DO Licensed Physicians	Optometrist	Physician Assistant	Advanced Practice Registered Nurse	Dentists	Podiatrists
Prescriptive Authority in Arkansas	Yes	Yes within scope	Yes with Collaborative Practice Agreement, Medical Board Rules require the name of the supervising physician to be on the prescription as well for any controlled substances.	Yes with Collaborative Practice Agreement	Yes within scope	Yes within scope
Non Controls	Yes	Yes within scope	Yes	Yes	Yes within scope	Yes within scope
C3-5 Hydrocodone Combination Products	Yes with appropriate DEA registration	Yes with appropriate DEA registration	Yes with appropriate DEA registration	Yes with appropriate DEA registration	Yes with appropriate DEA registration	Yes with appropriate DEA registration
Other C2 (DEA must include schedule 2 for Narcotics and 2n for non-narcotics)	Yes	No	A Physician Assistant's prescriptive authority also extends to drugs listed in Schedule II if: (A) An opioid, if the prescription is only for a five-day period or less; or (B) A stimulant, if the prescription meets the following criteria: (i) The prescription was originally initiated by a physician; (ii) The physician has evaluated the patient within six (6) months before the physician assistant issues a prescription; and (iii) The prescription by the physician assistant is to treat the same condition as the original prescription.	Yes, Limit of 5 days for Acute Pain, No defined limit on non-acute pain 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.	Yes	Yes

- Note, at this time Medical Board Rules require a PA prescription to contain the name of their supervising physician.

DEA Actions

- Criminal Cases against Doctors from DEA
- Registrant Actions – Administrative Actions Against Registrants
  - https://www.deadiversion.usdoj.gov/crim_admin_actions/index.html
  - 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.

Possible DEA Sanctions?

- Criminal – crime against the state
- Administrative-revoke state and federal licenses
- Civil-$15,000+ per count

FOR IMMEDIATE RELEASE Wednesday, September 27, 2017

Perryville Pharmacist Sent to Prison for 10 Years, to Pay $850,000 for Role in Pill Scheme

LITTLE ROCK— Patrick C. Harris, Acting United States Attorney for the Eastern District of Arkansas, Stephen G. Azzam, Special Agent in Charge of the Drug Enforcement Administration (DEA) New Orleans Field Division, and Diane Upchurch, Special Agent in Charge of the Little Rock Field Office of the Federal Bureau of Investigation (FBI) announced today that Christopher Grant Watson, 44, of Perryville, a former pharmacist and owner of Perry County Food and Drug Store, will be spending the next 10 years in federal prison.

United States District Court Judge James M. Moody sentenced Watson to a statutory maximum 120 months' imprisonment for Watson's lead role in a conspiracy to unlawfully distribute prescription opioid pills from his drug store, his participation in a scheme to defraud Medicare/Medicaid, and a structuring offense. Watson was also ordered to pay a monetary judgement in the amount of $850,000 representing unlawful proceeds from the offense, which includes $54,000 in restitution to Medicare/Medicaid.

DEA and U.S. Attorney in the Western District of Louisiana announce settlement with drug distributor

Morris & Dickson Company to pay $22 million in civil penalty claims

DEA United States Drug Enforcement Administration SEARCH FULL MENU

WHO WE ARE WHAT WE DO CAREERS RESOURCES SUBMIT A TIP GET UPDATES

Drug Enforcement Administration

Keith Martin
Special Agent in Charge
Detroit
@DEADetroitDiv

January 17, 2017 For Immediate Release
Contact: Brian McNeal
Phone Number: (571) 362-1498

McKesson Settlement: Pays $150 Million, Largest Fine In DEA History

McKesson to suspend sales of controlled substances from Washington Courthouse Distribution Center

LEXINGTON, Ky. - Carlton S. Shier, IV, Acting United States Attorney for the Eastern District of Kentucky, and Timothy J. Plancon, Special Agent-in-Charge of the DEA Detroit Field Division, announced today that McKesson (McKesson), one of the nation's largest distributors of pharmaceutical drugs, agreed to pay a record $150 million civil penalty for alleged violations of the Controlled Substances (CSA).

Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act

Settlement resolves multiple investigations against Cardinal in Maryland, Florida, New York and Washington

So How About We Scare Everyone?

THIS IS NOT FACTUAL BUT IS AN EXAMPLE OF WHAT SOME COMPANIES WILL USE AS A SCARE TACTIC TO DRUM UP BUSINESS! THIS IS NOT TRUE – If you have questions then you should be contacting DEA

There are several things that DEA Diversion has been looking for:

1. The filling of controlled substance prescriptions earlier than two days. This one they are always right. So, you decide to fill a prescription seven days early. Now you got the patient being given the same amount twice on the same month. This is a very serious violation that DEA and the Board of Pharmacy will take their actions against the pharmacy owner and the pharmacist who filled the prescription.
2. Dispensing an amphetamine and a benzodiazepine to the same patient. These prescriptions are causing many pharmacies headaches. Very easy civil fine of $72,683.00 per violation.
3. Exceeding the 90 Morphine milligram equivalent (MME) for dispensing opioids especially for pain. Here all they must show is that you didn't do a PMP profile, and that the pharmacist has not communicated with the prescriber to determine the necessity for the IR and ER opioid for the patient. Besides the civil fine of $72,683.00 per violation, DEA Diversion may want a consent agreement with the pharmacy.

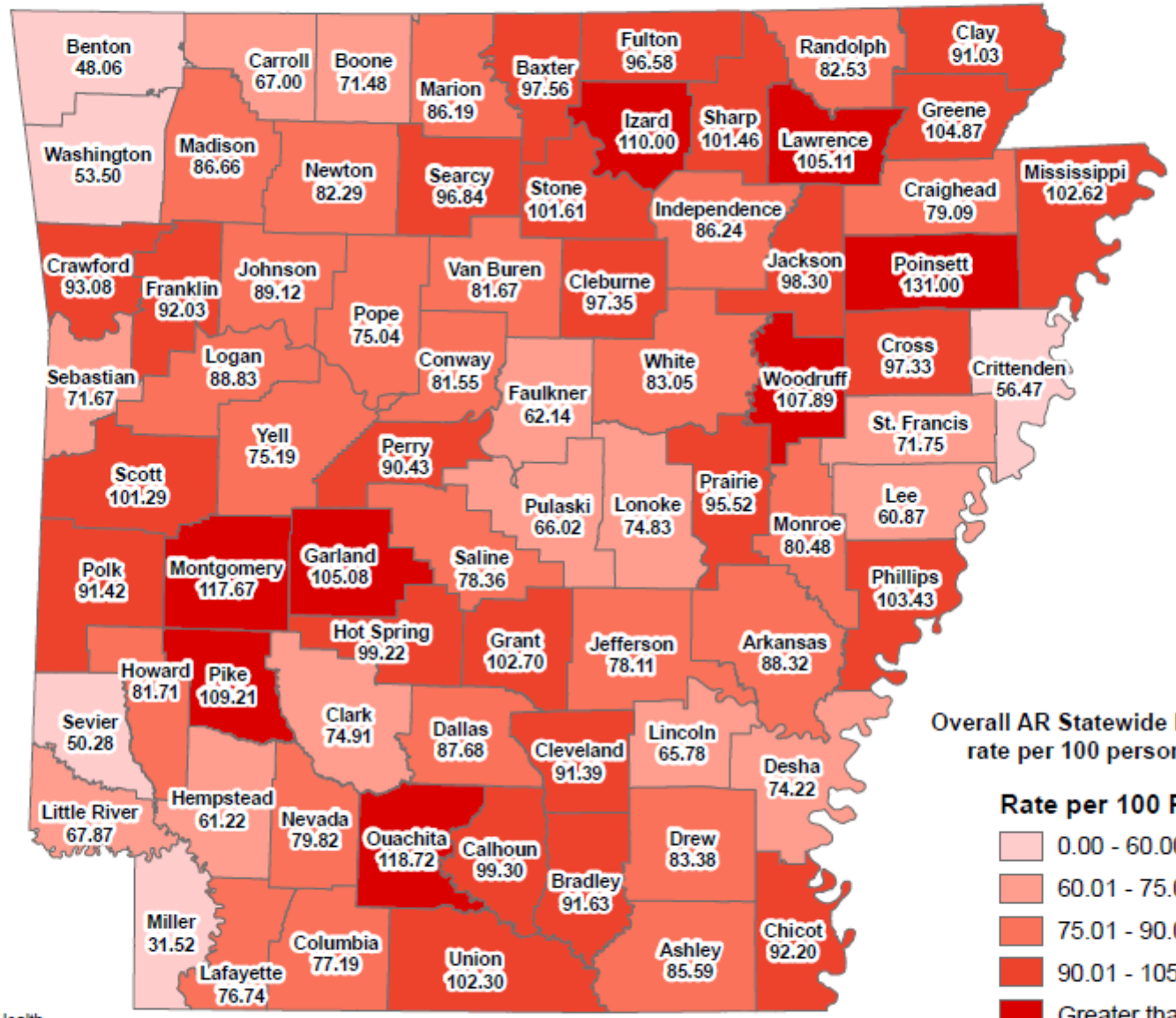
Wholesaler → Pharmacy

- Wholesalers review de-identified pharmacy data to see prescribing habits and prescription filling overview for pharmacies.
- We have seen instances where a wholesaler gave 5 days notice that a pharmacy would be cut off from all controlled substance purchasing.

Pharmacy Gets No Controls?

- What happens next?
- All those prescriptions move to other pharmacies that are immediately at risk as well?
- Starts a chain reaction that nobody in an area may have controls even though there is no DEA or State Action on the prescribers or dispensers.

Opioid Dispensing Rates per 100 Persons Based on the Patient Address, Arkansas 2021



Overall AR Statewide Dispensing rate per 100 persons: 75.31

Rate per 100 Population

- 0.00 - 60.00
- 60.01 - 75.00
- 75.01 - 90.00
- 90.01 - 105.00
- Greater than 105.00

Date: April 6, 2022
Source: Arkansas Department of Health
Map created by: Arch Robertson, Opioid Epidemiologist

