Clinical and Regulatory Updates Arkansas Stop Overdose Summit 2024

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Disclosure

- We 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
- Discuss challenges with controlled substance drug supply for patients

Anyone notice any changes?

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

CE Requirements from DEA

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

www.dea.gov

DEA Registered-Practitioners

Dear Registrants:

On December 29, 2022, the Consolidated Appropriations Act of 2023 enacted a new **one-time**, eight-hour training requirement for all Drug Enforcement Administration (DEA)-registered practitioners on the treatment and management of patients with opioid or other substance use disorders. Below is information on this new requirement.

Who is responsible for satisfying this new training requirement?

- All DEA-registered practitioners, with the exception of practitioners that are solely veterinarians.

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 en
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 a 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.

PRESS RELEASE

Texarkana Physician Found Guilty of Prescribing a Controlled Substance Without a Legitimate Medical Purpose

Saturday, October 29, 2022

Share

For Immediate Release

U.S. Attorney's Office, Western District of Arkansas

TEXARKANA, AR – A federal jury convicted a Texarkana Doctor yesterday on two counts of Distribution of a Schedule II Controlled Substance Without an Effective Prescription and two counts of Distribution of a Schedule V Controlled Substance Without an Effective Prescription.

According to court documents and evidence presented at trial, the Drug Enforcement Administration (DEA), Little Rock District Office (LRDO), Tactical Diversion and Diversion Groups initiated an investigation into **Dr. Lonnie Joseph Parker**, age 58, of Texarkana, Arkansas in 2018 after receiving complaints from local law enforcement about a suspected pill mill and possible overdose death of a patient. Investigators analyzed prescription drug monitoring data attributed to Dr. Parker, and the investigation revealed Dr. Parker was an over-prescriber of controlled substances, to include opioids, benzodiazepines, and promethazine with codeine cough syrup in the Texarkana area. In the two-year period analyzed, Dr. Parker prescribed approximately 1.2 million dosage units of opioid pain medications, including oxycodone, hydrocodone and fentanyl, to approximately 1,508 patients (approximately 847 dosage units per patient). Dr. Parker also prescribed approximately 16 gallons of Promethazine with Codeine cough syrup to approximately 29 patients during the same time frame. The prescriptions included narcotics written in combination with sedatives, creating a high risk of addiction and overdose to patients.

Parker is scheduled to be sentenced at a later date and faces a maximum penalty of 20 years in prison. He also faces a period of supervised release and monetary penalties. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors.

U.S. Attorney David Clay Fowlkes made the announcement.

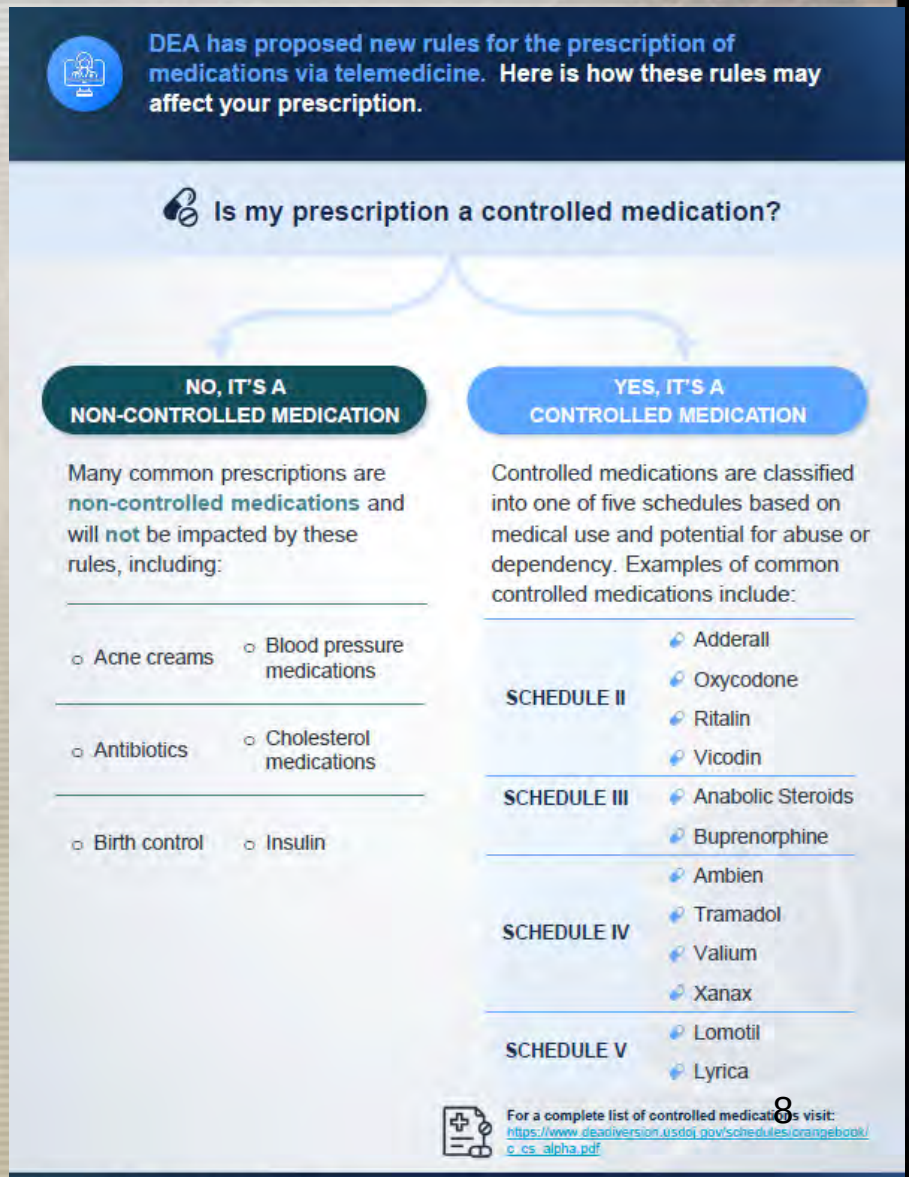
The Drug Enforcement Administration (DEA), Little Rock District Office (LRDO), Tactical Diversion and Diversion Group, the Federal Bureau of Investigation (FBI), the Texarkana Police Department, and the United States Department of Health and Human Services Office of Inspector General (HHS).

Assistant United States Attorney Anne Gardner and Assistant United States Attorney Graham Jones prosecuted the case for the United States.

Updated February 28, 2023

What do Patients Know?

- Most do not know what a “controlled substance” is.
- Many do not know what an “opioid” or “benzo” is.
- Many can only get their controls locally but must get other meds via mail.



DRUG SHORTAGES

- Why do we see them?
- Where are the shortages?
- Whose fault is it?

DEA?

- DEA has a Quota system
- Historically a manufacturer would get a Quota allotment that would define how much of a medication they are allowed to produce.
- Years ago a manufacturer could make 125% of that allotment

DEA Letter

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

November 1, 2023

Dear Americans:

On August 1, 2023, I wrote to you with FDA Commissioner Robert Califf to address the lack of availability of certain prescription stimulant medications. As we said then, the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) recognize the important role that prescription stimulants play in the treatment of conditions such as attention-deficit/hyperactivity disorder (ADHD), binge eating disorder, and narcolepsy. I am writing to you now to provide an update on actions DEA has taken, and is taking, to address shortages in prescription stimulant medications and prevent such shortages from occurring in the future.

As a reminder, DEA does not manufacture drugs and cannot require a pharmaceutical company to make a drug, make more of a drug, or change the distribution of a drug. That said, we regularly engage with manufacturers about their production of drugs, and we set limits (called quotas) for how much of these drugs can be produced.

For amphetamine medications, like Adderall, our data showed that in 2022, manufacturers did not produce the full amount that these limits permitted them to make—resulting in a shortfall of 1 billion doses that could have been produced but were not made or shipped—and the data for 2023 has shown a similar trend. DEA has been in communication with the relevant manufacturers, and 17 out of 18 manufacturers have informed us that they will use their allotted quota amounts and increase production of stimulant medications. Those manufacturers are currently in the process of providing us with information on how long it will take for those stimulant medications to hit pharmacy shelves.

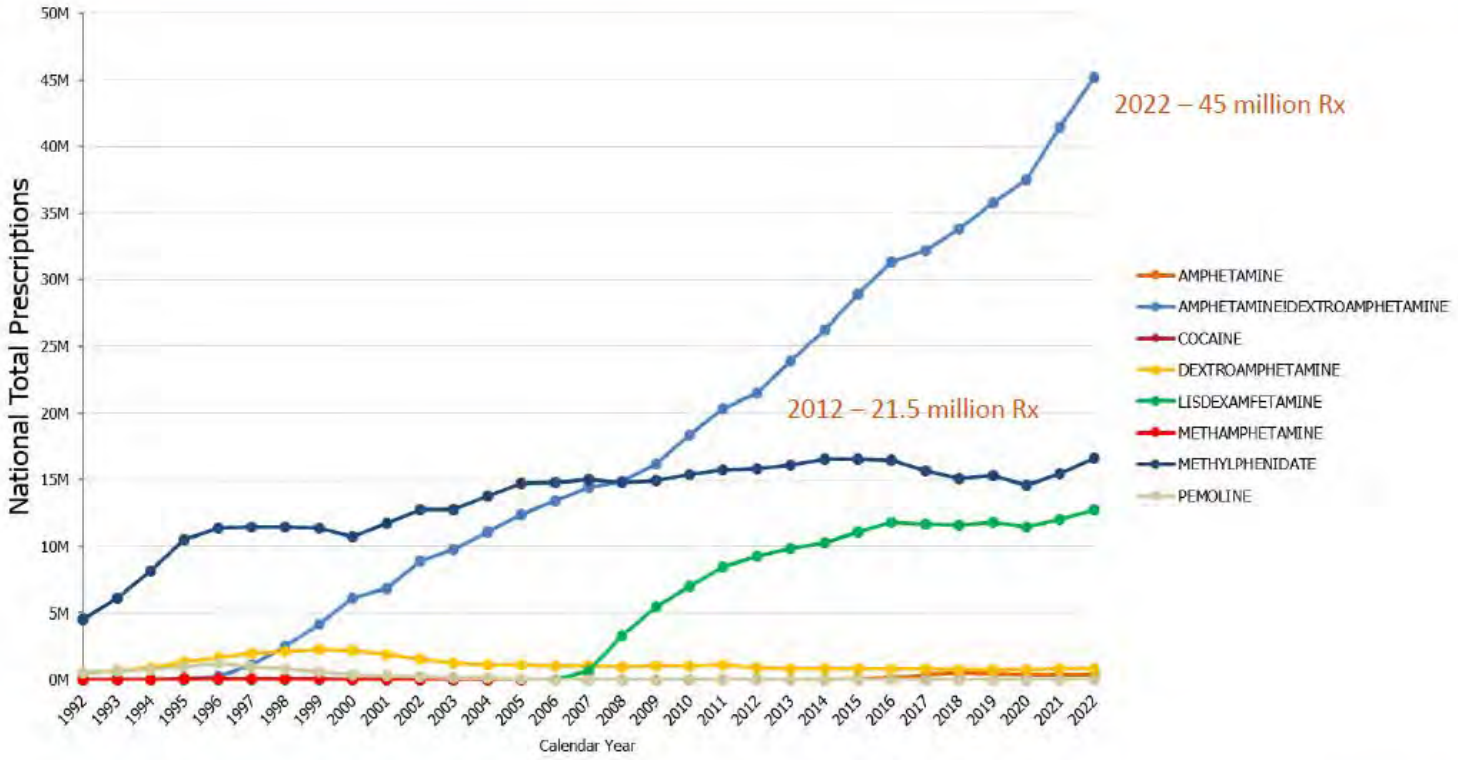
DEA is also actively making changes to our quota allocation process. On August 28, 2023, we changed our quota regulations to reduce the amount of a drug that manufacturers must keep in inventory and to make it easier for manufacturers to voluntarily relinquish their quota allotments in case they are not able to produce a drug. Earlier today, we announced steps we will take to increase manufacturer transparency and receive better real-time data on the status of drug production going forward. These changes include:

- Requiring drug manufacturers to submit their anticipated production timelines for medications to DEA in advance of receiving their quota allotments;
- Requiring drug manufacturers to apply for quota allotments on a quarterly (instead of yearly) basis, so that we are able to provide quota allotments to manufacturers that have demonstrated they are using them to actually make and sell medications for current use;

DEA Supply Chain Conference

- April 30 – May 2, 2024 in Little Rock
  - https://www.deadiversion.usdoj.gov/mtgs/supply_chain/conf_2024.html
- Quotas - Aggregate Production & Individual Quotas
- MOUD Update & Take Back - Disposal/Authorized Collectors
- Preparing for a DEA Inspection: What to expect and how to better prevent diversion
- NABP Pulse

Total Stimulant Prescriptions by Combined Molecule



Source: IQVIA, SMART – US Launch Edition
Accessed at https://smart.imshealth.com/ on 4/29/2022

ADDITIONAL CONSTRAINTS in this MOMENT

Highly genericized markets – shifts in market share from year-to-year

- Lisdexamfetamine

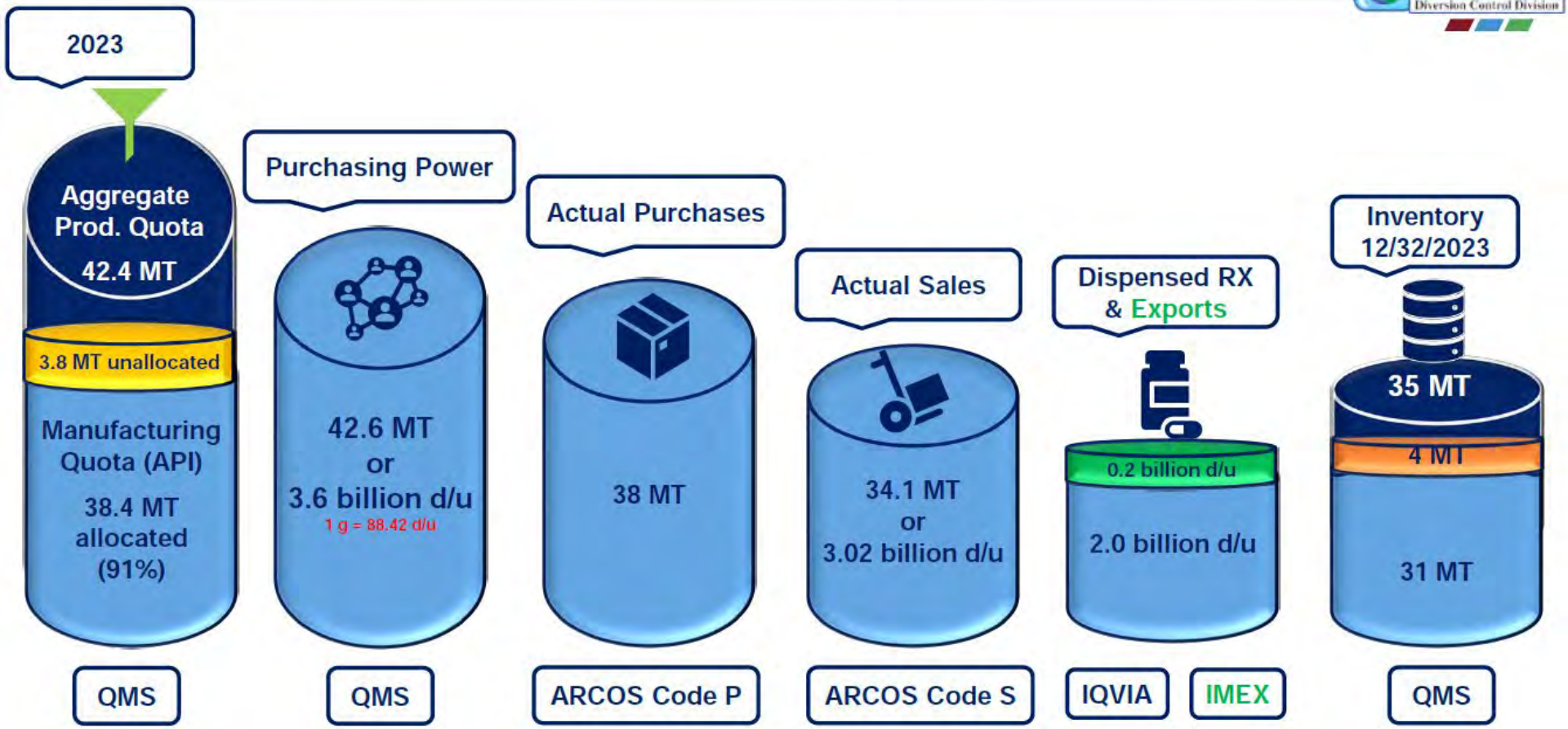
"*Schedule II market is radioactive*"*

- Impact of Multi-District Litigation
- Manufacturers electing to discontinue marketing
- Access to Capital
- Congress (and OIG) critical of DEA

