HANDOUT 1
ITEM D

Are Pain Management Questions in Patient Satisfaction Surveys Driving the Opioid Epidemic?

The United States is in the midst of a national opioid epidemic, with devastating consequences. We've seen an explosion of deaths and emergency room visits because of drug overdoses,[1] increasing morbidity and mortality from hepatitis C,[2] and recently in Indiana, the largest outbreak of HIV related to injection drug use in US history.[3]

We know that up to 80% of heroin users started by diverting prescription drugs,[4] and that the US Surgeon General has identified physician overprescribing as a causal link in this chain of addiction. Prescribing of opioid pain relievers has quadrupled since 1999, and the United States now consumes more than 90% of the world's opioids.[3] An underappreciated factor behind these statistics is the measurement of patient satisfaction related to pain.

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, used since 2006 by the Centers for Medicare and Medicaid Services (CMS), is one of the many patient satisfaction surveys that includes questions about pain management. The survey, which is administered after discharge, is designed to measure patient perceptions of hospital experience as one surrogate for hospital quality.

Much attention has focused on Question 14 in the HCAHPS survey, "How often did the hospital or provider do everything in their power to control your pain?" This question is inextricably linked to the "pain as the fifth vital sign" culture promoted by the Joint Commission and Agency for Healthcare Research and Quality—a culture responsible for the misperception that patients should experience no pain.

CMS says Question 14 is intended to evaluate patients' experience of their pain management, not to judge prescribing behavior or compare hospital staff members.[5] Scores are reported for an entire facility, not for individual physicians, nurses, or other staff. Yet pain management is the only clinical measurement among eight components of Hospital Value-Based Purchasing, and many physicians see their patient satisfaction scores in patient surveys drop as a result of changes in their prescribing practices. These scores affect compensation and promotion.

The link between patient satisfaction scores and pain management plays out daily in physician offices and emergency departments as physicians who recommend physical therapy and nonopioid pain management encounter resistance from patients who simply want a quicker "solution" with pain pills. This leaves well-meaning professionals with the unsavory choice of prescribing opioids or facing dissatisfaction from disappointed patients on patient surveys.

As we've seen across the country, the consequences are tragic. Nationally, drug overdoses claimed more lives than traffic crashes in 2013; since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids.[6] Drug overdoses are everywhere—they do not discriminate by age, income, or location. In rural Scott County, Indiana, the 2015 HIV outbreak was traced to people who shared needles while injecting the powerful opioid Opana. Many who contracted HIV said their opioid addiction started with a legitimate opioid prescription.

The US Department of Health and Human Services (HHS) is reviewing how pain management is evaluated by patient satisfaction surveys, how those may connect to opioid prescribing, and how best to educate health professionals about prescribing guidelines. More than 40 professional organizations have committed to training 540 000 health care professionals across the United States in safe opioid prescribing in the next two years.[7] The Centers for Disease Control and Prevention recently released new guidelines for prescribing opioids for chronic pain and is working to improve public understanding of the risks and benefits of opioid use.

States are responding forcefully as well. In Indiana, a task force assembled by Governor Mike Pence to address the opioid epidemic has directed health officials to develop new guidelines for prescribing medication to treat acute pain. The Arkansas Medical Board is sending educational alert letters to prescribers who exceed the controlled substance prescribing norm for their discipline. Florida, which had an abundance of pill mills masquerading as pain clinics, implemented an aggressive plan through coordinated action by the Governor, the Attorney General, law enforcement, and the Department of Health in 2011. As a result of law enforcement investigations, the regulation of pain clinics, use of a voluntary prescription drug

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This editorial was accepted April 6, 2016.
doi: 10.2105/AJPH.2016.303228

monitoring program, and health professional licensure suspensions, Florida has seen the number of deaths from prescription narcotics drop by more than 50%.

There is no single solution to the opioid abuse epidemic. We must educate the public and prescribers about the dangers of opioids, teach prescribers about opioid alternatives for pain management, optimize prescription drug monitoring programs, and increase the availability of substance-use disorder management.

We will not succeed unless CMS, HHS, pharmaceutical companies, prescribers, and communities take steps to counteract the driving incentives to overprescribe. Prescribers should not be scapegoats in a system that links patient perception of pain control to penalties in the setting of high consumer demand promoted by notions of "no pain is the norm."

It is time to acknowledge and eliminate the perverse incentives for overprescribing narcotics. We suggest four steps to effect real change: (1) The HCAHPS survey questions should be modified to reflect more appropriate pain management outcomes, such as return to function, multimodal pain management, and tolerable versus zero pain scores; (2) hospitals and systems should use standard acute and chronic opioid prescribing guidelines to assist health care professionals in doing right by patients with pain, without the fear of penalties for doing so; (3) states should encourage regional meetings of hospitals, health care professionals, and local health coalitions to standardize prescribing practices as a system; and (4) states should address the availability and outcomes of drug addiction treatment programs. By influencing the first step, CMS can partner with prescribers to be part of the solution, rather than part of the problem. AJPH

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ACKNOWLEDGMENTS

We would like to acknowledge Jennifer O'Malley for assistance with coordination of submission, and editing.

REFERENCES

1. Vital signs: today's heroin epidemic. Centers for Disease Control and Prevention. 2015. Available at: http://www.cdc.gov/vitalsigns/heroin/index.html. Accessed February 26, 2016.

2. Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006–2012. *Clin Infect Dis*. 2014;59(10):1411–1419.

3. Adams J. What are the state governments doing to combat the opioid abuse epidemic? Testimony presented to the US House of Representatives Committee on Energy and Commerce Subcommittee on Oversight and Investigations. 2015. Available at: http://docs.house.gov/meetings/IF/IF02/20150521/103501/HHRG-114-IF02-Wstate-AdamsJ-20150521.pdf. Accessed February 29, 2016.

4. National heroin threat assessment summary. US Drug Enforcement Administration. 2015. Available at: http://www.dea.gov/divisions/hq/2015/hq052215_National_Heroin_Threat_Assessment_Summary.pdf. Accessed February 22, 2016.

5. The HCAHPS survey, pain management, and opioid misuse. The CMS perspective: clarifying facts, myths, and approaches. Centers for Medicare and Medicaid Services. 2016. Available at: http://www.qualityreportingcenter.com/wp-content/uploads/2016/01/IQR-VBP_HCAHPS-and-Pain-Management_20160128_vFINAL508.pdf. Accessed February 23, 2016.

6. Rudd RA, Aleshire N, Zibbell JE, Gladden RM. Increases in drug and opioid overdose deaths—United States, 2000–2014. *MMWR Morb Mortal Wkly Rep*. 2016;64(50);1378–1382.

7. Obama administration announces public and private sector efforts to address prescription drug abuse and heroin use [news release]. The White House. October 21, 2015. Available at: https://www.whitehouse.gov/the-press-office/2015/10/21/fact-sheet-obama-administration-announces-public-and-private-sector. Accessed February 23, 2016.

2018: Annual Report

PRESCRIPTION DRUG MONITORING PROGRAM

ARKANSAS DEPARTMENT OF HEALTH | 4815 W. Markham St, Little Rock, AR 72205

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Update from the Program

The Arkansas Prescription Drug Monitoring Program (PDMP) welcomed two new staff members, Dr. Jamie Turpin, PharmD as the new PDMP Administrator and DeShawn Bryant as the PDMP Health Program Specialist. Dr. Turpin is an Arkansas native and obtained her Doctorate of Pharmacy from the University of Arkansas for Medical Sciences College of Pharmacy in 2013. Prior to starting at the PDMP last November, she had worked in a chain retail pharmacy for over 12 years. Mr. Bryant is also an Arkansas native and graduated from the University of Central Arkansas in 2013 with a Bachelor's Degree in Health Education with Minor in Family Consumer Science. Before starting at the PDMP, Mr. Bryant worked for the City of North Little Rock as a Healthy Program Leader.

Along with the new faces at the PDMP, there were some exciting enhancements to the program. In the Spring of 2018, the first round of Prescriber Comparison Reports was distributed to the all the healthcare providers in Arkansas who wrote a prescription for an opioid and had a user account in the PDMP system. The reports compare the prescribing habits of the prescribers to other prescribers within the same specialty. This tool can give the providers a better understanding of how others within their specialty prescribe opioids and other controlled substances. Furthermore, these reports are a valuable tool helping prescribers identify if their individual prescribing habits should be adjusted.

In 2019, the PDMP hopes to see even more helpful enhancements for prescribers, pharmacies, professional boards and law enforcement in an effort to decrease misuse and abuse of controlled substances in the state.