*Data exclude Buprenorphine.
Location is based on patient address.
Prescriptions written by AR prescribers to AR patients.

Why?

- Combination of Drugs
  - Opioid – Benzo – Muscle Relaxant
    - Muscle Relaxant includes baclofen, cyclobenzaprine, tizanidine, carisoprodol

Neurology®

SHARE

July 14, 2022 RESEARCH ARTICLE

Comparative Risk of Opioid Overdose With Concomitant use of Prescription Opioids and Skeletal Muscle Relaxants

Nazleen Khan, Katsiaryna Bykov, Michael Barnett, Robert Glynn, Seanna Vine, Joshua Gagne

First published July 14, 2022, DOI: https://doi.org/10.1212/WNL.0000000000200904

AmerisourceBergen

March 2, 2022

Dear valued customer,

Attached is a letter announcing that we, along with our pharmaceutical distribution peers, have agreed to a nationwide settlement that resolves most of the opioid-related lawsuits filed by state and local government entities across the country.

As part of the settlement agreement, we will be required to make some changes to our Controlled Substance Monitoring Program (CSMP). These changes will ensure consistency across the distribution industry and will impact the manner in which we conduct diligence reviews, data collection and analysis, monthly limits on controlled substance ordering, and suspicious order reporting. We are preparing for the changes to go into effect in July 2022.

These **new requirements will apply to all customers who are registered with the DEA as a Retail Pharmacy, including independents, chains and mail order pharmacies.** The new requirements will not apply to closed-door retail pharmacies servicing long-term care and hospice patient communities, hospital inpatient pharmacies, physician practices, clinics, distributors or researchers.

Over the next several months, we will work closely with you to prepare for the new requirements and ensure that all of your questions and concerns are addressed. We have created an Injunctive Relief webpage (https://amerisourcebergen.com/injunctiverelief) where we will provide up-to-date information and support materials.

AmerisourceBergen is committed to ensuring patients have access to needed medications while doing our part to combat the misuse, abuse and potential diversion of controlled substances, and we will work in partnership with you to help ensure continuity of care for your patients. We appreciate your support and partnership.