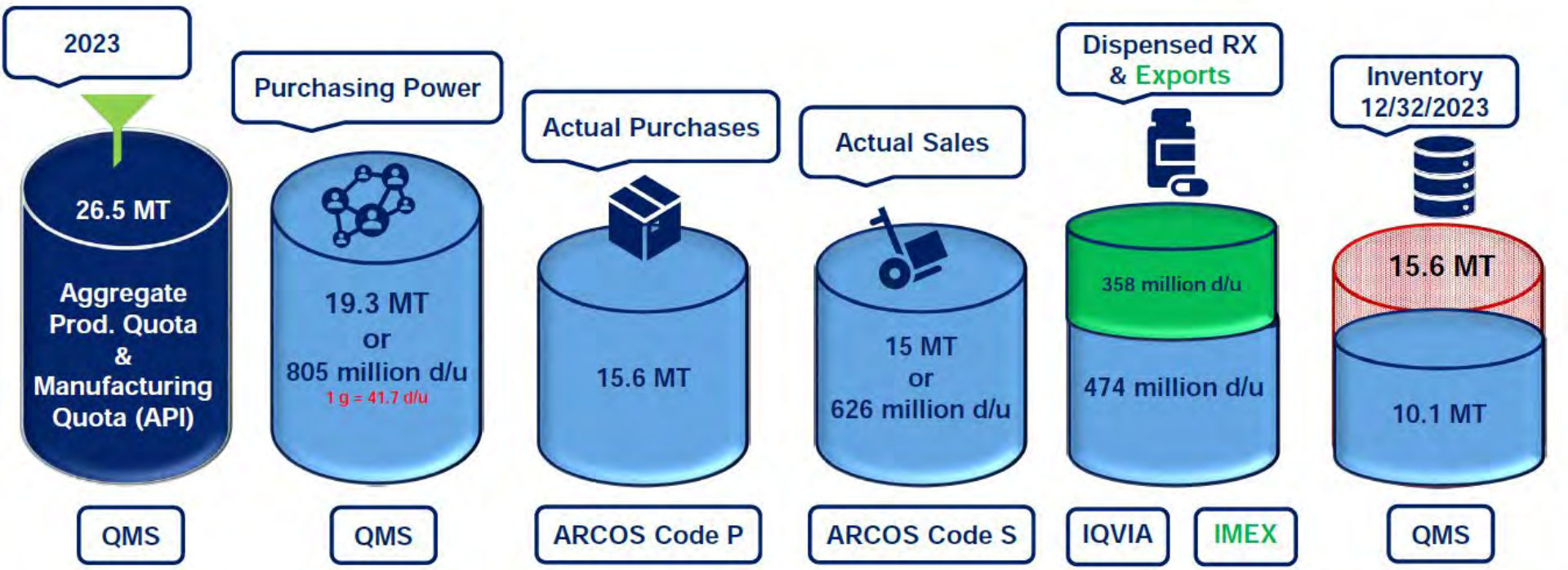
Role of Quota

*Quote from DEA Registrant

BY THE NUMBERS – AMPHETAMINE (CY 2023)



BY THE NUMBERS – Lisdexamfetamine (CY 2023)



ROLE OF QUOTA

When a PQ is granted, DEA cannot compel a company to:

Where are the delays?

- Quota awarded
- 84 days to receive API
- 56 days to produce drug
- 7 days to get to distributor
- 14 days to get to pharmacy

- 161 days from award-production-distribution-pharmacy

Control Tower BETA

DIVERSION CONTROL

Diversion Regulatory UN Reporting & Quotas Section

Drug Schedule | Drug Name | Data For Drug Class Not Yet Available

Dashboard Refreshed: 2024-04-02 22:50

MANAGEMENT: APQ

- HOME
- APPLICATIONS
- REGISTRANTS
- DRUG CODE
- APQ

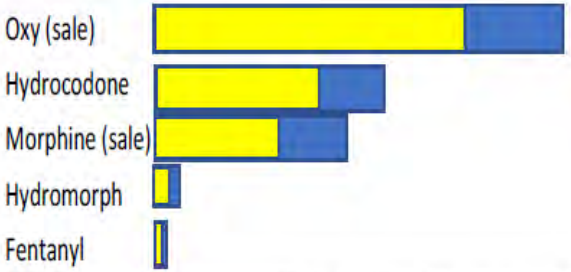
STIMULANTS OVERVIEW

DATA NOT YET AVAILABLE FOR APQ VIEWS

	APQ (kg)	MQ (kg)
Methylphenidate (sale)	53,283	51,088
Amphetamine	42,400	38,366
Lisdexamfetamine	26,500	26,500
Dexmethylphenidate (sa	6,200	3,956

OPIOIDS OVERVIEW

DATA NOT YET AVAILABLE FOR APQ VIEWS



	APQ (kg)	MQ (kg)
oxycodone (for sale)	53,840	40,480
hydrocodone	27,239	20,192
morphine (for sale)	21,747	14,412
hydromorphone	1,994	1,132
fentanyl	731	668

Manufacturers?

- DEA Quotas more recently were changed to quarterly for non-injected medications.
- DEA Quotas/allowances were approved for millions of doses that were either not produced or not distributed.

Wholesalers?

- Federal Injunctive relief document on the big 3 – McKesson, Cardinal, Amerisource
- Often see others that follow the same guidelines on KYC – know your customer, threshold limits being blinded to customers.
- Usually will cut off all controls including buprenorphine.

Slide T

- Your bullet poir

Dear DEA Registrant,

In 2022, 6.1 million people in the United States had an opioid use disorder (OUD). Among them, only 18.3% received medication-assisted treatment. The removal of the Drug Addiction Treatment Act of 2000 "x-waiver" in December 2022 eliminated a significant barrier to treatment for OUD, dramatically increasing the number of medical professionals who can prescribe buprenorphine from the previously eligible 130,000 prescribers.

The Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) are committed to ensuring safe and ready access to medications for opioid use disorder (MOUD), especially in rural or underserved areas where treatment options have been limited. With the passage of the Consolidated Appropriations Act, 2023,[1] there was an immediate and significant increase in the number of practitioners who can prescribe schedule III MOUD products (e.g., buprenorphine combination products containing buprenorphine and naloxone) for patients with OUD.

As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. DEA recognizes that there have been recent increases in demand for certain schedule III MOUD controlled substances as compared to years prior to the Opioid Public Health Emergency, and that there may be a corresponding increase in prescriptions for these medications from medical providers. DEA supports collaboration amongst all DEA registrants to ensure there is an adequate and uninterrupted supply of MOUD products when these products are appropriately prescribed. Distributors should carefully examine quantitative thresholds they have established to ensure that individuals with OUD who need buprenorphine are able to access it without undue delay. DEA has posted a guidance document on its portal related to this issue: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf.

For more information, please visit www.samhsa.gov and/or www.DEAdiversion.usdoj.gov. It is our sincere hope that the remarkable increase in the number of medical professionals who can prescribe this life-saving medication will not only change the lives of individuals with OUD, but will also stem the escalating rate of opioid-related deaths at a population level.

Please join us in this fight to save lives.

Sincerely,

Anne M. Milgram
Administrator,
Drug Enforcement Administration
Department of Justice

Rachel L. Levine, M.D.
ADM, USPHS
Assistant Secretary for Health
Department of Health and Human

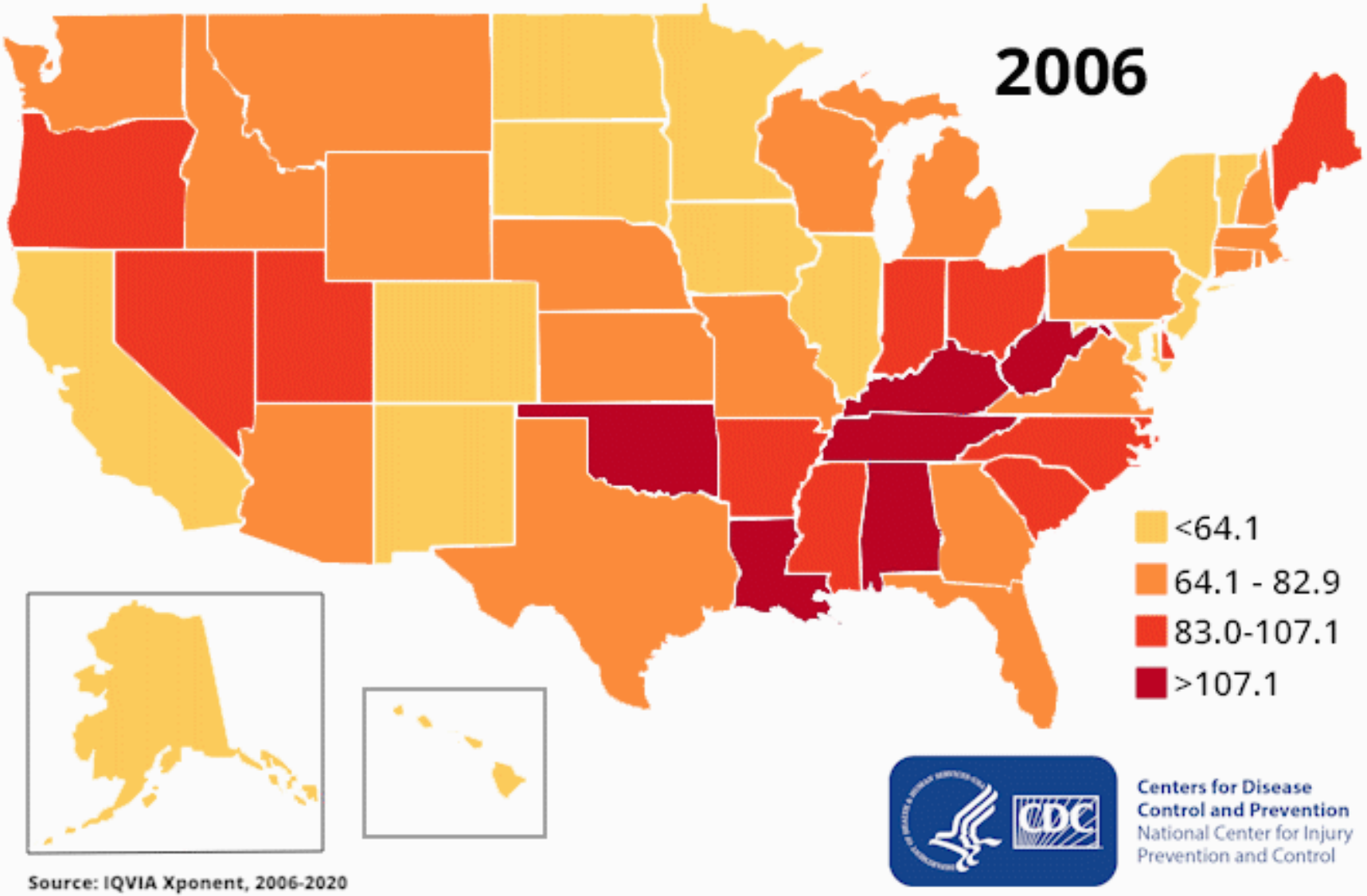
Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Department of Health and Human Services

Pharmacies?

- Where are the drugs coming from for patients.
- Controlled substances % filled by Arkansas pharmacies vs out of state pharmacies.

U.S. Opioid Dispensing Rates per 100 people, from 2006 to 2020

How have rates improved over time?



Source: IQVIA Xponent, 2006-2020

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

Message About Prescribers

- You need to be having conversations with your area pharmacies and pharmacists
- Talk about how you manage controlled substance prescribing and patient expectations
- Ask what problems each is facing
- Have a plan for your patients before surgery, discharge or other planned events!

Drug Enforcement Administration
Diversion Control Division
Guidance Document

Title: DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders

Summary: This guidance document clarifies that neither the Controlled Substance Act (CSA) nor the Drug Enforcement Administration (DEA) regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense. This document also reminds all DEA registrants of the requirement to establish systems to identify and report suspicious orders of controlled substances to include Medication for Opioid Use Disorder (MOUD).

Activity: Reporting Suspicious Orders of Controlled Substances Including MOUD

To Whom it Applies: DEA Registrants

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify suspicious orders for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. 21 U.S.C. 832(a). Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 U.S.C. 802(57). Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. 21 CFR 1301.71(a).

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer's controlled substance purchases and may prompt a report of a suspicious order to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributer may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

EO-DEA258, DEA-DC-065, January 20, 2023.

Upset Physician

- Physician upset that pharmacies were refusing to fill prescriptions from their clinics.

Firstly I read the corresponding responsibility paragraphs you sent to me and that I was already familiar with over and over again. I even had lay people read it and interpret it as well.

21 CFR § 1306.04 Purpose of issue of prescription.

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.

The corresponding responsibility says three main things. First it is better described as a corresponding liability than responsibility. It says that the prescriber is in charge of and responsible for the prescribing of controlled substances. There is no duel or shared determination of the meds being prescribed. It's at the discretion of the prescriber. Period. In cases where the prescriptions are being written for illegitimate reasons outside the practice of medicine then the corresponding liability would apply. However it still states in order to be correspondingly liable/responsible the pharmacist has to KNOW they are illegitimate and fill them anyway. If the scripts are legitimate the pharmacist isn't responsible or liable for the prescribers prescribing. If the pharmacist doesn't know they are illegitimate it doesn't apply either.

It clearly applies only to that unique and rare situation. It's obvious this was added because pharmacists at some point were complicit in illegitimate prescribing operations and had tried to claim immunity since they were not the prescribers. In the further clarification you sent of the corresponding responsibility it states that pharmacists are not required by law to fill prescriptions that meet the known illegitimate situation as mentioned above.

Who is Confused

- Attempts were made to educate the prescriber

This is the only reason it mentions that pharmacists are not required by law to fill them. No other reasons were mentioned, alluded to or suggested. Henceforth if that unique situation does not apply they are required by law to fill them. Again this is the guidelines I'm familiar with, and the only ones you sent me justifying the ten or more other reasons you claim that pharmacists aren't required to fill scripts. You did not provide me any other clarification expanding this other than your opinion. To use this guideline of corresponding responsibility to blacklist a physician's controlleds indefinitely is to say that somehow the pharmacy knows without knowing the meds prescribed or the patients being prescribed to are all going to be illegitimate and therefore can all be blocked in entirety. Of note I have never had a pharmacist refuse to fill a prescription because they knew it was illegitimate. It has always been some other reason not listed in the corresponding responsibility such as ignorance, arrogance, or bias. Occasionally they say they aren't comfortable with my prescriptions. That's not a surprise. They shouldn't be comfortable deciding what meds to prescribe to my patients they know nothing about. That's the whole point. Pharmacists weren't trained to be comfortable deciding those things. I was. I am comfortable with my prescriptions. You may be confusing or conflating "appropriate" with legitimate. Appropriateness would be a clinical term describing whether or not a particular drug or prescription is the best choice for a particular diagnosis or patient. While pharmacists would reasonably have some knowledge related to appropriateness, you are not charged with determining that by any governing body. Legitimacy is referring to whether a script was technically legally written and for proper legal intent and purpose. Meaning it wasn't written outside proper legal channels. For you to suggest that the "experts" at Walmart including former law enforcement as you emphasized, know ANYTHING about my prescriptions legitimacy is absurd. They have not viewed the medical records of any of my patients. Especially for future unwritten prescriptions to unknown patients. Nobody at Walmart knows my patients or anything about them. My patients have never spoken with a pharmacist at Walmart about their health or medical problems and rarely about their actual prescriptions. You refer to them in your email as patients but they are more like clients or customers. Patient implies you are providing care for them which is a very very very generous argument. Patients are not currently required by law to discuss their medical issues with a pharmacist in order to receive a prescription. In my 53 years as a patient myself I have never had a discussion with a pharmacist about any of my health issues. Yet you now propose that your profession is in a position to better understand what I might need than my own personal doctors?

About Controlled Substance Rules/Regulations

I don't know why pharmacies think they are exempt from HIPAA. They have tried to tell us that numerous times and you mentioned that as well. We have had pharmacies refuse to fill patients controlleds unless we would send the patient's medical records. They would tell the patients that they were required by law to get them in order to fill the scripts. None of that is true. No state or federal guidelines require medical records in order to dispense a prescription. There is no DEA requirement for that either as has been suggested by numerous local pharmacies. Nobody is exempt from HIPAA. Yes pharmacists can receive personal health information that is required on a prescription as part of the health care team. However diagnosis is not a required element. Certainly entire medical records aren't either. One pharmacy told us we were the only clinic who wasn't providing a patient's entire medical records at their request. I informed them that I would have to have a signed consent from the patient to send that to them. This is the law as I and my lawyers understand it. I don't know what having a patient's entire medical record would protect them from, or where they would store it, or who would review it, or who would interpret it for them anyway. Patients were misled numerous times about some new law requiring them to have that for their scripts and were coerced into signing consents only to find out from us later that was not true and not required at all. My patients were not happy about being misled.

Are there a subset of patients who sell their controlled substances? Yes. Law enforcement should prosecute those who do. Those who are doing this are not afraid to do it because there are rarely any consequences for it. And the whole process is funded by subsidized insurance. They should lose their insurance and serve time or community service or something. I've fired and reported patients suspected of this in the past. Nothing ever happens and they move on to the next clinic. Does this mean we should quit treating all the patients with certain problems because of the actions of a few? Of course not! The industry has marginalized and discriminated against patients who do have chronic conditions that are treated with controlleds and some doctors have quit even trying to figure out which patients are legit and which ones aren't and refuse to care for patients with certain problems. That's even more atrocious. This seems to be encouraged by groups like yourself and the DEA and politicians who are only treating and tracking group numbers and forgetting there are real patients behind that data. You will certainly experience that malice if you ever become a chronic pain or psych patient yourself. We draft laws that require them to see us for these problems and the treatments for them, then gaslight and belittle them when they do! The population policies are already causing individual patients to slip through the cracks. Putting quotas on the population undermines individual's access to care and treatments. Clearly we saw that with the shortages of amphetamines and pain meds this year due to the DEAs quota policies. This seems more about politics than patient care and as individual physicians we are supposed to be advocates for our patients as individuals.