Arkansas PDMP Background

In 2011, Act 304 enlisted the Arkansas Department of Health (ADH) to establish a Prescription Drug Monitoring Program (PDMP). The goal of this legislation was to: enhance patient care; help curtail the misuse and abuse of controlled substances; assist in combating the illegal trade in and diversion of controlled substances; and make prescription information available to practitioners, law enforcement, professional boards and other authorized users.

In 2013, the PDMP began accepting dispensed prescription information from outpatient pharmacies; however, medications administered while in hospitals or in clinics are exempt from reporting. Mail order pharmacies that ship prescriptions into Arkansas *are* required to report to the PDMP, however. Healthcare providers across the state are able to run patient reports that identify all the controlled medications dispensed at these pharmacies. Professional boards and law enforcement are able to utilize the PDMP data in their investigation of prescribers, dispensers and patients to help identify and decrease the misuse and abuse of controlled medications.

In 2015, legislation was passed, allowing all prescribers and pharmacists to each assign a delegate to assess the PDMP on their behalf. A delegate is an agent or employee of the prescriber or pharmacist that has been granted access to the PDMP in order to run patient reports for the supervising prescriber or pharmacist, thus increasing efficiency.

In 2017, Act 820 was signed into law that mandated prescriber usage of the PDMP. The law states that a prescriber must check the PDMP each time prior to prescribing a schedule II or schedule III opioid (i.e. hydrocodone, oxycodone, morphine, etc.) and the first time prescribing a benzodiazepine (i.e. alprazolam, diazepam, lorazepam, etc.). Exceptions to this rule are in the instances of hospice, nursing home, in-patient and emergent situations in an ambulance.

In the 2019 legislative session, the passing of Act 605 added the ability to share data with federal PDMPs. The Department of Defense established the Military Health System (MHS) PDMP and the sharing will allow authorized Arkansas users to see prescriptions filled on military bases and military prescribers to see prescriptions filled in Arkansas. Also in 2019, Act 141 allows the Office of Medicaid Inspector General to access to the PDMP as a part of their search for fraud, waste and abuse in the state.

PDMP Use

Who's using the PDMP?

The PDMP allows access to many different users. Access to the PDMP system occurs through a secure website, which requires authorized users to log in with a password. User accounts are granted to physicians, pharmacists, dentists, medical residents, physician assistants, veterinarians, nurse practitioners, Medicaid officials, law enforcement, regulatory boards, the state medical examiner, and prescriber and pharmacist delegates. All users must be approved for access according to statutory requirements. The number of user accounts are constantly increasing due to many factors, such as mandatory usage, opioid prescribing, internal office policies, etc. By the end of 2018, the PDMP had 19,835 user accounts, which was an increase from the 15,637 user accounts in 2017 (Table 1).

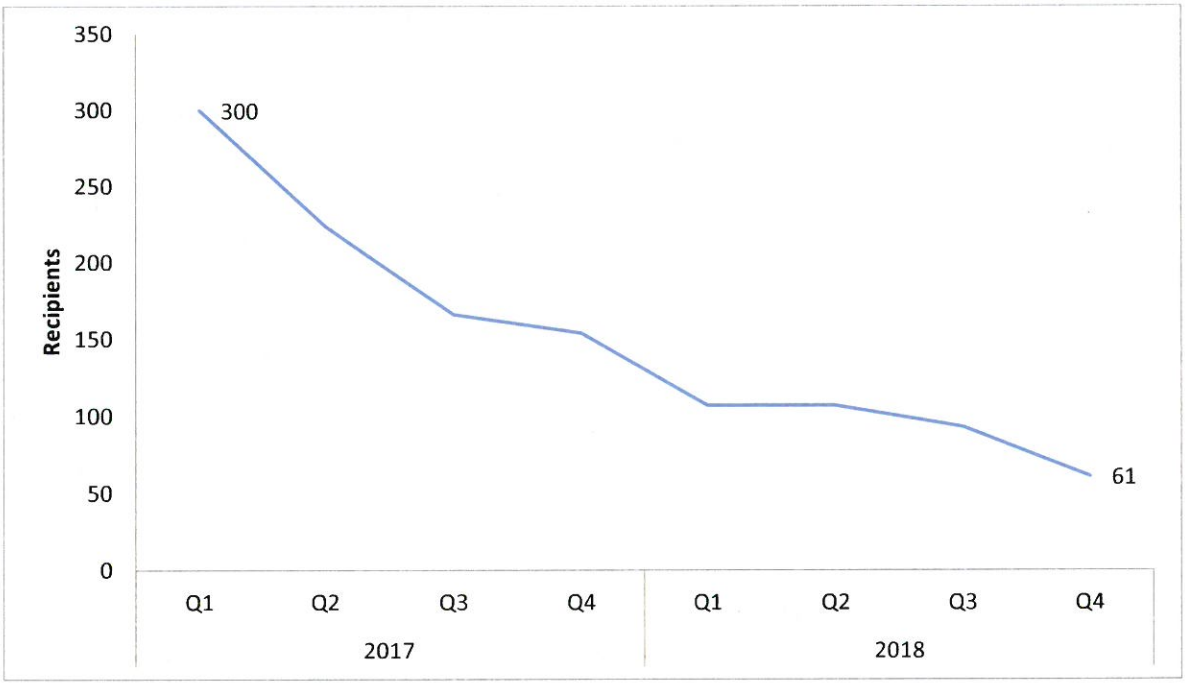
Table 1: Number of Registered PDMP Accounts—Arkansas—2018

Role	Accounts
Physician (MD/DO)	6,134
Pharmacist	3,117
Delegate	5,574
Adv. Practice Nurse	2,545
Dentist	1,265
Physician Assistant	401
Optometrist	115
Podiatrist	77
Law Enforcement	192
Veterinarian	95
Medical Resident	330
Licensing Board	5
Other	3
Total	**19,853**

"Doctor Shopping"

In an effort to curb the misuse and abuse of controlled substances, the PDMP is able to alert prescribers and dispensers of patients who seem to be "doctor shopping." "Doctor shopping" is defined as a patient going to multiple providers (prescribers and pharmacies) to obtain the same prescription or same class of medication. The PDMP flags patients who get multiple prescriptions from multiple providers and fill the prescriptions at multiple pharmacies. In previous years, the threshold for doctor shopping was 7 prescribers and 7 pharmacies in 90 days. However, the number of doctor shopping patients identified was low, which resulted in lowering the threshold. The new threshold is met once a patient sees 5 prescribers and 5 pharmacies in 90 days (5/5/90), at which point a patient alert is sent out to all providers and dispensers the patient has seen. Since quarter one of 2017, the state has seen a decrease in "doctor shopping" of the 5/5/90 threshold by 80% (Figure 1).

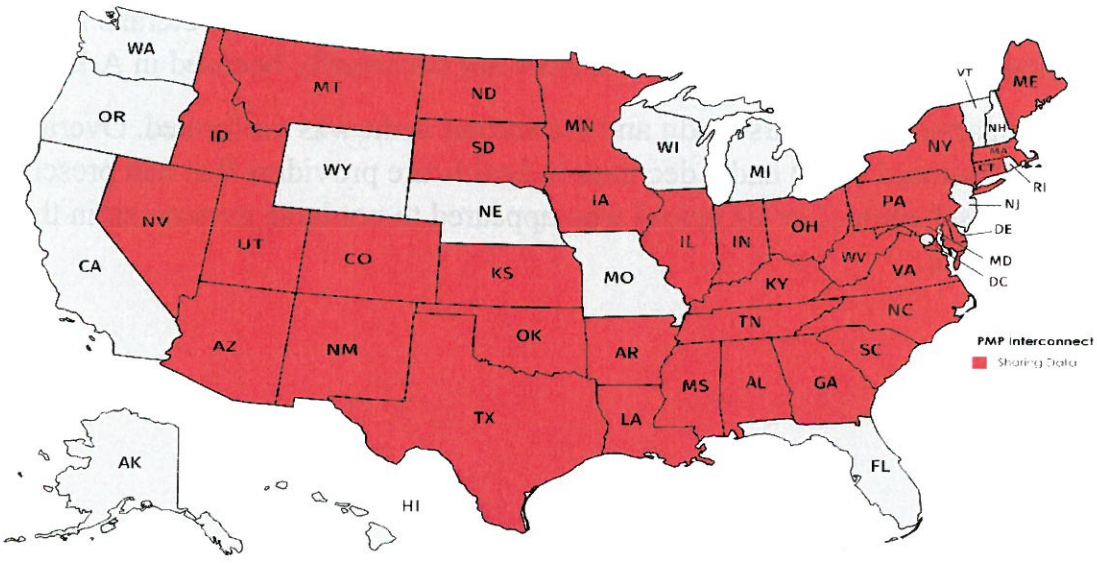
Figure 1: Recipients Seeing 5 or More Physicians and 5 or More Pharmacies in a 90-day Period—Arkansas—2017-2018



Interstate Data Sharing

The opioid crisis does not stop at state borders. Soon after states began establishing PDMPs, authorities recognized the need to share information between states. PDMP data are shared between states through an interface called PMP Interconnect. All the states in the country have a statewide PDMP with the exception of Missouri. Interstate data sharing allows prescribers, pharmacists and their delegates in Arkansas to see what controlled medications their patients have received in the 34 states with whom Arkansas currently shares data. The data sharing is bi-directional; Arkansas users are able to see information from other states and the other states are able to see prescription data in Arkansas. Sharing data across state lines prevents patients from "doctor shopping" from one state to another (Figure 2).