With questions, please check out our webpage of resources or contact your AB representative.

Sincerely,

AmerisourceBergen

EXHIBIT P

Injunctive Relief

I. INTRODUCTION

A. Within ninety (90) days of the Effective Date unless otherwise set forth herein, each Injunctive Relief Distributor shall implement the injunctive relief terms set forth in Sections II through XIX (the "*Injunctive Relief Terms*") in its Controlled Substance Monitoring Program ("*CSMP*").

B. The Effective Date of these Injunctive Relief Terms shall be defined by Section I.P of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P.

II. TERM AND SCOPE

A. The duration of the Injunctive Relief Terms contained in Sections IV through XVI shall be ten (10) years from the Effective Date.

B. McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation are referred to collectively throughout these Injunctive Relief Terms as the "*Injunctive Relief Distributors*" or individually as an "*Injunctive Relief Distributor*." Each Injunctive Relief Distributor is bound by the terms herein.

For purposes of the Injunctive Relief Terms, "*Red Flags*"

1. Ordering ratio of Highly Diverted Controlled Substances to non-

Controlled Substances: Analyze the ratio of the order volume of all Highly Diverted Controlled Substances to the order volume of all non-Controlled Substances to identify Customers with significant rates of ordering Highly Diverted Controlled Substances.

2. Ordering ratio of Highly Diverted Controlled Substance base codes or

drug families to non-Controlled Substances:

3. **Excessive ordering growth of Controlled Substances:**

4. **Unusual formulation ordering:**

5. **Out-of-area patients:**

6. **Cash prescriptions:**

For purposes of the Injunctive Relief Terms, "*Red Flags*"

7. **Prescriber activity of Customers:** Analyze Pharmacy Customer Data or Dispensing Data to identify Customers that are dispensing Highly Diverted Controlled Substance prescriptions for Top Prescribers as follows:

a) Top Prescribers representing a significant volume of dispensing where the prescriber's practice location is in excess of 50 miles from the pharmacy ("out-of-area"), relative to the percentage of out-of-area prescriptions for non-Controlled Substances.

b) Top Prescribers representing prescriptions for the same Highly Diverted Controlled Substances in the same quantities and dosage forms indicative of pattern prescribing (e.g., a prescriber providing many patients with the same high-dose, high-quantity supply of 30mg oxycodone HCL prescription without attention to the varying medical needs of the prescriber's patient population).

c) Top Prescribers where the top five (5) or fewer prescribers represent more than fifty percent (50%) of total prescriptions for Highly Diverted Controlled Substances during a specified period.

8. **Public regulatory actions against Customers:**

9. **Customer termination data:**

Red Flags / Controlled Substances / Federal Court Injunctive Relief with AmerisourceBergen McKesson and Cardinal effective

A. Within ninety (90) days of the Effective Date unless otherwise set forth herein, each Injunctive Relief Distributor shall implement the injunctive relief terms set forth in Sections II through XIX (the "*Injunctive Relief Terms*") in its Controlled Substance Monitoring Program ("*CSMP*").

B. The Effective Date of these Injunctive Relief Terms shall be defined by Section I.P of the Settlement Agreement, dated as of July 21, 2021, which incorporates these Injunctive Relief Terms as Exhibit P. :

Red Flags for suspicious controlled substance orders and dispensing:

1. Thresholds exceeded for red flags may result in an Arkansas retail pharmacy receiving a letter with a notice of having all controlled substance orders being shut down in 5 business days. This type of action would destroy a typical Arkansas pharmacy and cause operations to cease within a short time frame. If a pharmacy actual has this action occur, the federal court injunctive relief terms ban other wholesalers from providing services to the impacted Arkansas community pharmacy.

2. Thresholds exceeded for red flags may also mean that Arkansas community pharmacies will have individual orders for specific NDCs (specific drug, dose, quantity, and manufacturer) for controlled substances automatically denied by the wholesaler and reported to the Arkansas state board of pharmacy as a suspicious order.