Arkansas Law?

Stricken language would be deleted from and underlined language would be added to present law.
Act 462 of the Regular Session

State of Arkansas *As Engrossed: H3/9/21*
93rd General Assembly **A Bill**
Regular Session, 2021 SENATE BILL 289

By: Senators K. Hammer, Beckham, Bledsoe, Flippo, T. Garner, Gilmore, Hester, Irvin, B. Johnson, M. Johnson, Rapert, G. Stubblefield, D. Sullivan
By: Representatives B. Smith, Beck, Bentley, Breaux, Brown, Cloud, Gazaway, Ladyman, Lowery, Lundstrum, McCollum, Payton, Penzo, Richmond, Rye, Speaks, Womack

For An Act To Be Entitled

AN ACT TO CREATE THE MEDICAL ETHICS AND DIVERSITY ACT; AND FOR OTHER PURPOSES.

Subtitle

TO CREATE THE MEDICAL ETHICS AND DIVERSITY ACT.

(6) "Medical practitioner" means an individual who is:

(A) A physician;

(B) A physician assistant;

(C) An advanced practice registered nurse or other nurse practitioner;

(D) A pharmacist;

17-80-504. Right of conscience.

(a) A medical practitioner, healthcare institution, or healthcare payer:

(1) Has the right not to participate in a healthcare service that violates his, her, or its conscience;

(2) Is not required to participate in a healthcare service that violates his, her, or its conscience;

(3) Is not civilly, criminally, or administratively liable for declining to participate in a healthcare service that violates his, her, or its conscience;

(4) 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

(5) 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.*

(b) Exercise of the right of conscience is limited to conscience-based objections to a particular healthcare service.

(c) A medical practitioner, healthcare institution, or healthcare

Arkansas Act 462 – Conscience Clause

- **SB289 (ACT462) of 2021**
- **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

Other External Pressures

- PBM policies that encourage non-controls to be delivered from other states
- Other state rules that prevent patients from getting prescriptions from Arkansas filled in those states.

ATTORNEY GENERAL GRIFFIN SUES PHARMACY BENEFIT MANAGERS FOR ROLES IN ARKANSAS OPIOID EPIDEMIC

JUNE 24, 2024

Griffin: 'Pill by pill and dollar by dollar, PBMs enabled the opioid epidemic in Arkansas'

LITTLE ROCK – Attorney General Tim Griffin today announced he has filed a lawsuit against pharmacy benefit managers (PBMs) Optum, Inc., and Express Scripts, Inc., and their subsidiaries for their roles as a cause of the opioid epidemic in Arkansas and issued the following statement:

"Pill by pill and dollar by dollar, PBMs enabled the opioid epidemic in Arkansas. Today, we begin the process of holding them accountable for their roles in a crisis that has ravaged our state—a crisis they helped cause, contributed to, and furthered.

TIM GRIFFIN

ATTORNEY GENERAL OF ARKANSAS

FOR IMMEDIATE RELEASE

June 24, 2024
CONTACT: Jeff LeMaster
(501) 683-1532
jeff.lemaster@arkansasag.gov

Attorney General Griffin Sues Pharmacy Benefit Managers for Roles in Arkansas Opioid Epidemic

Griffin: 'Pill by pill and dollar by dollar, PBMs enabled the opioid epidemic in Arkansas'

LITTLE ROCK – Attorney General Tim Griffin today announced he has filed a lawsuit against pharmacy benefit managers (PBMs) Optum, Inc., and Express Scripts, Inc., and their subsidiaries for their roles as a cause of the opioid epidemic in Arkansas and issued the following statement:

"Pill by pill and dollar by dollar, PBMs enabled the opioid epidemic in Arkansas. Today, we begin the process of holding them accountable for their roles in a crisis that has ravaged our state—a crisis they helped cause, contributed to, and furthered.

OKLAHOMA STATE BOARD OF PHARMACY

All prescriptions for Controlled Dangerous Substances (CDS) should be received at the pharmacy either electronically or on the OBNDD pad. This requirement includes out of state prescribers.

Additionally, out of state prescribers (including physicians) of CDS are required to register with OBNDD and their appropriate Oklahoma licensing Board in order to prescribe CDS for Oklahoma patients to be filled in Oklahoma pharmacies.

63 O.S. § 2-302(A) provides clarity on the basis for this interpretation.

The Oklahoma Board of Osteopathic Examiners has already begun the notification process for physicians. They have established a deadline of July 1, 2024, to either file an application for licensure or to cease practice in the state of Oklahoma immediately.

J. KEVIN STITT
Governor

DONNIE ANDERSON
Director

OKLAHOMA STATE BUREAU OF NARCOTICS AND DANGEROUS DRUGS CONTROL
419 N.E. 38th Terrace
Oklahoma City, Oklahoma 73105
TELEPHONE 405-521-2866 · 1-800-522-8031

Statement from the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Relating to Oklahoma Pharmacies Filling Prescriptions Written by Out-of-State Practitioners

An issue has arisen within the Oklahoma medical community related to Oklahoma pharmacies filling prescriptions for controlled dangerous substances (CDS) issued by practitioners from other states (i.e., the entirety of the medical visit and treatment took place in the sister state with the prescription electronically transmitted to the Oklahoma pharmacy). I wish to state publicly the position of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control on this issue.

The question, and perhaps dispute, appears to relate to whether the electronic transmission of the prescription into Oklahoma constitutes prescribing "into this state" under 63 O.S. Section 2-302(A). The "into this state" language appears to have been added to the statute in 2019 and applied to all registrant activity including manufacturing, distributing, dispensing, administering, and use for scientific purposes.

For decades, it has been the accepted and well-known practice for Oklahoma pharmacies to recognize the legitimacy of prescriptions written by practitioners licensed in other states. There has been no substantive change to the law related to this issue other than the aforementioned additional language added five (5) years ago. In fact, the *Uniform Controlled Dangerous Substance Act* (UCDSA) defines "state" as Oklahoma or any other state of the United States. 63 O.S. Section 2-101(45). Consequently, the UCDSA's recognition of orders from practitioners from other states is exactly why a person passing through Oklahoma in possession of a CDS pursuant to a lawful prescription written and filled in a sister state is not in unlawful possession of that CDS.

As such, after consultation with both attorneys at my agency and the senior command staff of my diversion division, **it is my belief that neither the UCDSA nor OBNDD's administrative rules prohibit an Oklahoma pharmacy from filling a prescription for a CDS written by a practitioner who lawfully practiced and wrote that prescription in that state.** I will not cite all of the reasons for this statutory interpretation, but it is this agency's position that the act of prescribing is complete upon the practitioner writing/issuing the prescription in that state. The subsequent electronic transmission of the prescription (oftentimes done by a support staff member after the practitioner's patient contact is complete) to the patient's pharmacy of choice is not prescribing "into this state." Prescribing and dispensing are separate acts and registrants are oftentimes permitted to do one and not the other under their registration. It should be noted that pharmacies must still comply with all laws related to the filling of such prescriptions regardless of what state the practitioner is licensed (electronic prescriptions, refill and duration restrictions, etc.).

OBNDDC absolutely respects our colleagues from the regulatory bodies of our practitioners and this agency takes no position on what these agencies permit under their respective statutes and rules. This position statement is a narrow one – our interpretation as to what is permitted or prohibited under the UCDSA and our rules. I further respect and understand the different interpretation of these relevant statutes and rules. In fact,

I will be attempting to facilitate an official opinion from the Oklahoma Attorney General and intend on working with our partners at the next legislative session to address this issue. However, this issue affects thousands of patients and professionals today which I believe necessitates a public statement regarding where this agency has landed when examining this issue.

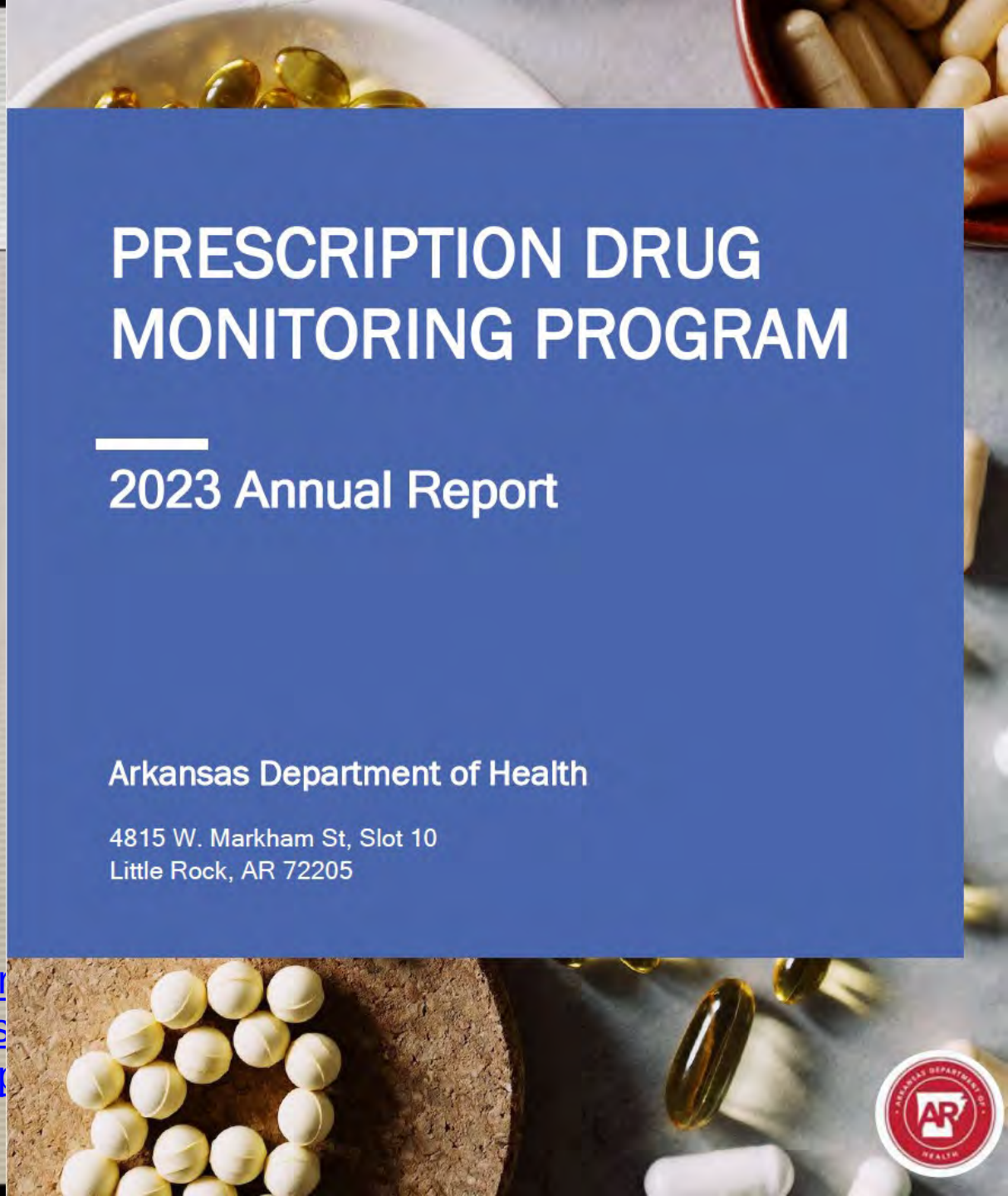
I wish to again emphasize that it is my firm belief that those professionals who have a different interpretation of this issue are absolutely acting in good faith and seeking to protect the public and comply with the law. I know we all will work together in the future with our lawmakers to add clarity to this very important issue.

Respectfully,

Donnie Anderson

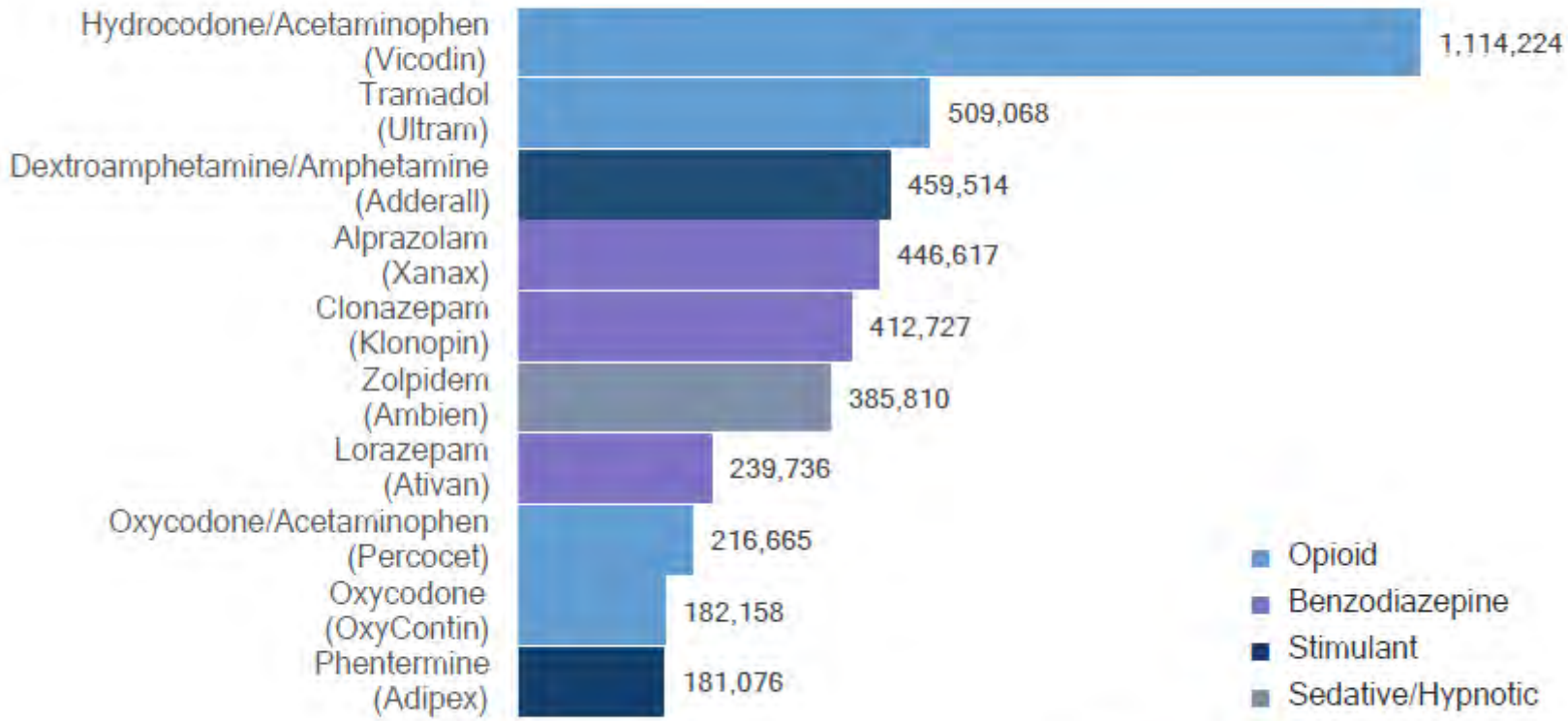
Donnie Anderson, Director
Oklahoma State Bureau of Narcotics
And Dangerous Drugs Control

PDMP Reports



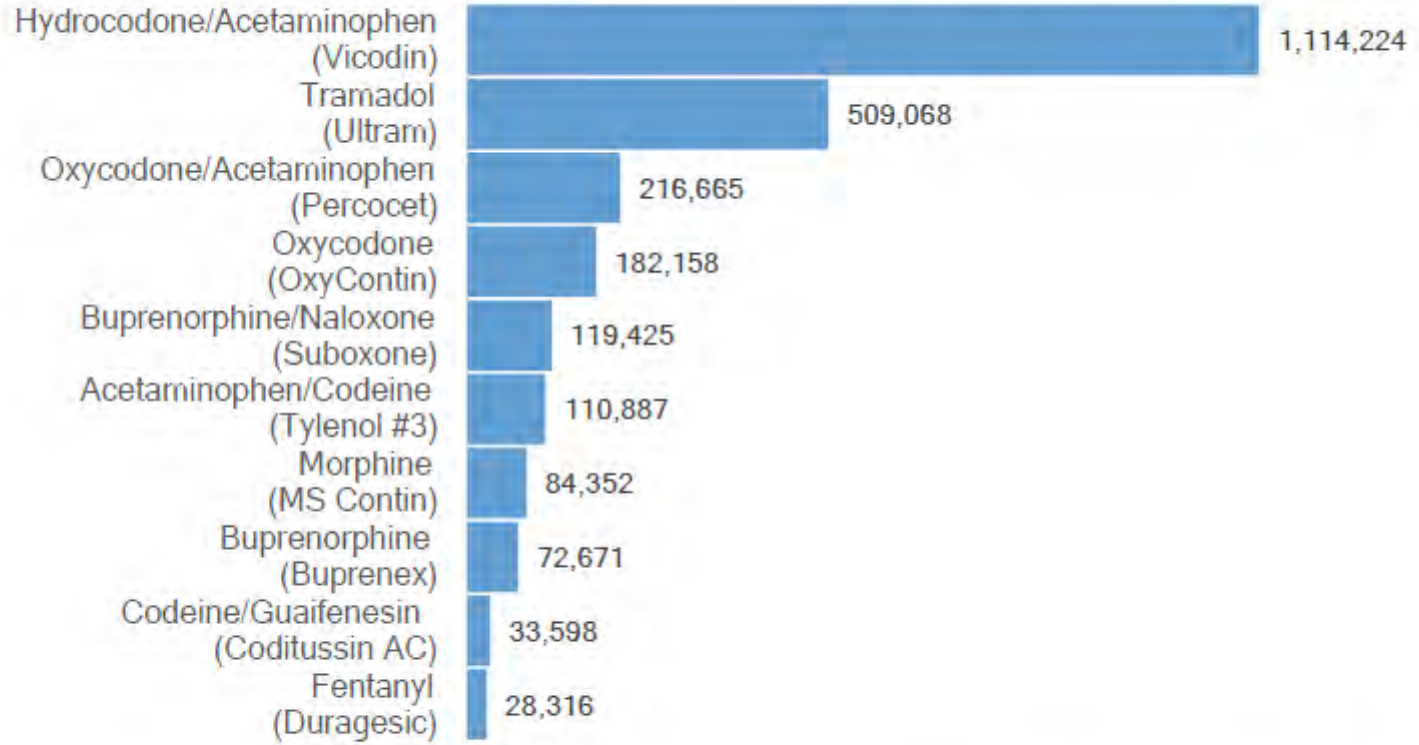
https://healthy.arkansas.gov/pr
healthy-living/substance-misus
drug-monitoring-program/pdmp

Figure 10: Most Frequently Prescribed Controlled Prescription Drugs, Arkansas 2023.