Figure 2: States that Share PDMP Data with Arkansas—2018



Non-registered Provider Audits

In the Summer of 2017, the mandatory use law went into effect. This law requires providers, with some exceptions, to check the PDMP prior to prescribing:

(1) a schedule II or schedule III opioid (i.e. oxycodone, hydrocodone, etc.) each time they are prescribed, and
(2) a benzodiazepine (i.e. alprazolam, diazepam, etc.) for the first prescription.

Two manual audits were performed by the PDMP to identify the providers who wrote a prescription for a schedule II or schedule III opioid between January 1, 2018, and June 30, 2018, and between July 1, 2018, and December 31, 2018, but appeared to not be registered with the Arkansas PDMP. If a provider is not registered with the PDMP and prescribes in one of the above categories, then the prescriber is not in compliance with the mandatory use law.

Each applicable professional board was notified of these providers, with the recommendation to send out a communication to educate on the new law. It is possible that some of these prescribers are not under the purview of the state licensing board—as an example, some of the prescribers may be Veterans Affairs (VA) healthcare professionals, and therefore not necessarily licensed in Arkansas.

A comparison of the first audit and the second audit was performed. Overall, every professional board had a decrease in healthcare providers that had prescribed at least one schedule II or III opioid who appeared to not have an account in the PDMP website.

Prescription Drug Use

Data by Drug Classes

The top selling controlled prescription drug type in 2018 in Arkansas filled by Arkansas residents was opioids. Opioids are medications used primarily to treat pain. This class of drugs includes hydrocodone, oxycodone, morphine, and others. Over 3.2 million prescriptions were given to Arkansas residents in 2018. Between 2016 and 2018, the total number of opioid pills sold decreased from 235,934,613 to 186,424,459. This is a 21% decrease in total number of opioid pills sold.

The second top-selling controlled class was benzodiazepines (Benzo), such as Xanax and Valium, which can be prescribed for anxiety, panic attacks, insomnia, seizures, and muscle spasms. In 2018, over 1.7 million prescriptions to Arkansans equated to 86 million pills.

Ranking third in the top-selling list is the stimulant class with drugs such as Adderall and Ritalin. Stimulants are mostly indicated for attention deficit hyperactivity disorder (ADHD) and narcolepsy. In 2018, 762,057 prescriptions to Arkansans totaled 26 million pills (Table 2).

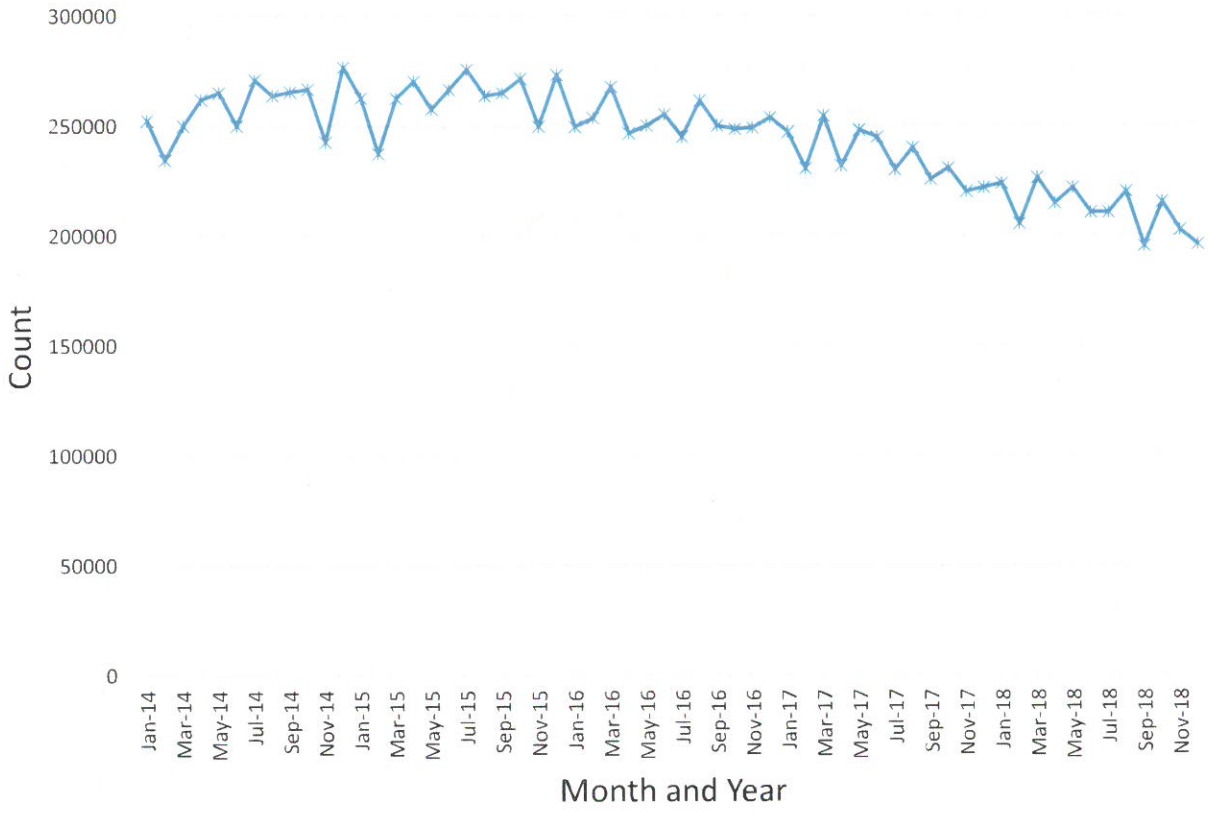
Table 2: Top-Selling Prescription Drugs by Class—Arkansas, 2018

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

Opioid Prescribing in Arkansas

The number of opioid prescriptions issued monthly from Arkansas prescribers to Arkansas residents is on the decline, from approximately 250,000 opioid prescriptions per month in 2014 to nearly 220,000 opioid prescriptions per month in the later portions of 2018. That is a 12% decrease in 4 years (Figure 3).

Figure 3: Total Opioid Prescriptions from Arkansas Prescribers to Arkansas Patients—Arkansas, 2014-2018