3. The red flags established by the federal courts in the injunctive relief are high level and not specific. The specific red flags and the established thresholds are developed by each wholesaler. They are not published or shared with the providers being monitored. The federal court injunctive relief prohibits the 3 wholesalers from providing specific data and the thresholds established to the pharmacists and retail pharmacy customers being measured.

Example AmerisourceBergen Red flags seen in letters to Arkansas pharmacies

- Dispensing the widely abused combination of opioids and benzodiazepines
- Dispensing of an opioid, a benzodiazepine and muscle relaxer concurrently in individual patients
- Dispensing readily abused, diverted and dangerous “trinity” and “Houston” controlled substance cocktails (opioid + benzodiazepine + carisoprodol)
- Dispensing for patients of General Practice / Family Medicine / mid-level providers conducting chronic pain and co-morbid mental health therapy
- Dispensing opioids in combinations with potentiators, i.e. opioids with benzodiazepines, gabapentin, and/or controlled and non-controlled muscle relaxers
- Dispensing antagonistic combinations , i.e. opioids and/or benzodiazepines with stimulant controlled substances (opioid + stimulant, benzodiazepine + stimulant, opioid+benzodiazepine+stimulant)
- Dispensing of antagonistic drugs concurrently to individual patients – opioids with stimulants
- Elevated cash Payment rates for controlled substance prescriptions (rather than using health insurance)
- High percentage of immediate release hydrocodone purchased and dispensed (hydrocodone with acetaminophen – Lortab / Vicodin / Lorcet + etc.)
- Purchase / dispensing of large quantities of promethazine with codeine
- Observance of Individual patients traveling a significant distance to obtain prescriptions for widely abused controlled substances

Message from Prescriber

Today, I am alarmed that a patient of mine could not only get their Adderall filled at several pharmacies they contacted, but also was told by CVS Pharmacy in Fayetteville, AR, that they were "no longer accepting new patients who needed Adderall." I had my staff call two local CVS Pharmacies and also ARCare Pharmacy in Bentonville, AR, to confirm that none of them are accepting new patients who need Adderall. All three pharmacies stated the same issue: they are at ordering capacity and with their wholesaler and can not even fill their current patients requests for Adderall.

THE WALL STREET JOURNAL.

U.S.

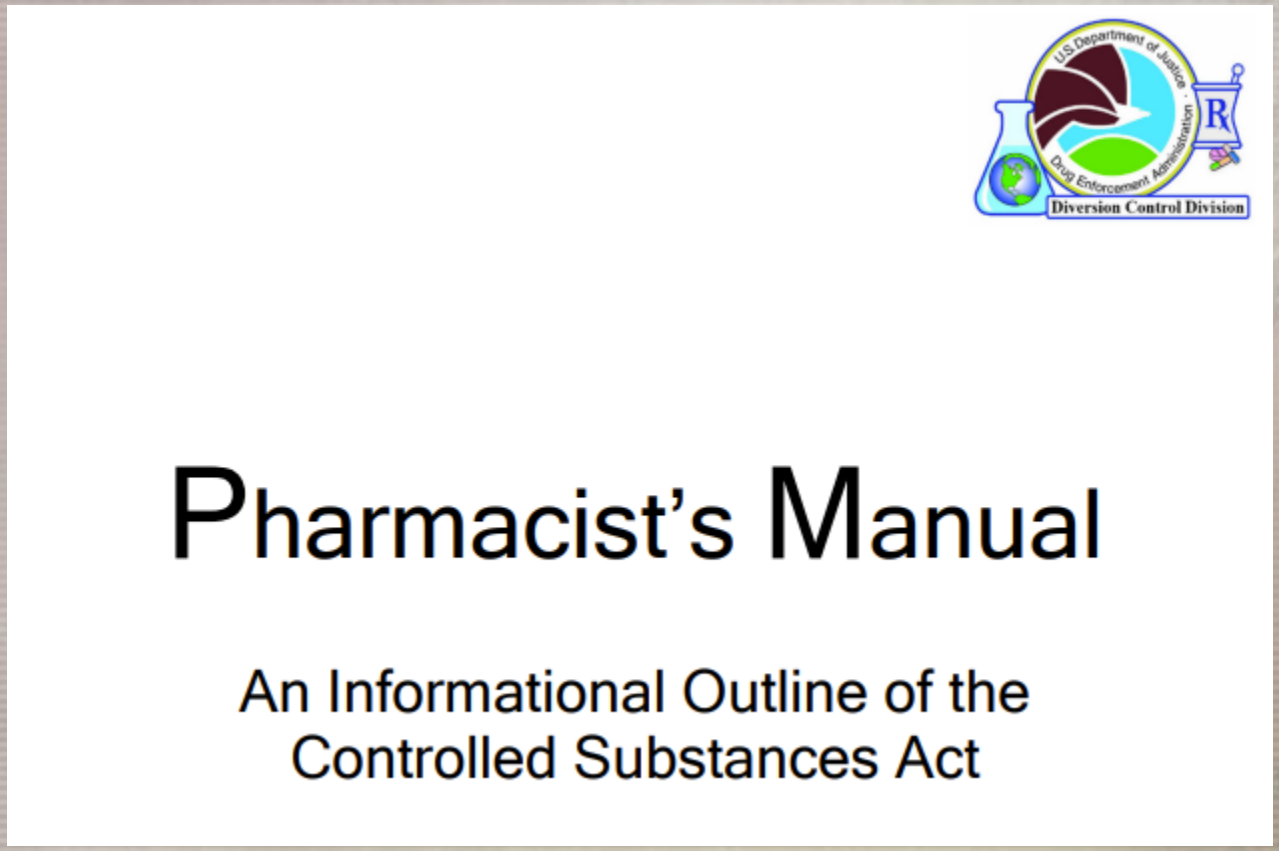
Adderall Shortages Push ADHD Patients to Make Adjustments