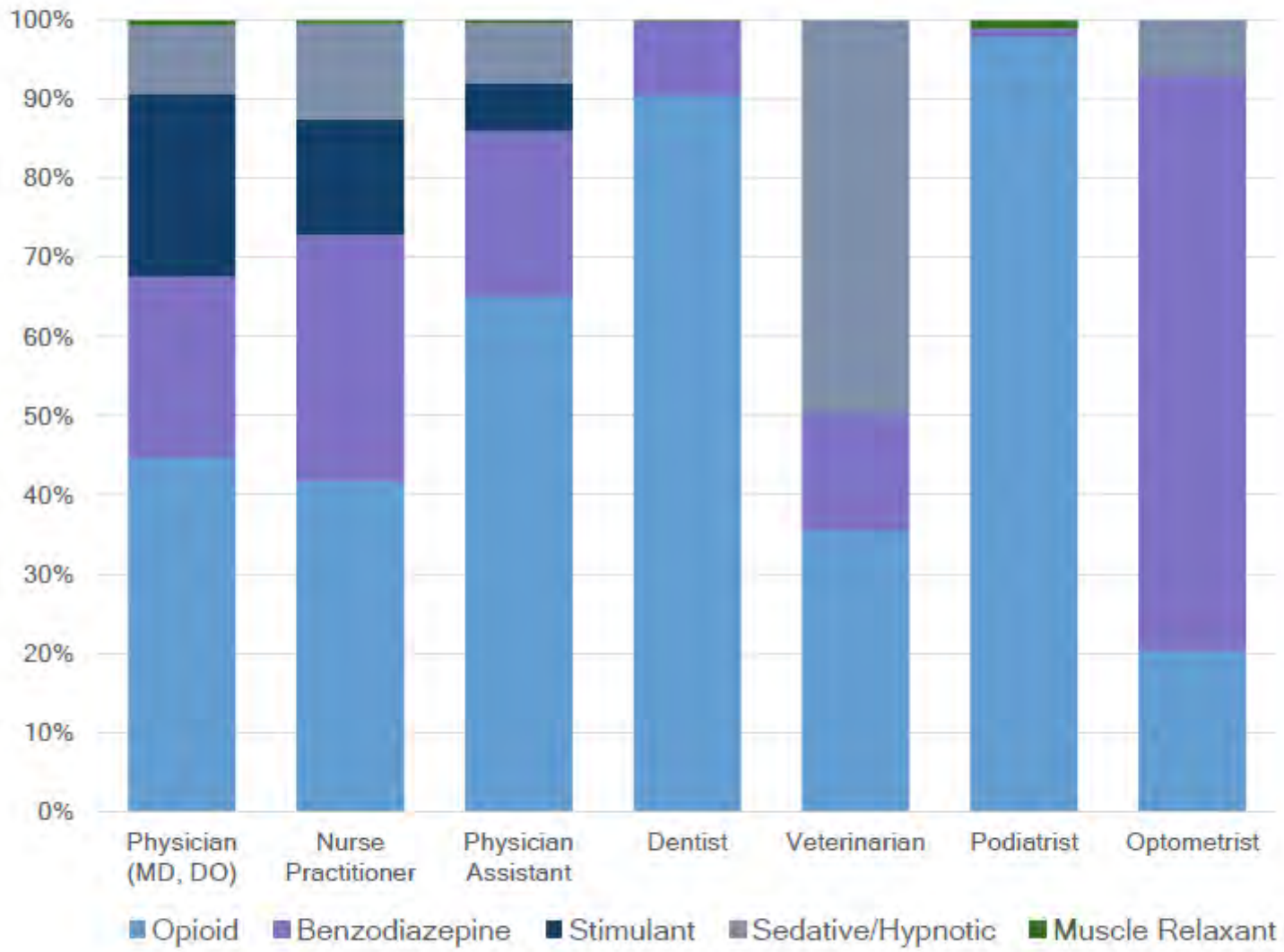
Source: AR PDMP merged with RxNorm
Prescriptions written by AR prescribers to AR residents

Figure 11: Most Frequently Prescribed Opioids, Arkansas 2023.



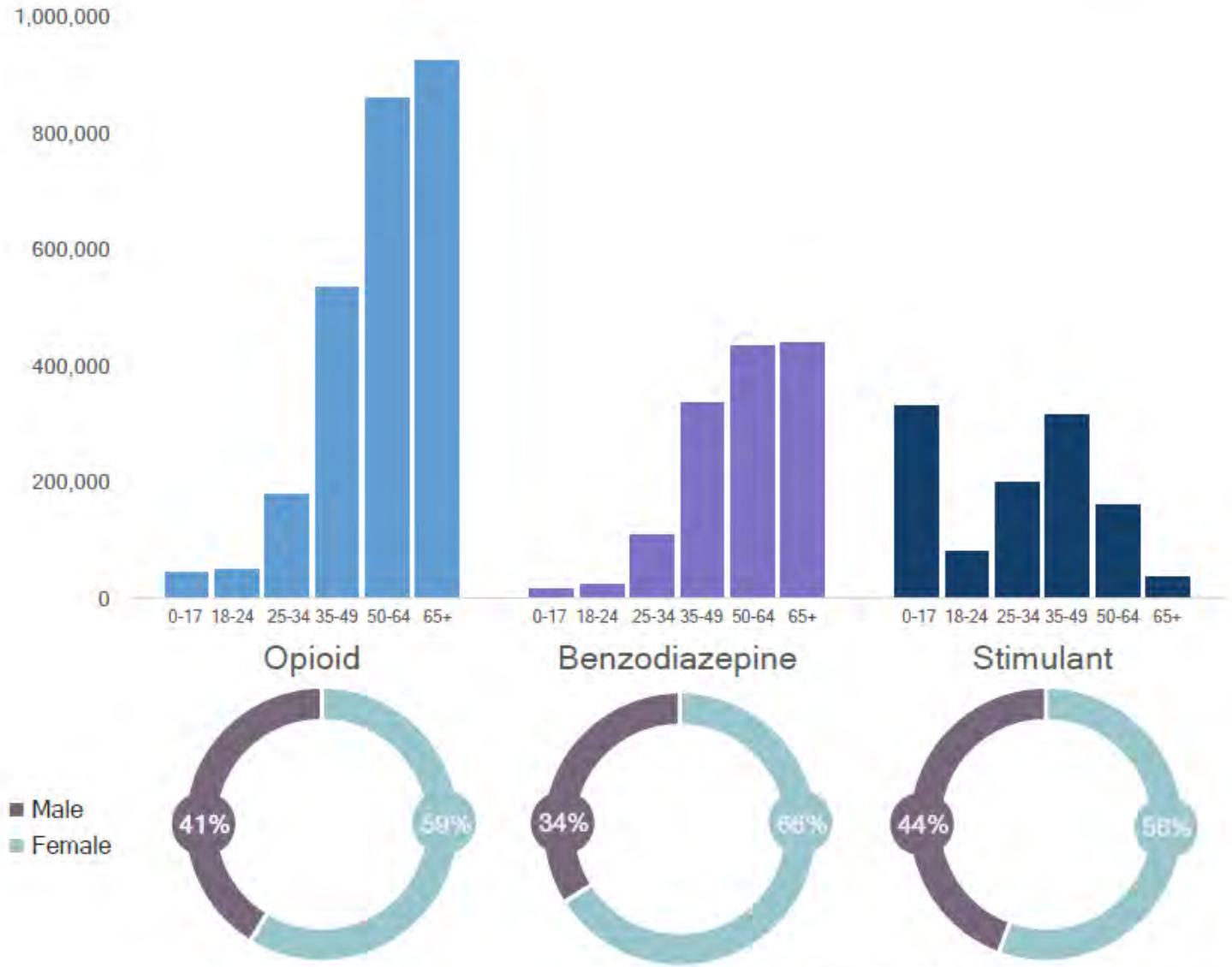
Source: AR PDMP merged with RxNorm
Prescriptions written by AR prescribers to AR residents

Figure 9: Most Frequently Prescribed High Risk Drug Classes by AR Providers to AR Residents, Arkansas 2023.



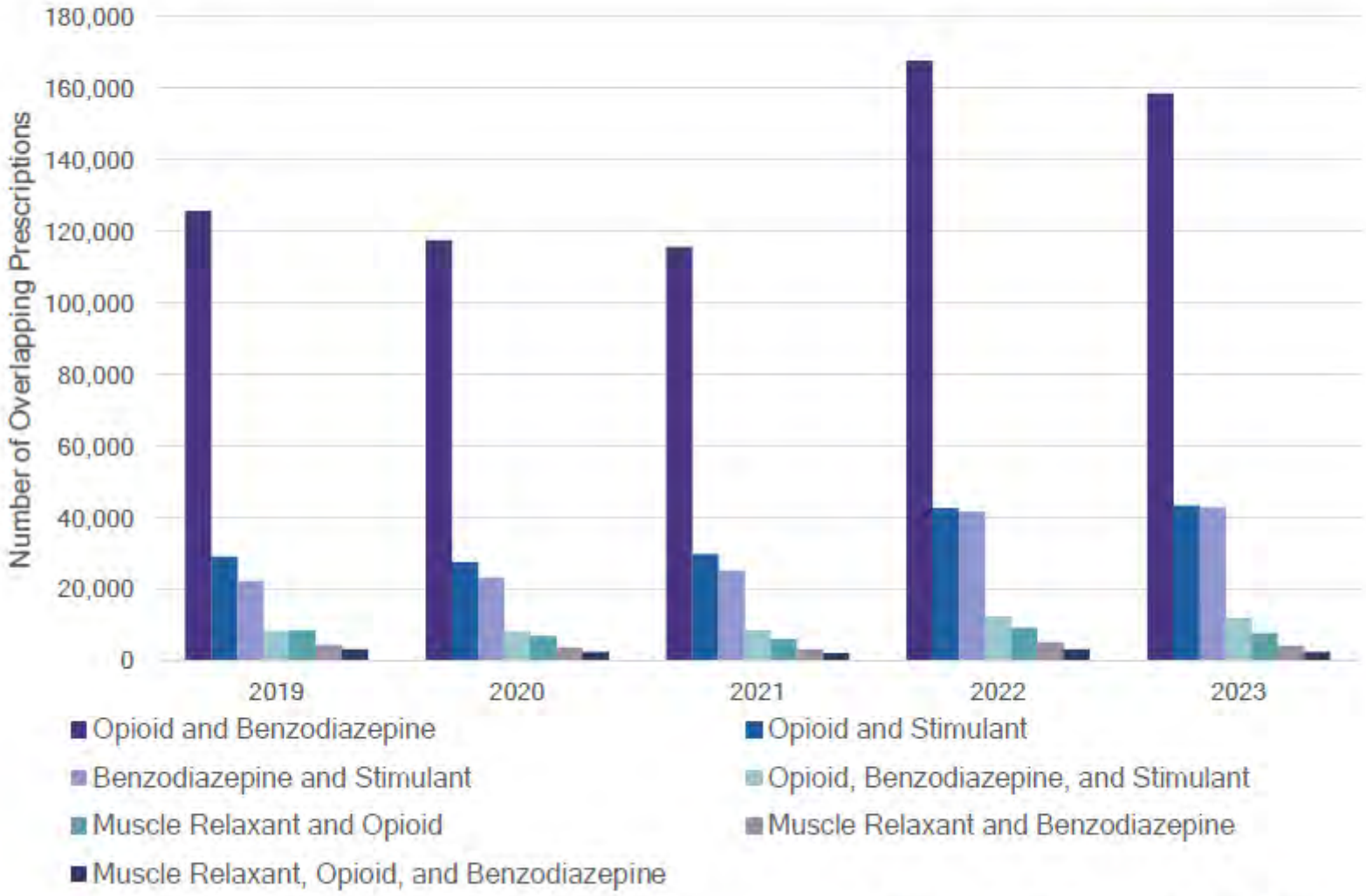
Source: AR PDMP

Figure 13: Opioid, Benzodiazepine, and Stimulant Prescriptions by Age and Sex, Arkansas 2023.



Source: AR PDMP merged with RxNorm
Prescriptions written by AR prescribers to AR residents

Figure 19: Overlapping Prescriptions of Multiple Controlled Drug Classes, Arkansas 2019-2023.



Source: AR PDMP merged with RxNorm
Prescriptions written by AR prescribers to AR residents

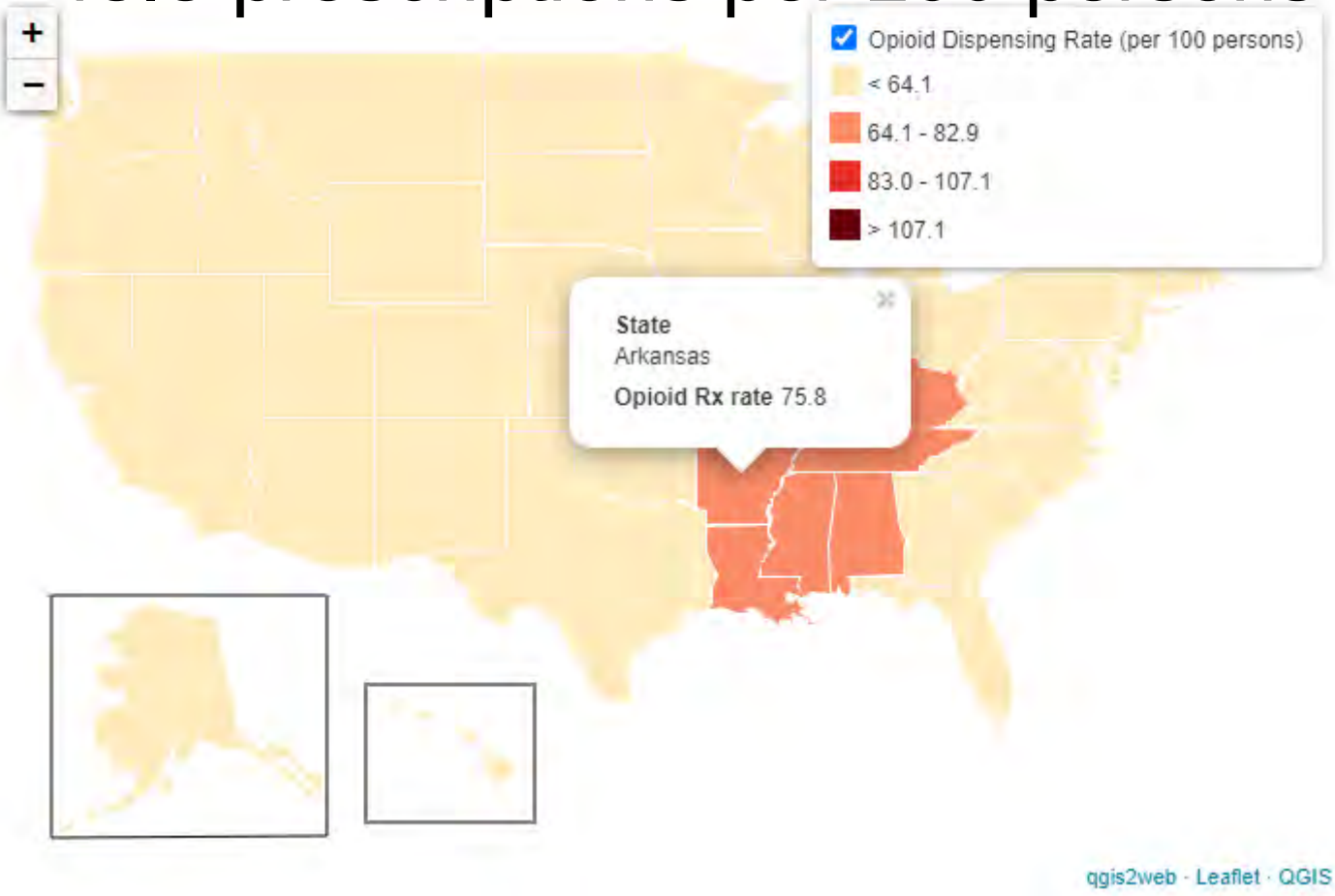
U.S. State Opioid Dispensing Rates, 2020