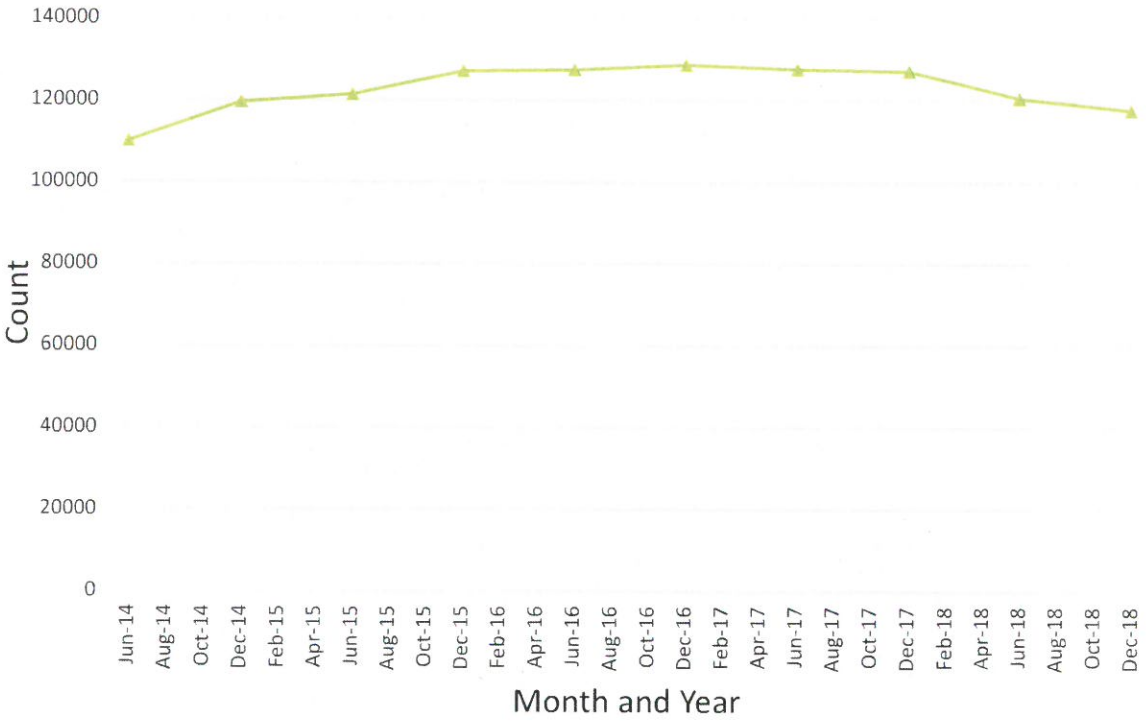


Source: Arkansas Prescription Drug Monitoring Program

Chronic Pain—Opioid Patients

While the number of opioid prescriptions being dispensed in the state has declined over the past 4 years, the number of chronic opioid users remains relatively stable. A chronic opioid user is defined as a patient who received 90 days of an opioid prescription in a 180-day period, with no more than a 30-day gap in usage. The number of Arkansans on chronic opioid therapy in any given 180-day period is between 120,000 to 130,000. However, even at its lowest, that number shows that almost 4% of Arkansans are on chronic opioids in any given 180-day period (Figure 4).

Figure 4: Number of Chronic Opioid Users in Arkansas Prescribed by Arkansas Prescribers—Arkansas, 2014-2018

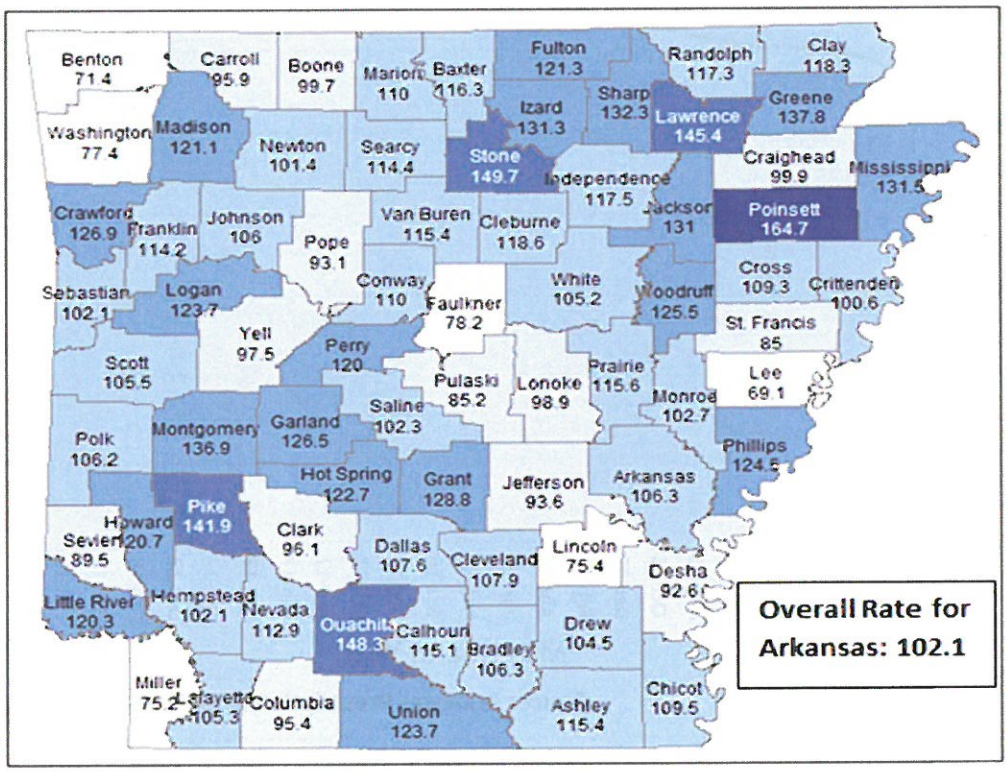


Souce: Arkansas Prescription Drug Monitoring Program

County Rates for Opioids

For the state, the opioid prescription rate per 100 people in 2018 was 102.1. To put this figure into perspective, a rate of 102.1 opioid prescriptions per 100 people suggests that there were more opioid prescriptions dispensed in the state than there are Arkansas residents. Even though this number has been decreasing in the past couple years, Arkansas is almost double the Centers for Disease Control's (CDC) determined national average rate of 58.7 per 100 in 2017. Every county in the state is over this national average with the highest prescribing counties being Poinsett (164.7), Stone (149.7), Ouachita (148.3) and Lawrence (145.4) (Figure 5). Counties are determined by the addresses of patients who received the prescription. Therefore, the map does not reflect the rates of prescriptions from providers in each county, but instead rates of prescriptions received by individuals in the county.

Figure 5: Opioid* Prescription Rates per 100 People per County Based on the Address of the Patient—Arkansas, 2018



*Note: Does not include buprenorphine products

Source: Arkansas Prescription Drug Monitoring Program

Opioid by Types

Since opioids are the most prescribed controlled drug type for the state, it is important to identify which specific opioids are being prescribed the most. In 2018 the top three types of opioids dispensed were hydrocodone, tramadol, and oxycodone. These three opioids combined make up 82% of all opioid prescriptions dispensed.

The state's highest prescribed opioid in 2018 was hydrocodone, with almost 1.37 million prescriptions. In 2018, hydrocodone accounted for 43% of all the opioid prescriptions sold. In 2015, 111,987,967 hydrocodone pills were dispensed compared to 76,613,992 pills in 2018, which is a 31.5% decrease.

The number of prescriptions for tramadol was almost half of the number for hydrocodone at 702,668, in 2018. Tramadol accounted for 22% of all the opioid prescriptions dispensed in Arkansas. Since 2015, the total number of tramadol pills sold decreased from 58,672,813 to 45,130,539, which is a 23% decrease.

Oxycodone was the third highest dispensed opioid for 2018 in the state with almost 535,000 prescriptions. Oxycodone prescriptions made up 17% of the total opioid prescriptions dispensed in the state. The number of oxycodone pills sold has decreased 31% since 2015 from 50,244,192 to 34,659,919 (Table 3) (Figure 6).

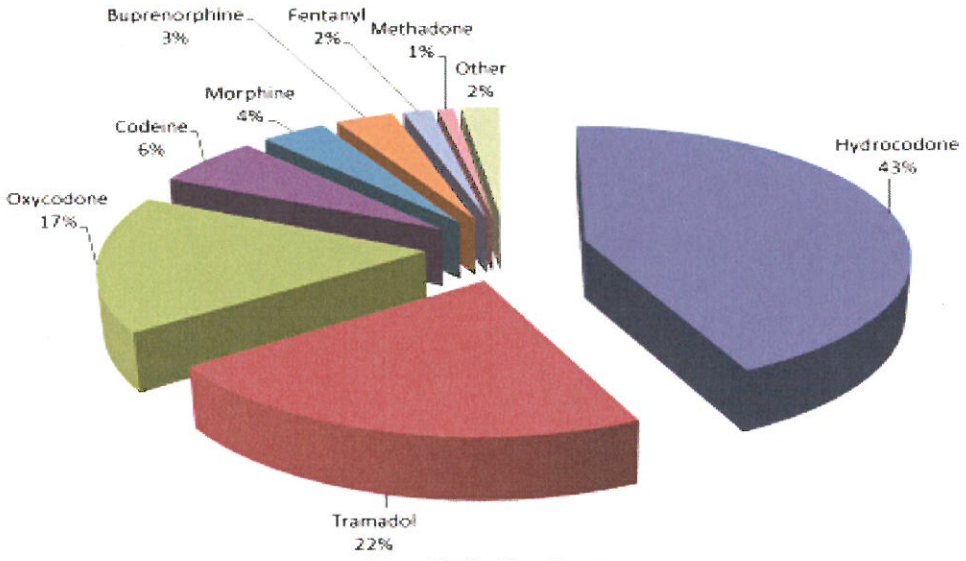
Table 3: Top Five Types of Opioids Dispensed*—Arkansas, 2018