Labor shortage at pharmaceutical company, increased demand puts drug on back-order at many pharmacies nationwide

Resources…

- DEA Pharmacist's Manual
  - An Informational Outline of the Controlled Substances Act
    - 129 pages of summary notes
    - https://www.deadiversion.usdoj.gov/pubs/manuals/index.html
- DEA Practitioner's Manual
  - Should be republished any time
    - old one is 62 pages
    - https://www.in.gov/dhs/files/DEA_Practicioner_Manual.pdf

DEA Pharmacist's Manual



- https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf

DEA Pharm

- Updated October 8, 2020
- This is a more thorough review of how the federal regulations work for pharmacists.

Drug Enforcement Administration

Pharmacist's Manual

EO-DEA154

Required Information for Prescription Labels Cont'd

Federal Food and Drug Administration (FDA) regulations found in 21 CFR 290.5 require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: *"CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."* In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. 21 U.S.C. 802(10) and (27). To deliver the controlled substance to anyone other than the patient or a member of the patient's household is distributing, not dispensing. 21 U.S.C. 802(10) and (11).

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.
- Physician, physician assistant, APRN, pharmacist, pharmacy technician, nurse…… all named in the legislation in addition to a comprehensive list of other 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 462 – Conscience Clause

- 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
  - Is not required to participate in a healthcare service that violates his, her, or its conscience
  - Is not civilly, criminally, or administratively liable for declining to participate in a healthcare service that violates his, her, or its conscience
  - Is not civilly, criminally, or administratively liable for the exercise of conscience rights not to participate in a healthcare service by a medical practitioner employed, contracted, or granted admitting privileges by a healthcare institution; and
  - Shall not be discriminated against in any manner based upon his, her, or its declining to participate in a healthcare service that *violates his, her, or its conscience.*
- Is not required to participate in a healthcare service that violates his, her, or its conscience
- "Healthcare service" means medical care provided to a patient at any time over the entire course of treatment, including without limitation:
- …Dispensing or administering, or both, of any drug, medication, or device

Arkansas Act 462 – Scenarios

- Controlled Substance Prescriptions
  - Opioids
  - Benzodiazepines
  - Promethazine with Codeine Cough Syrup
  - Common Combinations

- Off Label Use
  - COVID 19

What Was Missed?

- Is there anything you wish you were taught earlier that you only know now due to exposure and experience regarding drug abuse, misuse and dependence?

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