Print

< U.S. State Opioid Dispensing Rates, 2019

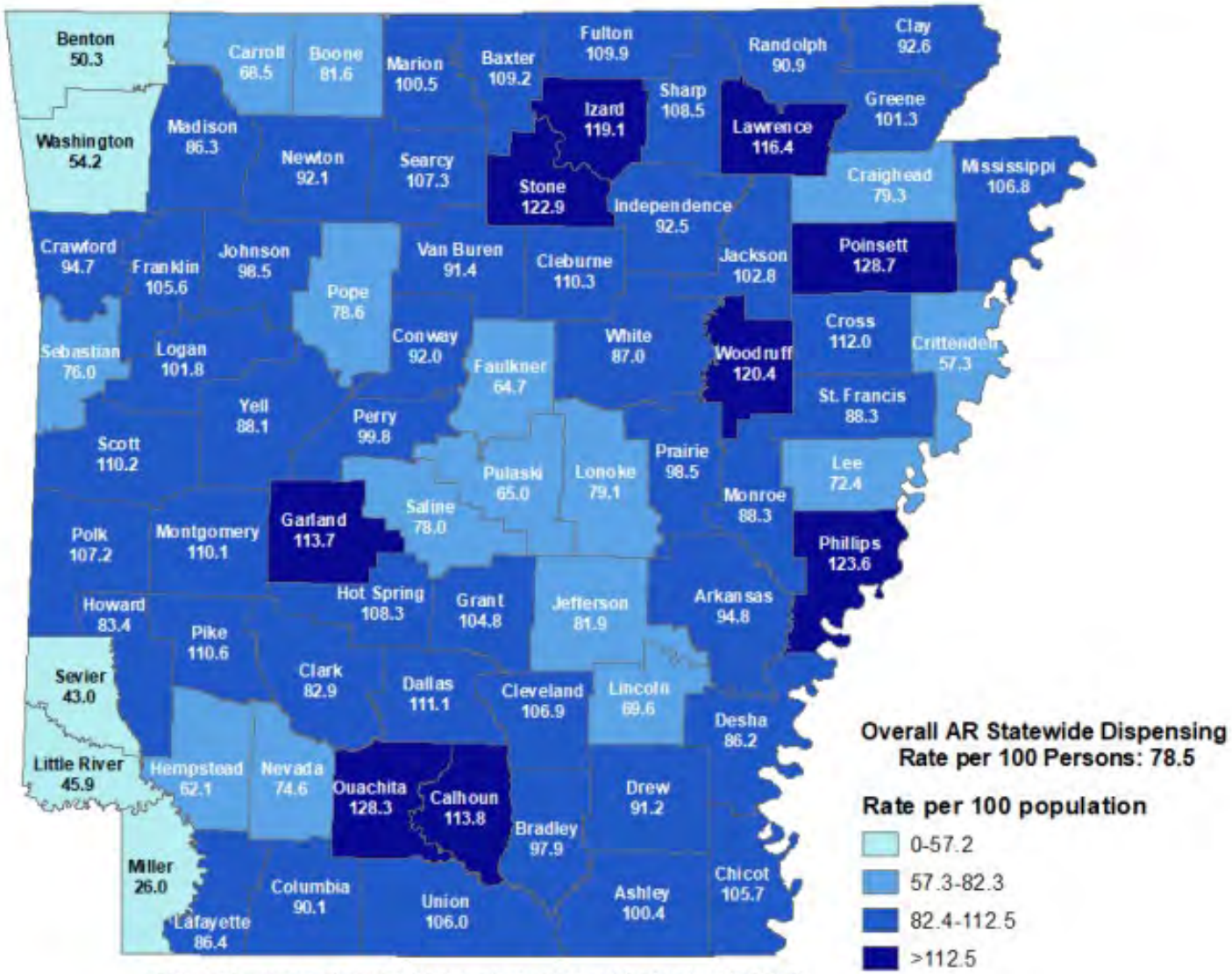
U.S. Opioid Dispensing Rate Maps

- 43.3 prescriptions per 100 persons



https://www.cdc.gov/drugoverdose/rxrate-maps/index.html

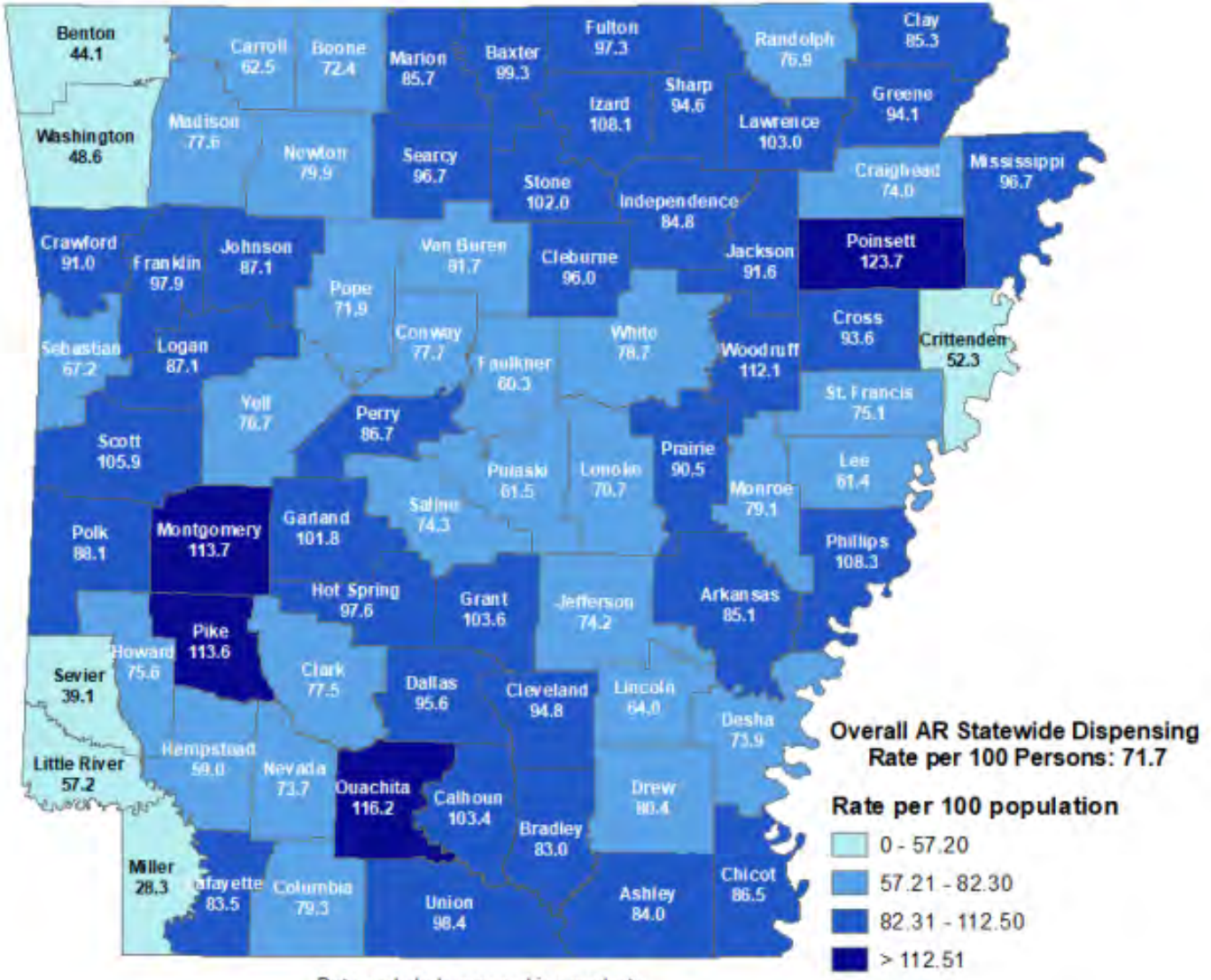
Figure 14: Opioid Dispensing Rates per 100 People per County, Arkansas 2023.



Excludes buprenorphine-containing products approved for treatment of OUD.
Location is based on county of patient address.
Prescriptions written by AR prescribers to AR patients.

Source: AR PDMP merged with RxNorm

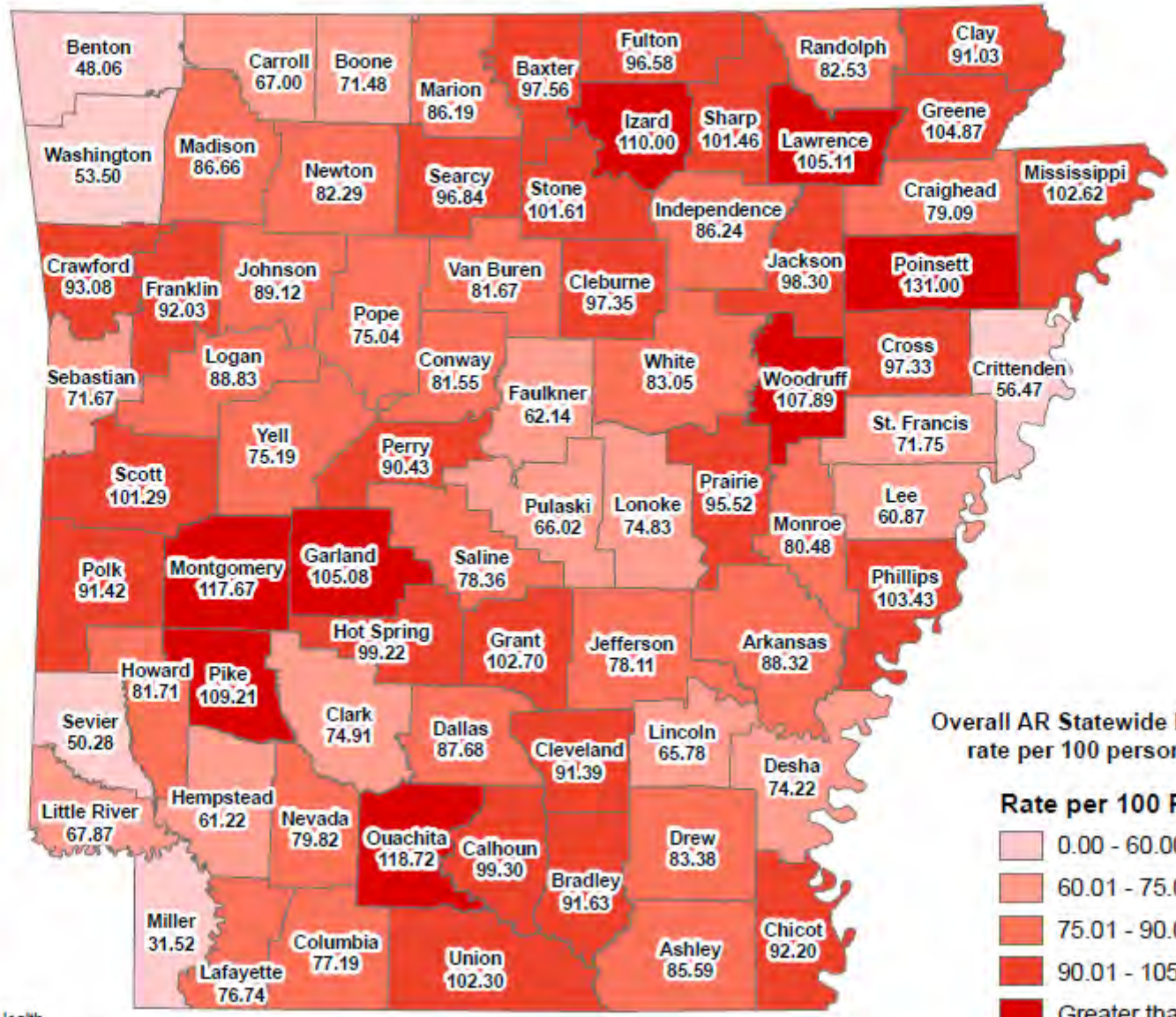
Figure 11: Opioid Dispensing Rates per 100 People per County, Arkansas 2022.



Data exclude buprenorphine products.
Location is based on county of patient address.
Prescriptions written by AR prescribers to AR patients.

Source: AR PDMP

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



Overall AR Statewide Dispensing rate per 100 persons: 75.31

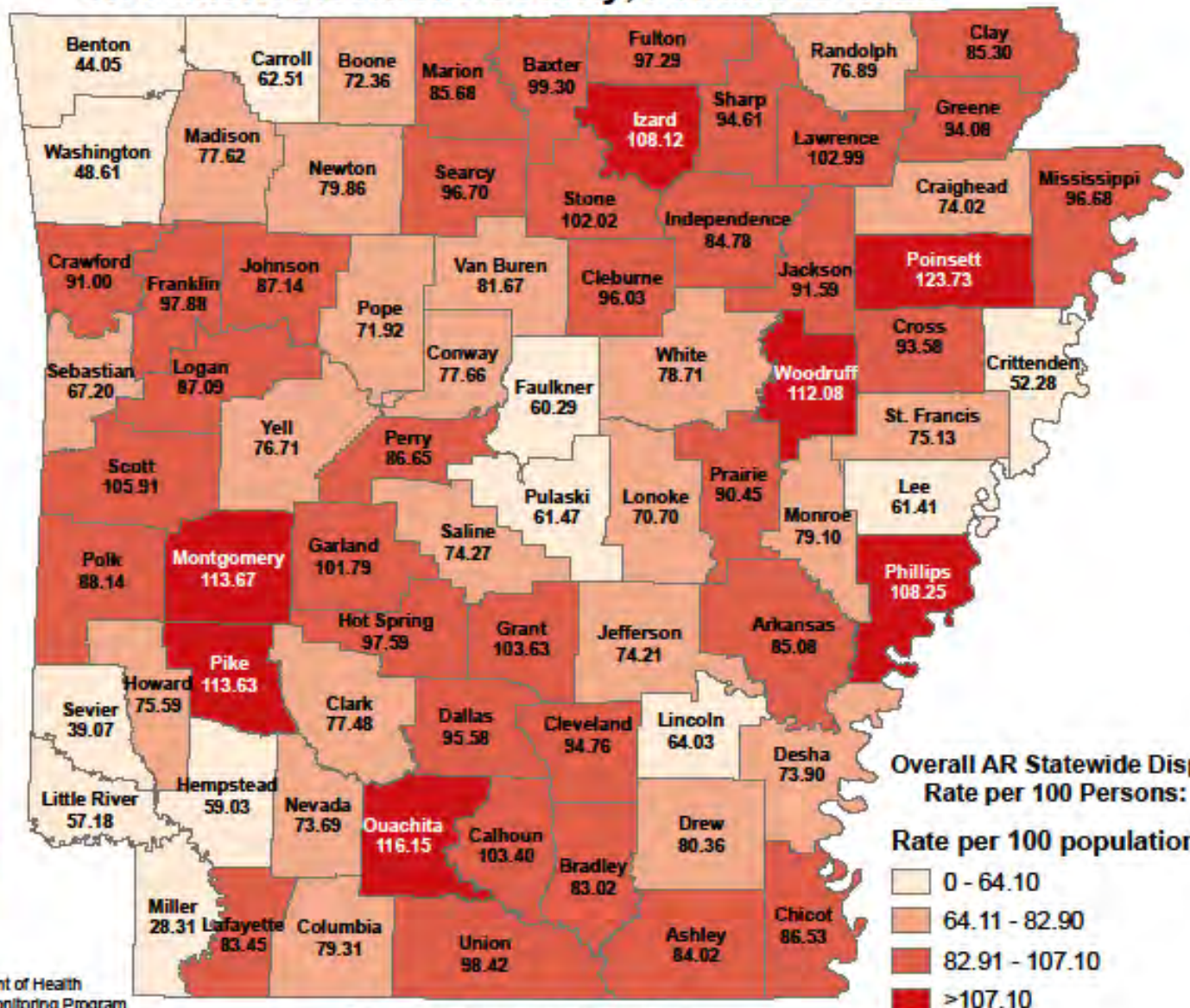
Rate per 100 Population

- 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.

Opioid Dispensing Rates per 100 Persons Based on Patient Resident County, Arkansas 2022



Date: April 18, 2023
Source: Arkansas Department of Health
Prescription Drug Monitoring Program
Map created by: J. Jacobs, Epidemiologist

Data exclude buprenorphine products.
Location is based on county of patient address.
Prescriptions written by AR prescribers to AR patients.