Drug Name	Number of prescriptions	Pill Counts
Hydrocodone	1,369,322	76,613,992
Tramadol	702,668	45,130,539
Oxycodone	534,590	34,659,919
Codeine	192,613	7,734,391
Morphine	116,847	5,542,745

*Note: Filled by AR residents

Source: Arkansas Prescription Drug Monitoring Program

Figure 6: Percentage of Total Opioid Prescriptions by Type—Arkansas, 2018



*Note: Filled by AR residents

Source: Arkansas Prescription Drug Monitoring Program

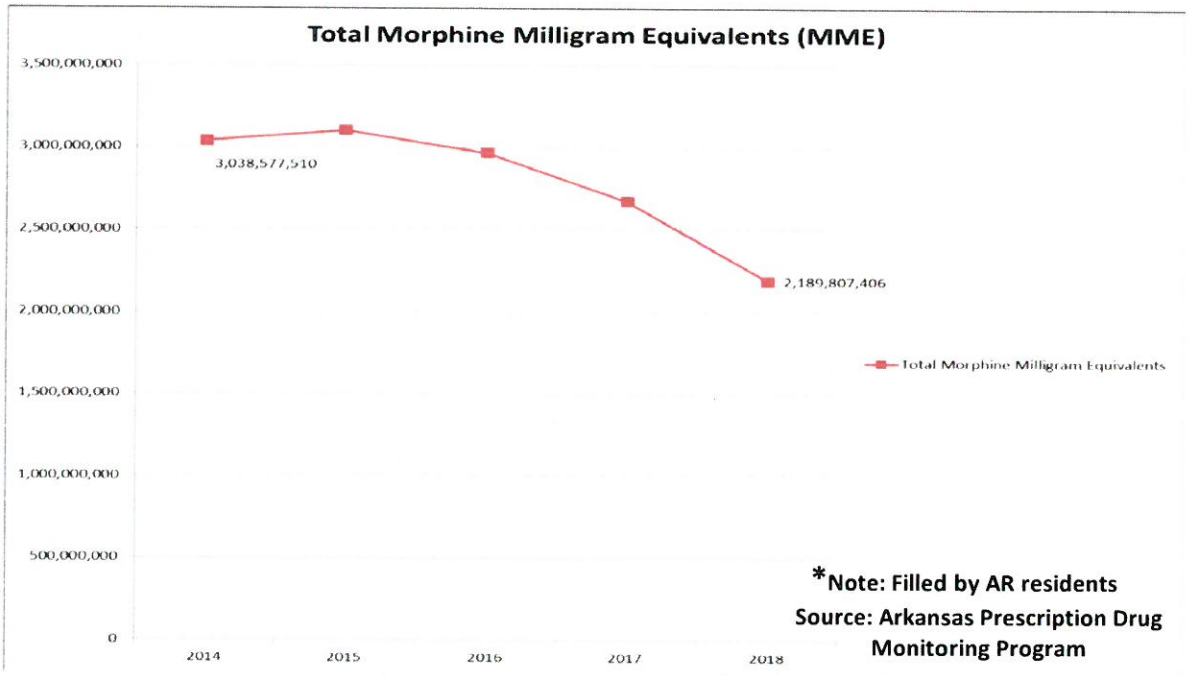
Morphine Milligram Equivalents (MME)

Not all opioids are equal. Some opioid medications are more potent than others; fentanyl is 50-100 times more potent than morphine, as an example. In order to compare the strengths of all opioids across the board, a conversion factor called the morphine milligram equivalent (MME) was established. The higher the MME of a prescription, the higher the risk of overdose. The formula for calculating is:

Strength of opioid X (number of units/days supply) X MME conversion factor = MME/Day

By looking at the trends of MME over the years, the PDMP is able to gauge the overall potency of the total opioid prescriptions dispensed in Arkansas. From 2014 to 2018, the total morphine milligram equivalent dispensed to Arkansas residents decreased by 28%. Not only has the state seen a decrease in the overall number of prescriptions for opioids and pills sold, there has been a decrease in the total MME dispensed (Figure 7).

Figure 7: Total Morphine Milligram Equivalents Dispensed* Arkansas, 2014-2018

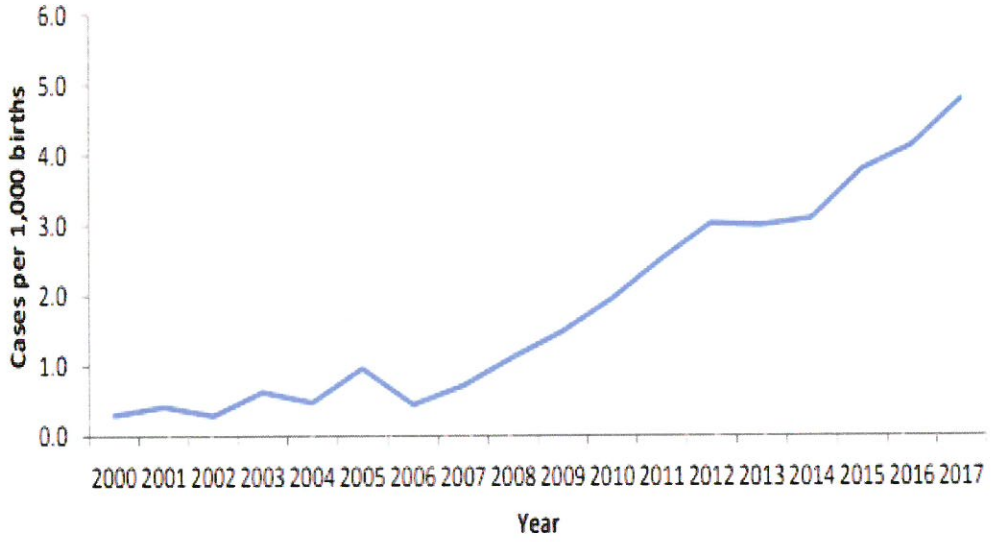


Problems Related to Drug Misuse

Neonatal Abstinence Syndrome

Neonatal Abstinence Syndrome (NAS) is a group of symptoms resulting from drug use during pregnancy. Since 2000, the rate of NAS per 1,000 hospital births increased from 0.3 per 1,000 births to 4.8 per 1,000 births in 2017 (Figure 8). The demographic breakdown of NAS cases in 2017 show the condition is more common among white than non-white Arkansans. Comparing the mother's insurance coverage, NAS rates for women with Medicaid were twice as high as women with other types of insurance. Rates in the northeast and northwestern regions of Arkansas show some of the highest rates. [1]

Figure 8: Rate of Neonatal Abstinence Syndrome per 1,000 Births, Arkansas Residents, 2000-2017*



*Does not include births to Arkansas mothers occurring in out-of-state hospitals

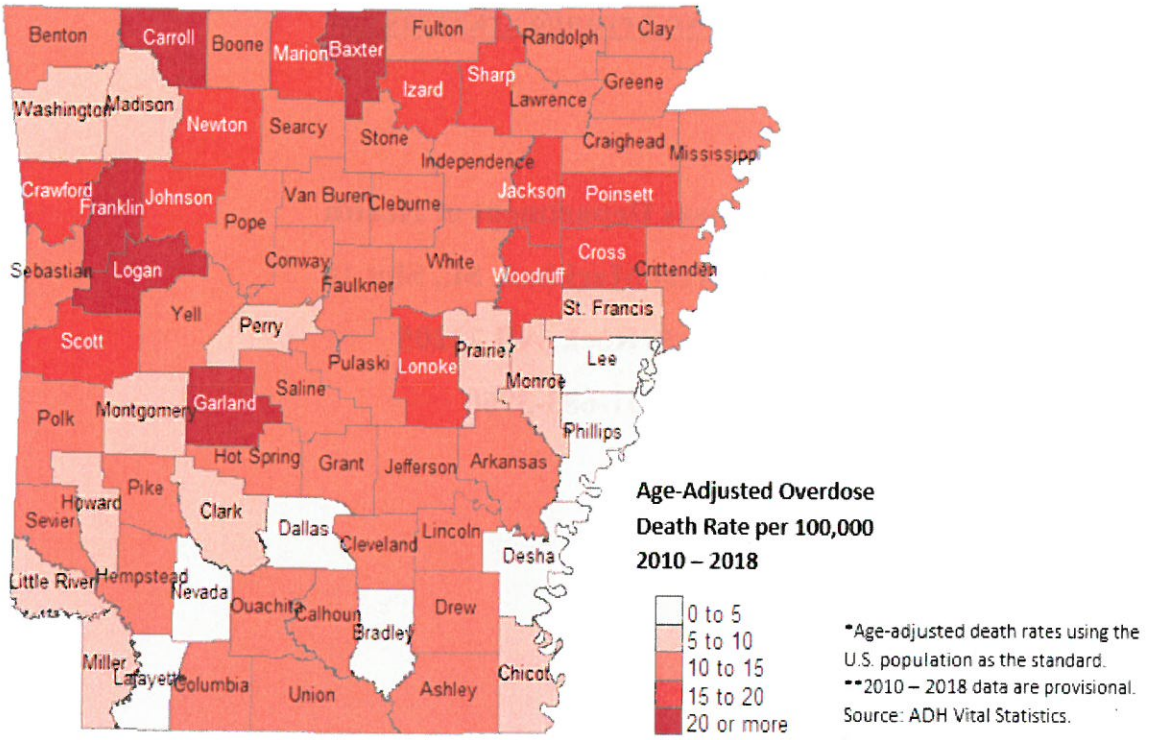
Source: ADH Hospital Discharge Data System

[1] Neonatal Abstinence Syndrome in Arkansas 2000-2017. Arkansas Department of Health.