How About a Project then?

- Arkansas Pharmacists Association
  - Under 100 Project
  - Targeting 5 areas of the state
  - Prescribers and Dispensers have to get on the same page so let's start with a joint meeting to get the information out there!

Drugs By Class-Prescriptions

Top-Selling Prescription Drugs by Class – Arkansas, 2020-2022 Total Number of Prescriptions*			
Drug Class	**2020 Number of Prescriptions**	**2021 Number of Prescriptions**	**2022 Number of Prescriptions**
Opioid	2,749,916	2,677,232	2,611,077
Benzodiazepine	1,480,161	1,434,249	1,399,576
Stimulant	933,118	1,004,916	1,072,434
Sedative/Hypnotic	508,139	499,629	495,370
Muscle Relaxant	51,875	45,341	39,359
Total	**5,723,209**	**5,661,367**	**5,617,816**

Data based on dispensations to only Arkansas residents by Arkansas prescribers

Buprenorphine products not removed.

Number of prescriptions includes all dosage forms – Liquids, patches, tablets, capsules, suspensions, etc.

Drugs By Class-Pills Sold

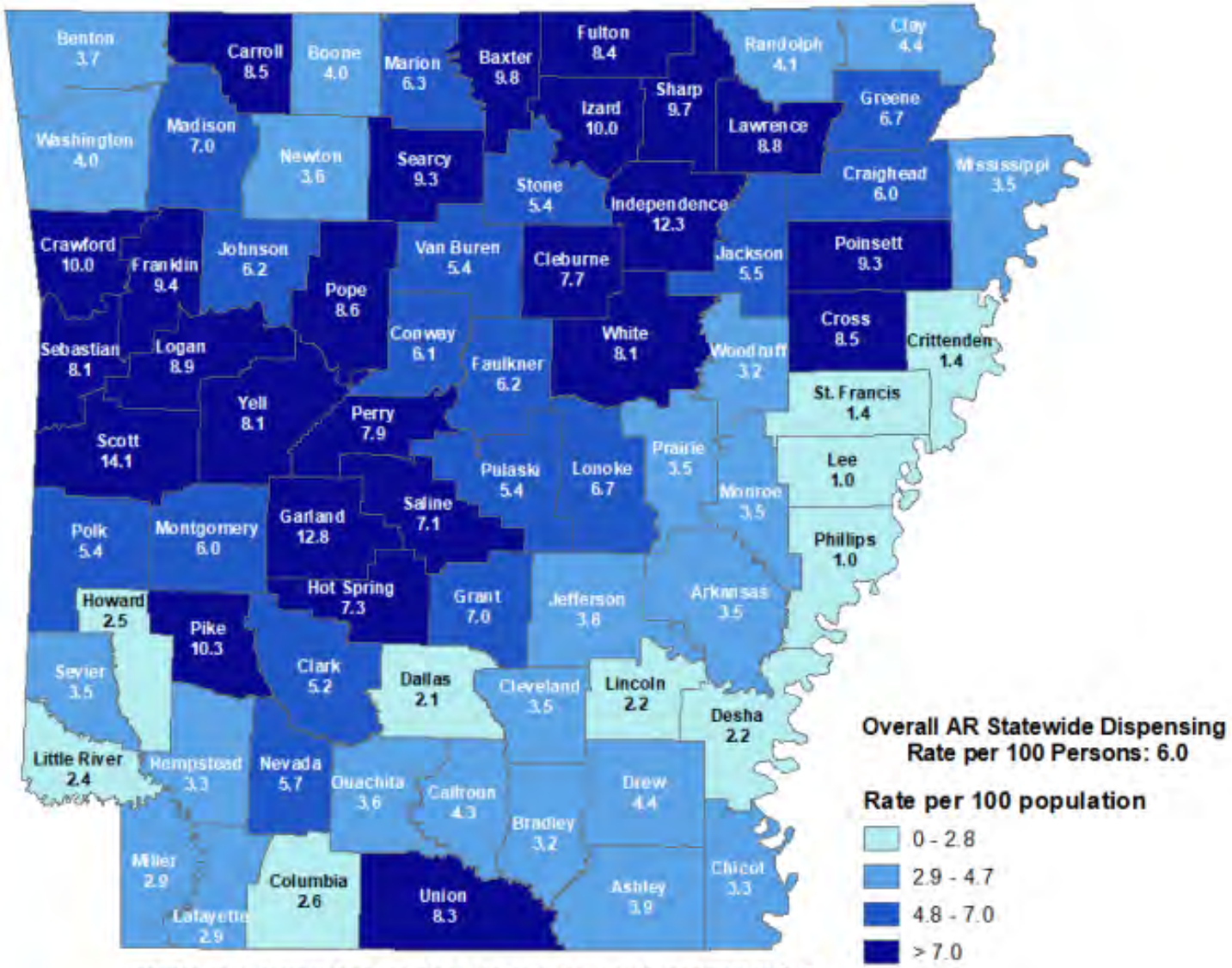
Top-Selling Prescription Drugs by Class – Arkansas, 2020-2022 Total Number of Pills Sold**			
Drug Class	**2020 Number of Pills Sold**	**2021 Number of Pills Sold**	**2022 Number of Pills Sold**
Opioid	151,960,831	141,544,277	133,103,034
Benzodiazepine	76,713,983	73,637,175	67,426,050
Stimulant	36,058,725	38,754,858	40,691,718
Sedative/Hypnotic	16,537,960	16,395,112	16,289,917
Muscle Relaxant	3,485,145	3,046,754	2,667,442
Total	**284,756,642**	**273,378,176**	**260,178,160**

Data based on dispensations to only Arkansas residents by Arkansas prescribers

Buprenorphine not removed.

***Number of Pills Sold - only solid dosage forms, ie. capsules, tablets, etc. Does not include liquids, suspensions, patches, injections, sprays, etc.*

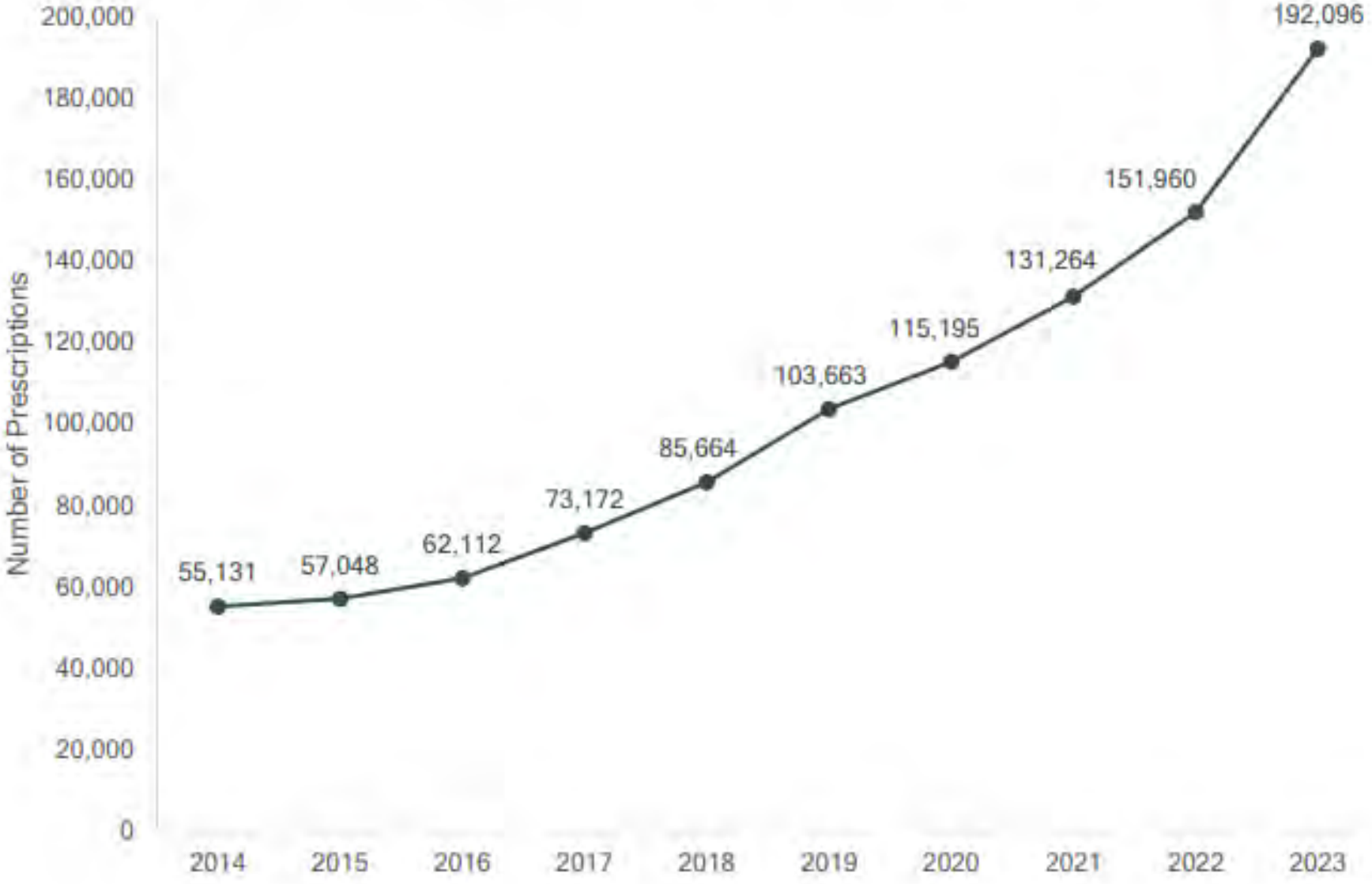
Figure 18: Buprenorphine Dispensing Rates per 100 People per County, Arkansas 2023.



Includes only buprenorphine-containing products approved for treatment of OUD.
Excludes veterinary prescriptions.
Location is based on county of patient address.
Prescriptions written by AR prescribers to AR patients.

Source: AR PDMP merged with RxNorm

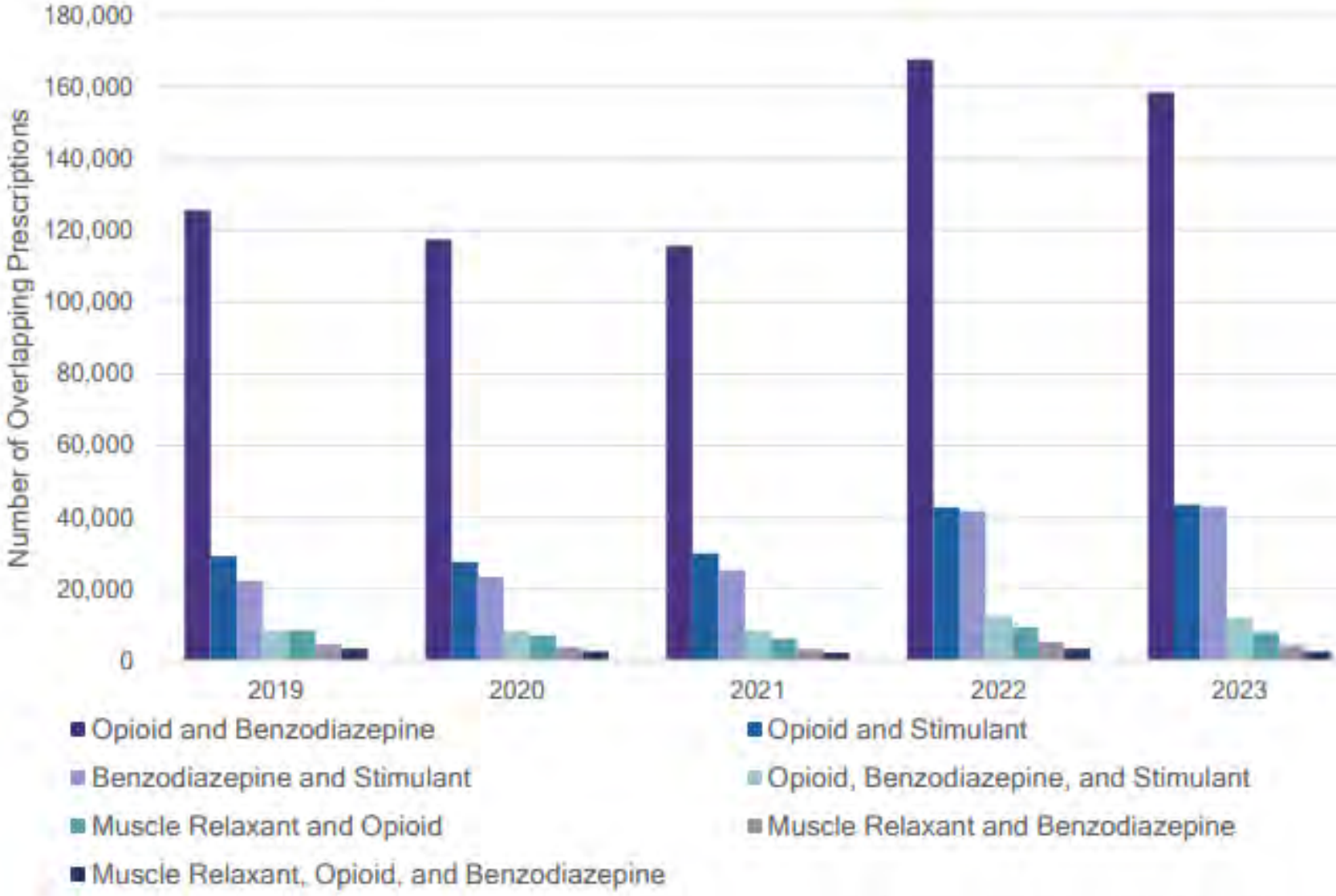
Figure 17: Buprenorphine Prescriptions* by Year for AR Residents by AR Prescribers, Arkansas 2014-2023.



Source: AR PDMP

**Includes all buprenorphine-containing products*

Figure 19: Overlapping Prescriptions of Multiple Controlled Drug Classes, Arkansas 2019-2023.



Source: AR PDMP merged with RxNorm
Prescriptions written by AR prescribers to AR residents

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

Pharmacies on Notice?

AmerisourceBergen Drug Corporation (AB) is committed to meeting applicable regulatory guidance and protecting the integrity of our country's pharmaceutical supply chain. As such, AB is required to conduct due diligence and maintain continuous oversight of the sales of controlled substances and listed chemicals. Over the course of monitoring Super Sav Drug #3 by members from our Controlled Substance Monitoring Program (CSMP), circumstances were discovered that raise concerns regarding the controlled substance sales which may place both AB and our customer at risk for regulatory action by state and/or federal agencies. Following a review of the controlled substance ordering, which included a 90-day dispensing report, several red flags were identified, including:

- Dispensing controlled substance prescriptions for chronic pain therapy prescribed by family/general medicine practitioners
- Dispensing combinations of opioids and benzodiazepines
- Dispensing multiple controlled substances in the same therapeutic class concurrently, i.e. multiple IR opioids/stimulants to same patient
- Dispensing/distributing controlled substances to a dentist in large quantities, i.e., Diazepam 10mg #80

As a result, AB is restricting sales of all controlled substances and listed chemicals to your account but will continue to service your account for non-controlled products. This restriction will take effect five business days from the delivery date of this letter.

Because in rare cases there could be a misunderstanding of the facts or other extenuating circumstances that could shed further light on the situation, you may request that we reconsider this decision. For your reconsideration request to be considered, it must be received in writing within five business days of the delivery date of this letter. You must present the case for why and under what conditions AB should resume sales of controlled substances to this pharmacy and attach any documentation supporting your assertions. When providing documentation, please do not include any HIPAA protected patient information, as doing so will result in the immediate deletion of any submitted documentation. If you submit a timely reconsideration request along with appropriate documentation, sales to your account will continue while the request is reviewed.

Final restriction will take place no later than 15 business days from the receipt of a reconsideration request unless AB, at its sole discretion, extends this period or reverses the restriction action against this pharmacy. All reviews and final determinations will be made exclusively at the discretion of the AB Controlled Substance Monitoring Program.

Thank you for your response received via email requesting reconsideration of our decision to restrict the sale of all controlled substances and listed chemicals to Super Sav Drug #3. Unfortunately, your response failed to adequately address the concerns we outlined in our original letter to you. We are, therefore, proceeding with the restriction of controlled substance and listed chemicals sales to your account(s). We will, however, continue to service your account for non-controlled substance products.

The restriction of controlled substance and listed chemical sales will take effect on Wednesday, November 30, 2022.

2:22-cv-2186

12-09-2022

MANES' PHARMACY, INC. v. AMERISOURCEBERGEN DRUG CORPORATION
PLAINTIFF DEFENDANT

P.K. HOLMES, III U.S. DISTRICT JUDGE

OPINION AND ORDER

P.K. HOLMES, III U.S. DISTRICT JUDGE

Before the Court are Plaintiff Manes' Pharmacy, Inc.'s ("Manes") motion for temporary restraining order and preliminary injunction (Doc. 5), and Defendant AmerisourceBergen Drug Corporation's ("AmerisourceBergen") response in opposition (Doc. 16). For the reasons given below, Manes' request for a temporary restraining order is DENIED, but the Court will DEFER RULING on Manes' request for a preliminary injunction until an evidentiary hearing is conducted on the matter.

This dispute arises between a pharmacy and the pharmacy's wholesale distributor of, among other products, controlled substances. Manes is a pharmacy that has served the local Van Buren, Arkansas community for nearly 40 years. (Doc. 4, p. 2). AmerisourceBergen is a wholesale distributor of pharmaceutical products, including controlled substances. (Doc. 16, p. 4). Manes alleges that it has purchased pharmaceuticals from AmerisourceBergen for over 15 years. (Doc. 4, p. 3). Manes purchases "many different medications" from AmerisourceBergen's facility in Tulsa, Oklahoma. *Id.* According to AmerisourceBergen, the wholesaler sells Manes both controlled and non-controlled substances. (Doc. 16, p. 10).

DIFFERENT STORE 2020

AmerisourceBergen Drug Corporation (ABDC) is committed to meeting all legal and regulatory requirements imposed upon it as a wholesale distributor and constantly strives to protect the integrity of our country's pharmaceutical supply chain. As such, ABDC follows a procedure of due diligence and continuous oversight of controlled substances sales to its registrant customers. Through the use of advanced analytics and other means, ABDC will sometimes discover purchasing activities of interest that are not able to be resolved and or adequately explained by the customer. Under such circumstances, ABDC will terminate the customer's ability to order controlled substances from ABDC and add the customer to ABDC's Do Not Ship List.

Following a review of the controlled substance ordering activity for Pharmacy over the past several months, we were particularly troubled by the high ratio of controlled substances purchased (57% by dosage unit volume) versus non-controlled substances. As a result, ABDC terminated the sale of all controlled substances and listed chemicals to the pharmacy on February 7th, 2020. We are sending this letter to you for informational purposes only.

Right or Wrong?

NEW ISSUES? Fall 2024

- Pharmacy was asked if they were aware of the “Public Record” of a prescriber and what they were doing with it.
- Public Record was the fact they were before the medical board and asked to take a course on prescribing.
- No punishment
- License is Active and Unrestricted

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:**

D. For purposes of the Injunctive Relief Terms, "*Red Flags*" are defined as follows:

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:** Analyze the ratio of the order volume of each Highly Diverted Controlled Substance base code or drug family to the total order volume of all non-Controlled Substances to identify Customers with significant rates of ordering each Highly Diverted Controlled Substance base code or drug family.

3. **Excessive ordering growth of Controlled Substances:** Analyze significant increases in the ordering volume of Controlled Substances using criteria to identify customers that exhibit percentage growth of Controlled Substances substantially in excess of the percentage growth of non-Controlled Substances.

4. **Unusual formulation ordering:** Analyze ordering of Highly Diverted Controlled Substances to identify customers with significant ordering of high-risk formulations. High-risk formulations include, but are not limited to, 10mg hydrocodone, 8mg hydromorphone, 2mg alprazolam, single-ingredient buprenorphine (*i.e.*, buprenorphine without naloxone), and highly-abused formulations of oxycodone. On an annual basis (or as otherwise necessary), high-risk formulations of Highly Diverted Controlled Substances may be added, removed, or revised based on the Injunctive Relief Distributors' assessment and regulatory guidance.

5. **Out-of-area patients:** Analyze Pharmacy Customer Data or Dispensing Data to assess volume of prescriptions for Highly Diverted Controlled Substances for out-of-area patients (based on number of miles traveled between a patient's zip code and the pharmacy location, depending on the geographic area of interest) taking into consideration the percentage of out-of-area patients for non-Controlled Substances.

6. **Cash prescriptions:** Analyze Pharmacy Customer Data or Dispensing Data to assess percentage of cash payments for purchases of Controlled Substances taking into consideration the percentage of cash payments for purchases of non-Controlled Substances.

XI. SITE VISITS

A. Each Injunctive Relief Distributor shall conduct site visits, including unannounced site visits, where appropriate, of Customers, as necessary, as part of Customer due diligence.

B. During site visits, an Injunctive Relief Distributor's CSMP personnel or qualified third-party compliance consultants shall interview the pharmacist-in-charge or other relevant Customer employees, if appropriate, about any potential Red Flags and the Customer's maintenance of effective controls against the potential diversion of Controlled Substances.

C. An Injunctive Relief Distributor's CSMP personnel or qualified third-party compliance consultants who conduct site visits shall document the findings of any site visit.

D. Site visit and all other compliance reports shall be maintained by each Injunctive Relief Distributor in a database accessible to all CSMP personnel.

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

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.

Red Flags???

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

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.

Suspicious Orders?

- Some wholesalers identify any order that would exceed the pharmacy's threshold number to be suspicious and report that information to DEA and state authorities.
- Pharmacies are not told/cannot be told what their "threshold" numbers are under the federal injunctive relief.

Injunctive Relief Requirement

XIII. SUSPICIOUS ORDER REPORTING AND NON-SHIPMENT

D. In reporting Suspicious Orders to the Settling States, the Injunctive Relief Distributors shall file SORs in a standardized electronic format that is uniform among the Settling States and contains the following information fields:

8. Explanation for why the order is suspicious (up to 250 characters): Details that are order-specific regarding why an order was flagged as a Suspicious Order, including specific criteria used by an Injunctive Relief Distributor's Threshold system (except phrases such as "order is of unusual size" without any additional detail are not acceptable); and
9. Name and contact information for a knowledgeable designee within the Injunctive Relief Distributor's CSMP department to be a point of contact for the SORs.

What We See

AmerisourceBergen State Suspicious Order Reporting

Report for: 06/30/2023-00/00/0000

Registrant:

AMERISOURCEBERGEN DRUG CORPORA,12577 STATELINE ROAD,OLIVE BRANCH,MS

Licenses:	License Numbers
Wholesale Drug Distribut	15270/16.5
Controlled Substances	CS-15270
DEA Registration	RA0504743

Suspicious Orders Rejected:

Customer D	Cus Pharmacy License	Customer Name	Addr	Order Da	Drug Description	NDC	Ord	Ordere	Deliver	Adj Rea	Adj Reas Code Desc
Store A	DEA	Independent Pharmacy		6/30/2023	CARISOPRODOL 350 MG TAB 100	50228010901	3	300	0	CRJ22	CONTROLLED SUBSTANCES
Store B	DEA	Independent Pharmacy		6/30/2023	ALPRAZOLAM 1 MG TAB 1000	65862067899	2	2000	0	CRJ22	CONTROLLED SUBSTANCES
Store C	DEA	Independent Pharmacy		7/1/2023	HYDROMORPHONE HCL 4 MG TAB 500	42858030250	1	500	0	CRJ22	CONTROLLED SUBSTANCES
Store D	DEA	Independent Pharmacy		7/2/2023	XCOPRI 100 MG TAB 30	71699010030	1	30	0	CRJ22	CONTROLLED SUBSTANCES
Store A	DEA	Independent Pharmacy		7/3/2023	CARISOPRODOL 350 MG TAB 100	50228010901	2	200	0	CRJ22	CONTROLLED SUBSTANCES
Store D	DEA	Independent Pharmacy		7/3/2023	XCOPRI 100 MG TAB 30	71699010030	1	30	0	CRJ22	CONTROLLED SUBSTANCES
Store E	DEA	Independent Pharmacy		7/3/2023	ALPRAZOLAM 0.5 MG TAB 1000	00228202996	1	1000	0	CRJ22	CONTROLLED SUBSTANCES
Store E	DEA	Independent Pharmacy		7/3/2023	ALPRAZOLAM 1 MG TAB 1000	00228203196	1	1000	0	CRJ22	CONTROLLED SUBSTANCES
Store E	DEA	Independent Pharmacy		7/5/2023	ALPRAZOLAM 1 MG TAB 1000	00228203196	1	1000	0	CRJ22	CONTROLLED SUBSTANCES
Store E	DEA	Independent Pharmacy		7/5/2023	ALPRAZOLAM 0.5 MG TAB 1000	00228202996	1	1000	0	CRJ22	CONTROLLED SUBSTANCES
Store C	DEA	Independent Pharmacy		7/5/2023	HYDROMORPHONE HCL 4 MG TAB 500	42858030250	1	500	0	CRJ22	CONTROLLED SUBSTANCES
Store C	DEA	Independent Pharmacy		7/5/2023	HYDROMORPHONE HCL 4 MG TAB 100	60687059001	1	100	0	CRJ22	CONTROLLED SUBSTANCES
Store F	DEA	Independent Pharmacy		7/5/2023	HYDROCODONE/CHLORPH 10/8MG/5M	27808008601	2	240	0	CRJ22	CONTROLLED SUBSTANCES
Store A	DEA	Independent Pharmacy		7/5/2023	CARISOPRODOL 350 MG TAB 100	50228010901	1	100	0	CRJ22	CONTROLLED SUBSTANCES
Store A	DEA	Independent Pharmacy		7/5/2023	CARISOPRODOL 350 MG TAB 100	50228010901	1	100	0	CRJ22	CONTROLLED SUBSTANCES
Store A	DEA	Independent Pharmacy		7/5/2023	CARISOPRODOL 350 MG TAB 100	50228010901	3	300	0	CRJ22	CONTROLLED SUBSTANCES
Store G	DEA	Independent Pharmacy		7/5/2023	HYDROMORPHONE HCL 4 MG TAB 500	42858030250	1	500	0	CRJ22	CONTROLLED SUBSTANCES
Store B	DEA	Independent Pharmacy		7/5/2023	HYDROCODONE/ACETAM 10/325 MG T	00406012510	3	3000	0	CRJ22	CONTROLLED SUBSTANCES
Store B	DEA	Independent Pharmacy		7/5/2023	HYDROCODONE/ACETAM 7.5/325MG T	00406012410	2	2000	0	CRJ22	CONTROLLED SUBSTANCES
Store B	DEA	Independent Pharmacy		7/5/2023	HYDROCODONE/ACETAM 5/325MG TA	00406012310	1	1000	0	CRJ22	CONTROLLED SUBSTANCES
Store D	DEA	Independent Pharmacy		7/6/2023	XCOPRI 100 MG TAB 30	71699010030	1	30	0	CRJ22	CONTROLLED SUBSTANCES
Store C	DEA	Independent Pharmacy		7/6/2023	HYDROMORPHONE HCL 4 MG TAB 500	42858030250	1	500	0	CRJ22	CONTROLLED SUBSTANCES
Store F	DEA	Independent Pharmacy		7/6/2023	HYDROCO/CHLORPHN 10/8MG/5ML ER	62542030104	1	120	0	CRJ22	CONTROLLED SUBSTANCES
Store F	DEA	Independent Pharmacy		7/6/2023	HYDROCO/ACETA 7.5/325MG/15ML SO	71930002743	1	480	0	CRJ22	CONTROLLED SUBSTANCES

Pharmacy Gets No Controls?

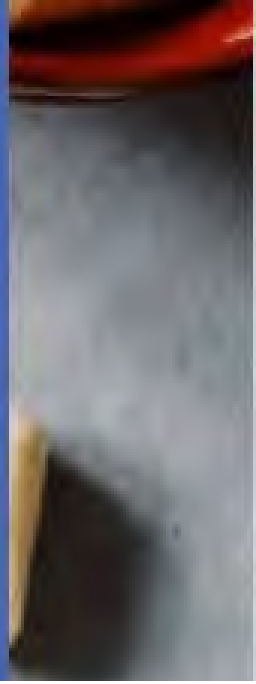
- What happens next?
- All those prescriptions move to other pharmacies that are immediately at risk as well?
- Starts a chain reaction that nobody in an area may have controls even though there is no DEA or State Action on the prescribers or dispensers.

Which Controls?

- Suspicious ones, highly diverted ones?
- ALL OF THEM
- Including MAT medications such as Buprenorphine in single entitly or combination used for Opioid Use Disorder.
- This appears contrary to DEA statements regarding the importance of having these medications available for OUD treatment.

OUT OF STATE PRESCRIPTIONS

Prescription Drug Monitoring Program 2021-2023



Arkansas Department of Health

4815 W. Markham St, Slot 10
Little Rock, AR 72205

Acknowledgements

Prescription Drug Monitoring Program Staff

PDMP Administrator
Jamie Turpin, PharmD

PDMP Epidemiologist
Keilya Embry, MPH

PDMP Registered Pharmacist
Laura Cima, PharmD

PDMP Health Program Specialist II
Job Toussaint, MPH

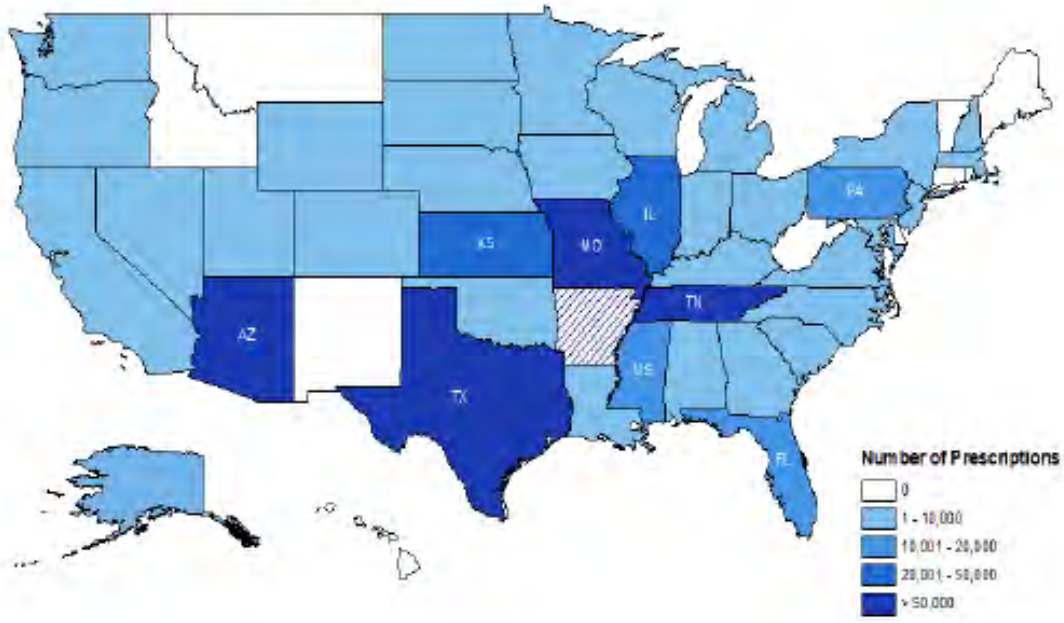
Out of State Dispensaries

Some patients in Arkansas receive their medications from out of state pharmacies by mail-order. Any controlled substances dispensed via mail-order to an Arkansas residence from out of state pharmacies are reported to the AR PDMP.

Dispensary Locations

Between 2021 and 2023, Arkansas residences received mail-order controlled medications from pharmacies located in 40 states. The states that had more than 50,000 medications dispensed over those three years were Missouri, Tennessee, Texas, and Arizona.