Overdose Death Rates

According to the Arkansas Department of Health Vital Statistics Section, provisional data based on death certificates indicate that 426 Arkansas residents died from a drug overdose in 2018. This number is an increase from the 417 overdose deaths in 2017. The overdose death rates vary by county, with some of the higher ranking counties found in north central, central and south east Arkansas. The county with the highest overdose death rate is Garland County (Figure 9). Counties are determined by the individual's address of residence.

Figure 9: Overdose Death Rates per 100,000 People per County Based on the Individual's Address-- Arkansas, 2018



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ARKANSAS DEPARTMENT OF HEALTH

E-Cigarette Products, Nicotine Exposure, and Vaping

Nate Smith, MD, MPH
Secretary of Health

Vaping

- Used broadly today to include e-cigarettes and all vaping devices where nicotine containing fluids are aerosolized and inhaled
- Use among teens has risen dramatically in the last few years
- Early data are worrisome for health effects (cardiovascular)
- Teens who might otherwise not try tobacco products are trying vaping as they perceive that it is safe
- Teens who start vaping often take up combustible tobacco products (cigarettes, cigars)

E-Cigarette Use Among Students

Figure 1. Percentage of U.S. Students in Grades 6-12 That Ever Used an E-Cigarette, 2011-2015

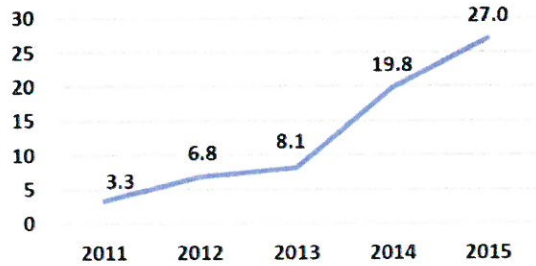
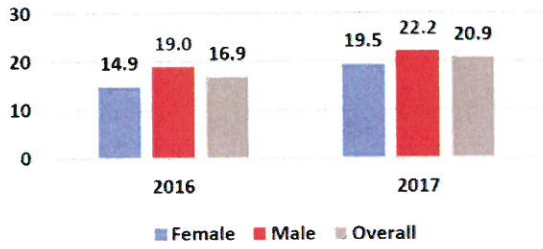


Figure 2. Percentage of Arkansas Students Grades 6-12 That Ever Used An E-Cigarette, 2016-2017



ACHI, November 2018

ARKANSAS DEPARTMENT OF HEALTH

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
August 30, 2019, 0935 ET (9:35 AM ET)
CDCHAN-00421

Severe Pulmonary Disease Associated with Using E-Cigarette Products

Summary

The Centers for Disease Control and Prevention (CDC) is providing: 1) background information on the forms of e-cigarette products, 2) information on the multistate outbreak of severe pulmonary disease associated with using e-cigarette products (devices, liquids, refill pods, and cartridges), and 3) clinical features of patients with severe pulmonary disease. This health advisory also provides recommendations for clinicians, public health officials, and the public based on currently available information.

ARKANSAS DEPARTMENT OF HEALTH

Product Placement & Advertising

- Another factor in youth purchases (and theft) of tobacco purchases is impulsivity at the cash register.
- A number of policies have been implemented nationwide to limit placement of products within a certain distance of the register.
- Billboards and outdoor advertising
  - Limiting placement within a certain distance of a school, parks, etc.
- Indoor advertising
  - Limiting advertising in certain types of facilities

Other Measures

- Addressing web sales
  - Tax
  - Under 21-yo sales
- Increased state enforcement of current purchasing laws
- Revising the pre-emption rules in Act 580 of 2019
- Clarifying and tightening the oversight of vape shops

Flavorings

Limiting/Banning Flavorings

- Flavorings are approved by FDA for use as additives to foods and beverages. There is no assumption of approval for heating and inhalation.
- Flavors and names of flavors are very appealing to young people.
- One state (Michigan) and several cities (Boston, NYC, San Francisco, Providence) have banned sales of flavored products.
- Menthol is a particular offender in that is targeted and preferred by African Americans.

Opinion No. 2009-072

July 9, 2009

The Honorable Kathy Webb
State Representative
Post Office Box 251018
Little Rock, Arkansas 72225-1018

Dear Representative Webb:

I am writing in response to your request for an opinion concerning a newly marked product called "e-cigs." You report that one manufacturer has described e-cigs as "a fantastic alternative to traditional cigarettes [that] can be legally smoked in bars, restaurants, and the work place." Your specific questions are as follows:

1. Does the Arkansas Clean Indoor Air Act regulate where this type of nicotine injection system may be used?

2. Are e-cigs subject to the same tax requirements as other tobacco products?

RESPONSE

The answer to both of your questions is "no," in my opinion.

Taxes/Price Manipulation

- Youth are remarkably price sensitive due to relatively limited resources.
- For combustible tobacco products, a 10% increase in price has been associated with a 6-7% decrease in under 18 smokers.
- Currently, only sales taxes apply to vaping products.
- Other tobacco products are taxed at **68% of price** in Arkansas.
- E-cigarettes are taxed in 15 states, seven of which tax by value (12.5-95%) vs eight that use low taxes by volume (the latter low tax programs promoted by industry).
- Price can be affected by coupons, on-line purchases and other manipulations as well.

Clean Indoor Air Laws

- Act 8, Arkansas Clean Indoor Act, passed during the special session of 2006 did not refer to non-combustible products.
- Therefore, vaping devices can be used in private and public spaces unless the owners voluntarily restrict their use.
- This creates the perception for kids that these devices are an acceptable activity.
- Adding vaping devices to the current Arkansas law would predictably reduce youth initiation.

E-cigarette policy options

- T-21
- Clean indoor air laws (public spaces and automobiles)
- Taxes or other price adjustments
- Restriction on flavorings
- Point of sale restrictions
- Advertising

T-21

- Effective Sept 1, 2019 in Arkansas
- Applies to all tobacco products including vaping products
- Graduated so that begins with no sales to under 19-yo this year, 20-yo next year, and 21-yo in 2021
- Expectation is slow, sustained reduction in tobacco use
- Earlier impact may occur with multiple interventions

Vaping-associated Respiratory Illness

- All patients have reported using e-cigarette products.
- The symptom onset has ranged from a few days to several weeks after e-cigarette use.
- Within two states, recent inhalation of cannabinoid products, THC or CBD, have been reported in many of the patients. One third of e-cig users also use marijuana (NCOTH-2019).
- To date, no single substance or e-cigarette product has been consistently associated with illness.

ARKANSAS DEPARTMENT OF HEALTH

Arkansas Cases (as of 9/6/2019)

- 6 cases- 2 confirmed, 4 probable
- Age 19-50, 4 males
- 5 were hospitalized
  - 1 was intubated
- All with similar clinical picture:
  - Shortness of breath/coughing/nausea/diarrhea/fever
  - Hypoxia, pulmonary infiltrates (CT, X-ray), leukocytosis

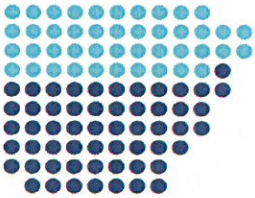
ARKANSAS DEPARTMENT OF HEALTH

100 ARKANSANS PROJECT — A CLOSER LOOK:

E-Cigarette Use Trends Among Public High School Seniors[1]

SEPTEMBER 2019

E-CIGARETTE USE



For every 100 public high school seniors in 2018, 44 reported using e-cigarettes at least once during their lifetime.

The percentage of public high school seniors who used e-cigarettes at least once during their lifetime increased 7.0 percentage points from 2014 to 2018.

[1] Visit achi.net/library/trends-among-high-school-seniors for this reference

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FEDERAL ACTION ON E-CIGARETTES

- Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA the authority to regulate tobacco products
- "Deeming" clause gave FDA the option to extend regulatory reach to any tobacco product that it deemed to be within its authority
- In May 2016, FDA extended its authority under the deeming clause to regulate electronic nicotine delivery systems (ENDS)
  - Vapes, vaporizers, vape pens, hookah pens, e-cigarettes, and e-pipes
  - May look like conventional cigarettes, cigars, or pipes; some resemble pens or flash drives

FDA REGULATION ON E-CIGARETTES

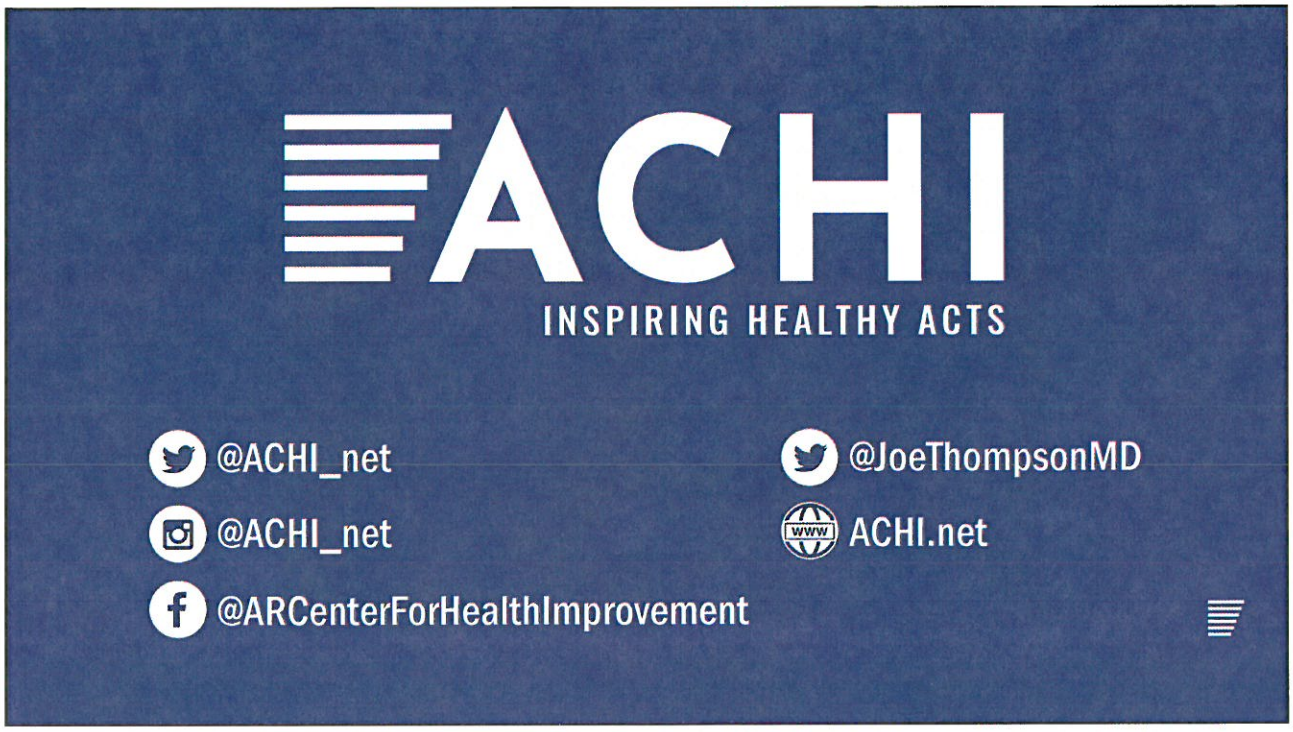
- FDA regulates manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS,
  - Includes components but excludes accessories
  - Beginning in 2018, all "covered" products must have the required nicotine addictiveness warning statement on packages and ads
  - Vape shops may be both retailers and manufacturers if they mix e-liquids

CONSUMER MARKETING STRATEGIES

- Advertising restrictions for traditional tobacco products and ENDS products differ
  - Tobacco litigation has resulted in settlements including additional advertising restrictions
  - Tobacco companies and magazine publishers in 2003 agreed to cease placement of advertisements in school library editions of magazines

JUUL AD IN MAY 2015 'VICE' MAGAZINE

JUUL SIGN IN LR CONVENIENCE STORE WINDOW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@JoeThompsonMD
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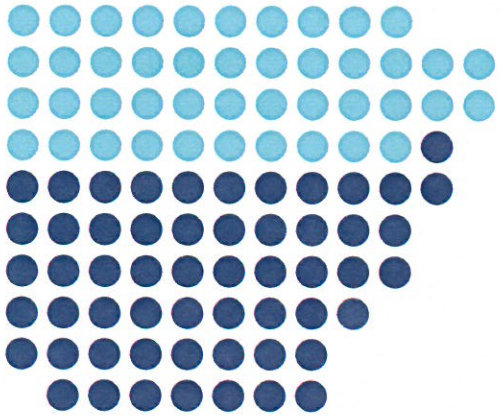
100 ARKANSANS PROJECT — A CLOSER LOOK:

E-Cigarette Use Trends Among Public High School Seniors[1]

SEPTEMBER 2019

E-CIGARETTE USE



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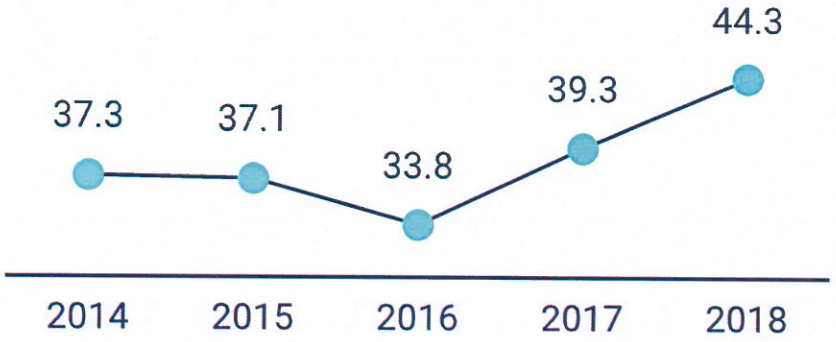

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SMOKING-ATTRIBUTABLE COSTS

Medicaid

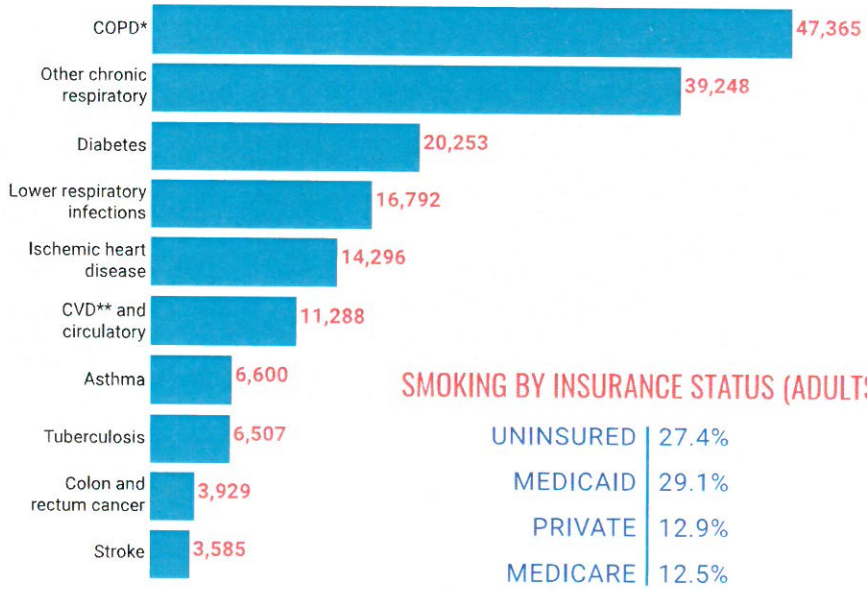
JANUARY 2019

- The Arkansas Tax Reform and Relief Task Force examined tax policy changes in 2018, among which were increases in the tobacco excise tax.
- A report provided to the task force noted that the Campaign for Tobacco-Free Kids has estimated smoking-related costs to Medicaid at $293.1 million annually.
  - That estimate uses 1998 Medicaid expenditures obtained from the Centers for Medicare and Medicaid Services (CMS), inflated to 2009 dollars, and does not account for the 2014 expansion of Medicaid coverage to more than 250,000 adult Arkansans.
- Using the Arkansas All-Payer Claims Database, the Arkansas Center for Health Improvement developed a new estimate of $795 million in smoking-attributable spending in Medicaid for individuals ages 30–65.[1]
  - This estimate does not account for smoking-attributable costs associated with pregnancy-related conditions, pre-term delivery, neonatal care, or childhood conditions triggered by smoking.
  - Medicaid spending far exceeds the anticipated revenue at either the current or proposed tobacco excise tax rates. Sales tax revenue estimates from tobacco products were not available at the time of this publication.