Figure1: Number of Controlled Medications Mailed to an Arkansas Address from other States, 2021-2023



Source: AR PDMP

Rx Mailed Into Arkansas

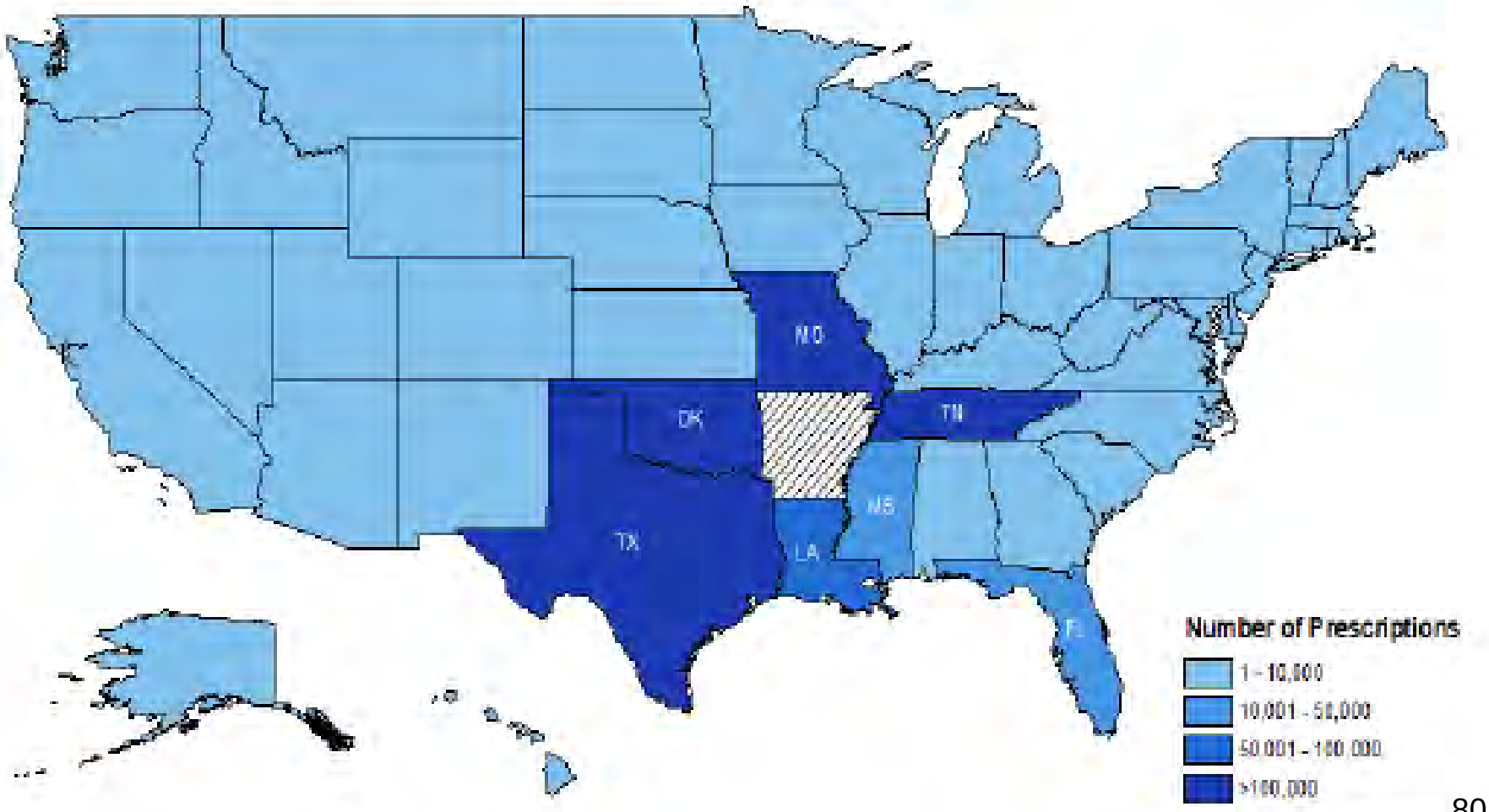
Table 1: Percentage of Controlled Medications Mailed into AR by other States, 2021-2023

	Drug Class				
Year	Benzodiazepine	Buprenorphine	Opioid*	Stimulant	All Controls
2021	2.9%	0.5%	2.1%	0.5%	2.3%
2022	3.0%	0.5%	2.1%	0.6%	2.4%
2023	2.9%	0.7%	2.1%	0.6%	2.5%

Source: AR PDMP

**Excludes buprenorphine*

Figure 2: Number of Controlled Medications Prescribed by Out of State Providers Reported to the AR PDMP, 2021-2023



Source: AR PDMP

OOS Prescribers

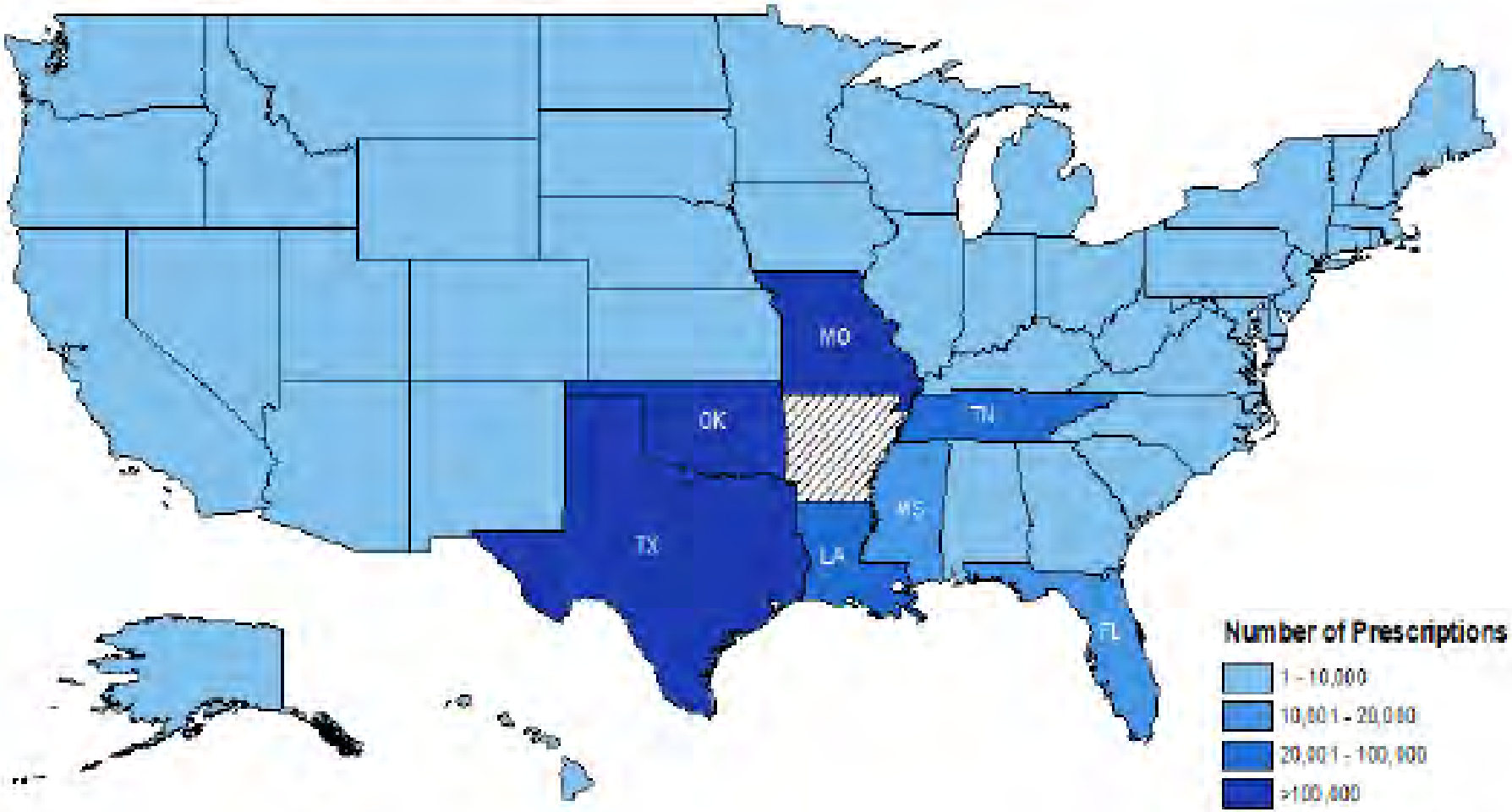
Table 2: Percentage of Controlled Medications Dispensed in AR and Prescribed by Out of State Prescribers, 2021-2023

	Drug Class				
Year	Benzodiazepine	Buprenorphine	Opioid*	Stimulant	All Controls
2021	3.8%	7.8%	4.7%	3.8%	4.5%
2022	3.6%	5.9%	4.3%	3.6%	4.2%
2023	3.3%	4.8%	4.4%	3.3%	3.9%

Source: AR PDMP

**Excludes buprenorphine*

Figure 3: Number of Controlled Medications Dispensed in AR to non-Arkansas Patients, 2021-2023



Source: AR PDMP

Dispensed to OOS Patients

Table 3: Percentage of Controlled Medications Dispensed to non-Arkansas Patients and Filled in AR, 2021-2023

	Drug Class				
Year	Benzodiazepine	Buprenorphine	Opioid*	Stimulant	All Controls
2021	2.6%	3.6%	3.6%	3.0%	3.2%
2022	2.4%	3.5%	3.1%	2.9%	2.9%
2023	2.4%	3.1%	2.9%	2.8%	2.8%

Source: AR PDMP

**Excludes buprenorphine*

Drug Shortages

- Many Pharmacies are unable to get the amount or variety of controlled substances needed for the prescriptions they see.
- Some of this is true shortage of drugs
- Some of this is due to supplier policies

Message TO Prescribers

- You need to be having conversations with your area pharmacies and pharmacists
- Talk about how you manage controlled substance prescribing and patient expectations
- Ask what problems each is facing
- Have a plan for your patients before surgery, discharge or other planned events!

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/

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

January 17, 2017

For Immediate Release

Contact: Brian McNeal

Phone Number: (571) 362-1498

Drug Enforcement Administration

Keith Martin
Special Agent in Charge
Detroit
@DEADetroitDiv

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).

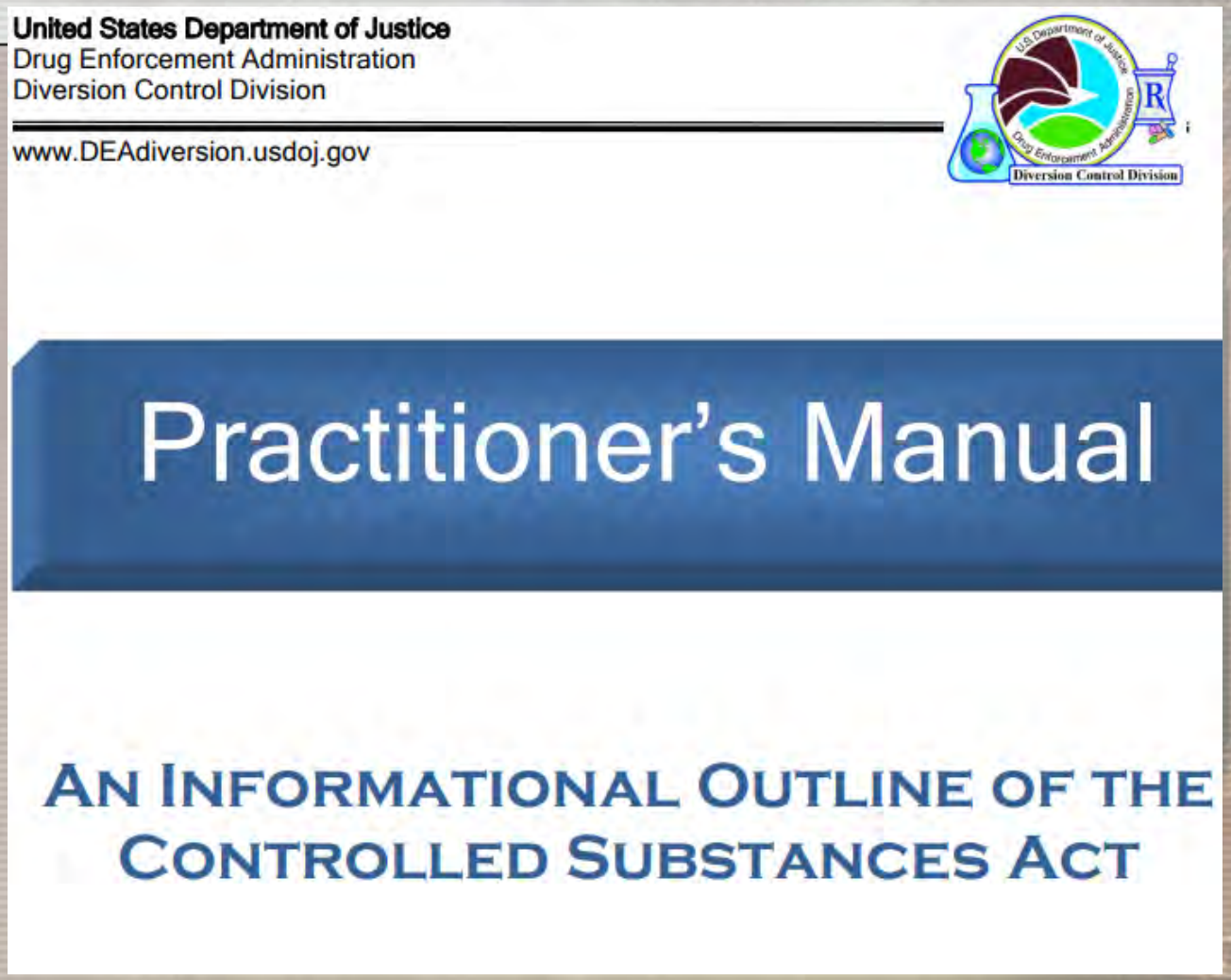
Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act

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

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
  - New Manual recently published
    - 56 pages
    - https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf

DEA Practitioner's Manual



- https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf

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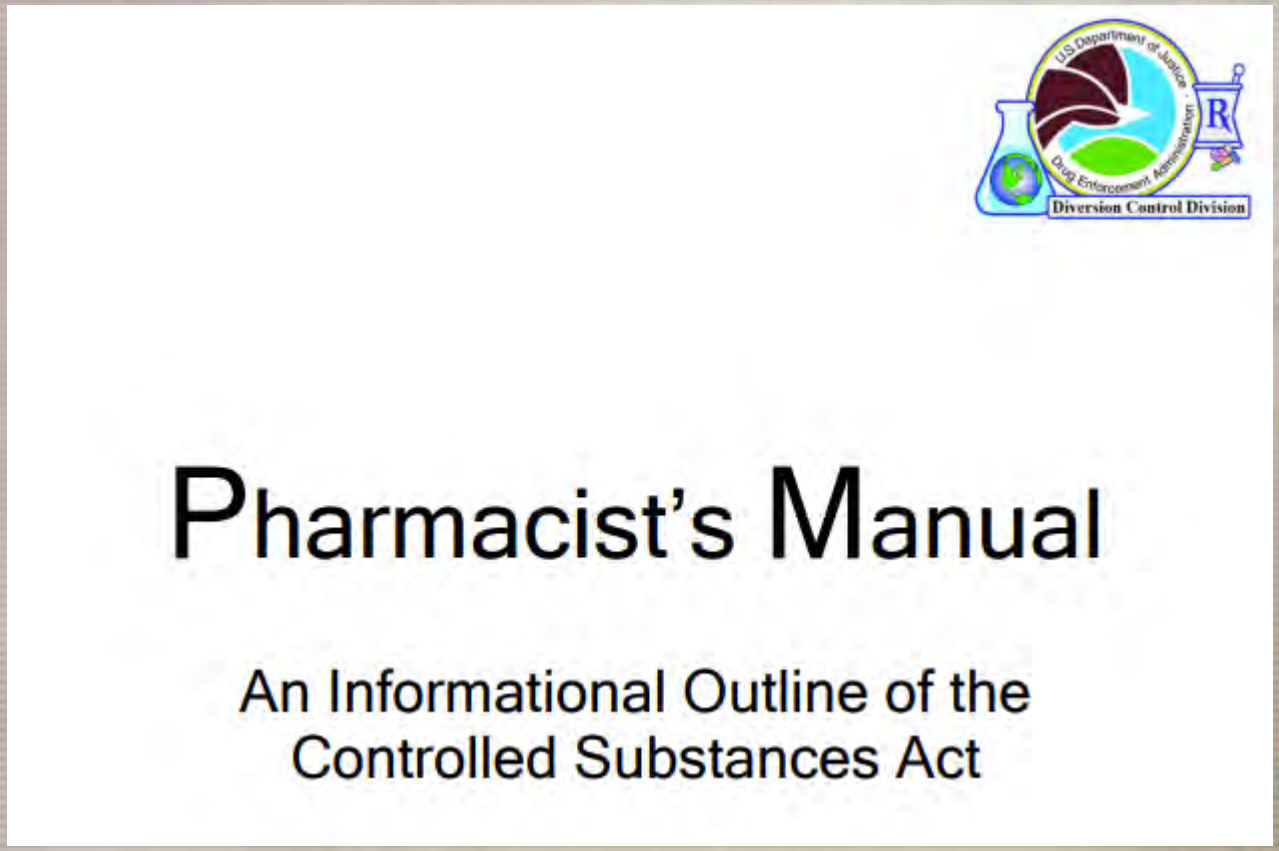

- https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf

- 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

On November 19, 2021, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking (NPRM) proposing to permit the transfer of electronic prescriptions for controlled substances (EPCS) in schedules II–V between registered retail pharmacies for initial filling on a one-time basis only.[1] In this rulemaking, DEA is finalizing the regulatory text proposed in the NPRM with modifications to address concerns brought forth by commenters.

- CURRENTLY UNWORKABLE
- EPCS and Pharmacy switch systems do not have the capability to "Forward" an EPCS

Table 1: Persons and Activities, Current vs. Proposed

Persons	Change in Activity		Economic Impact
	Current	Proposed	
First or Transferring Pharmacy	First pharmacy contacts patient to inform that they are unable to fill the prescription. Note action taken (i.e., void, cancel, etc.), as needed.	Transferring pharmacy contacts patient to inform that they are unable to fill the prescription. Transfer prescription. "Transfer" includes: contacting the receiving pharmacy, exchanging information, and recording the required information regarding transfer.	Assume duration of call/contact is same ==> no impact Additional cost to transfer vs. noting action taken.
Patient	Receive call from pharmacy that they are unable to fill the prescription. Contact prescriber to request new prescription. Receive filled prescription from second (receiving) pharmacy.	Receive call from pharmacy that they are unable to fill the prescription, request transfer of the prescription to an alternate (receiving) pharmacy. N/A. Receive filled prescription from receiving pharmacy.	Assume duration of call/contact is same ==> no impact. Cost savings from not having to contact prescriber. Assume same burden ==> no impact.
Prescriber	Receive call from patient. (prescriber's secretary) Cancel prescription sent to first pharmacy and issue new prescription at second (receiving) pharmacy.	N/A. N/A.	Cost savings. Cost savings.
Second (Receiving) Pharmacy	Receive prescription and fill.	Receive transfer and fill. "Transfer" includes: being contacted by the transferring pharmacy, exchanging information, and recording the required information regarding transfer.	Additional cost to receive and record transfer.

Questions?