SMOKING-ATTRIBUTABLE SPENDING

$795 Million

TOP 10 | NUMBER OF MEDICAID ENROLLEES WITH CONDITION[2]



SMOKING BY INSURANCE STATUS (ADULTS)[3]

UNINSURED	27.4%
MEDICAID	29.1%
PRIVATE	12.9%
MEDICARE	12.5%

[1]Individuals ages 30–65 with a smoking-attributable condition were identified (includes traditional and expansion Medicaid populations in fiscal year 2015).
[2]Enrollees may have more than one condition but were only attributed to the condition with the highest smoking-attributable risk.
[3]Xu, X., et al., Annual healthcare spending attributable to cigarette smoking: an update. American Journal of Preventive Medicine. 2015. 48(3): pp. 326–333.
*Chronic obstructive pulmonary disease
**Cardiovascular disease

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MODIFIED-RISK TOBACCO PRODUCTS

MARCH 2019

Arkansas House Bill 1565, which would provide funding for a National Cancer Institute-designated cancer center in Arkansas, contains provisions regarding modified-risk tobacco products. If enacted, the bill would trigger an automatic 25 to 50 percent excise tax reduction for a product that is designated as a modified-risk tobacco product by the U.S. Department of Health and Human Services. The current excise tax on cigarettes in Arkansas is $1.15 per pack, which generated revenue of nearly $165 million in state fiscal year 2018.

Background

In 2009, Congress granted authority to the federal Food and Drug Administration (FDA) to designate certain products as modified-risk tobacco products (MRTPs). This legislation coincided with the introduction of new e-cigarettes and vaping products. However, it was not until 2016 that the FDA exercised its authority to regulate these new products. Under the federal Tobacco Control Act, a product seeking to make modified-risk claims to the public can only be introduced into the market after application for and receipt of a risk modification order by the FDA.

What is a modified-risk tobacco product?

According to the FDA, "**modified** risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco **products.**"[1]

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A tobacco product may receive a *risk* modification order for claims of reduced *risk* if the FDA determines that the product will:

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- Benefit the health of the population, including users and non-users of tobacco products.[2]

Alternatively, a tobacco product may receive an *exposure* modification order for claims of reduced exposure (e.g., claims that a product has "no tar") if the FDA determines that:

- An order would be appropriate to promote the public health;
- Scientific evidence is not available and cannot be made available without conducting long-term studies required to receive a risk modification order; and
- Existing evidence that is available in the absence of long-term studies shows that a measurable and substantial reduction in morbidity and mortality among tobacco users is reasonably likely in future studies.[3]

The FDA has not yet granted modified-risk status to any tobacco products via the application process. There are currently four MRTP applications under scientific review.

Conclusion

States relying on the federal process for determining modified risk should carefully examine the scientific review conducted on each product to assess for any localized impacts. Additionally, states seeking to reduce taxes on MRTPs should compare the level of the tax benefit to the level of potential risk reduction for a tobacco user and the expected use of the MRTP in the population. Tax reductions that are automatically triggered without an assessment of the evidence could result in the inability of the state to offset the level of risk that nonetheless exists with all tobacco products.

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[1] https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm410712.htm
[2] 21 U.S.C. § 387k(g)(1)
[3] 21 U.S.C. § 387k(g)(2)

HANDOUT 4
ITEM F.2

SOUTHEASTRANS

DRIVING THE FUTURE OF TRANSPORTATION MANAGEMENT

Southeastrans commitment to the State of Arkansas and its NEMT Program is unwavering, and we have had a proud partnership with the State for over six years. The commitment outlined in this response will allow SETI to continue to improve service levels and meet the applicable service requirements by September 30, 2019. We are working daily to fix the missed trips. SETI will be the first to admit we thought we had a solid plan to hire local providers, drivers and find people willing to let us assist them with business start-ups. Our business model has always been to hire locally and use local assets. The low Arkansas unemployment rate has made this extremely difficult despite our efforts of job fairs and outreach. In fact, if any of you know hard working individuals who will assist us with taking care of your constituents, please let us know. We have a job for qualified drivers and will even assist entrepreneurs who are interested in opening their own NEMT business.

We are successfully delivering over 3,200 Arkansans per day to their destinations and completing over 71,000 trips per month here in Arkansas. SETI successfully coordinate the transportation of 99.5% of all scheduled trips each month and 99.88% of these are complaint-free trips.

Southeastrans Actions to Eliminate Missed Trips

1. SETI is adding an additional 28 company vehicles (20 wheelchair and 8 ambulatory) and drivers to eliminate missed trips occurring in Regions A, B, C, D and G. This will bring SETI's total fleet and drivers to 67 in the state.
2. We will continue to eliminate this driver and vehicle shortage by bringing in vehicles and hire drivers as needed.
3. SETI is committed to making an additional investment of over $840,000 to purchase vehicles, equipment and cameras.
4. The company is hiring an additional 28 drivers at an additional annual payroll expense of over $900,000.
5. The annual payroll expense for all 67 van drivers will now total over $2.1mm.
6. We have targeted the following dates for the placement of drivers and vehicles into service:
    - Week of 9/9: 15 additional vehicles and drivers
    - Week of 9/23: 13 additional vehicles and drivers
7. Pay raises for providers - In a further attempt to increase network capacity, SETI has been increasing the rates it pays many current and prospective Providers. This has already motivated Providers to add additional vehicles and expand service hours and days to the network.
8. SETI also increased our own drivers' pay by $2 per hour to increase recruiting and retention.
9. ROBO Calls for Beneficiaries – We have submitted a proposal to DHS to establish an "automated appointment reminder" system, which would contact Beneficiaries the night before a scheduled pickup to verify the Beneficiary will be attending a given appointment. Much the same as doctors' offices do now with their patients, like you and me.

Implementation Challenges and SETI Actions Upon Start-up in February:

1. 62 Call Center Agents were hired in 8 days of notification of additional regions
2. As the second highest bidder, we agreed in mid-January 2019 to accept four additional Regions on extremely short notice, to start February 1, 2019.
3. Our Arkansas operations triaged Beneficiaries' individual transportation needs so the most fragile populations were assured transportation (i.e., chemo, radiation, dialysis, wound care, high risk Beneficiaries)
4. More Providers left the network and/or reduced their fleet size, which compounds the challenge of meeting service demand. The primary contributing factors were:
    - Historically low unemployment rate (causing a shortage of drivers)
    - Increasing insurance premiums on vehicles
    - Increased frequency of Beneficiaries cancelling trips with no notice (or short notice)
    - Beneficiaries simply failing to show up at all.
    - In addition, some Providers are reluctant to add to their fleets because they lack confidence that the EIDT/ADDT programs will remain as part of the NEMT Program in 2020.
5. SETI have purchased 16 unbudgeted transport vehicles in February 2019 (both wheelchair and ambulatory vans) to assist in supporting the shrinking Provider network. This was in addition to the existing fleet of 12 vehicles already providing transportation.
6. SETI hired 16 additional unbudgeted drivers to operate our transport vehicles.
7. SETI provided $118,300 in interest free loans to Providers to assist with:
    - Improving fleet quality and repairing vehicles;
    - Installing cameras;
    - Purchasing additional vehicles; and
    - Making down payments on insurance premiums.
8. SETI provided an additional $29,700 in loans to help stabilize two Providers because the prior broker had not paid claims associated with completed trips. This action was in concert with DHS' pursuit of the prior broker for such payments.

SETI Efforts and Unbudgeted Expenses

Southeastrans will annually expense over $3.5mm since 1/17/19 in unbudgeted costs. These expenses were not part of our bid to the State. These are extraordinary expenses caused by the challenges listed above and our continual attempt to bridge the provider shortfalls in the State. To date, the unbudgeted dollars spent by SETI to solidify the network total:

o Loans for transportation providers	$ 118,300
o Advances for transportation providers	$ 29,700
o Purchase of 54 vehicles	$1,620,000
o Annual pay and benefits for 54 drivers	$1,752,192
o Total	$3,520,192

Should you have further questions on this information, contact our local counsel, Ron Fuller at 501-960-6611.