STATE & FEDERAL EFFORTS TO COMBAT THE OPIOID EPIDEMIC & IMPACT ON COMPLIANCE PROGRAMS

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Arizona Corporate Counsel Presentation
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Agenda

1. Overview of the Opioid Crisis
2. Arizona’s Efforts to Combat the Crisis
3. Federal Efforts to Combat the Crisis
4. Compliance Issues
Origins of the Crisis

Several factors have contributed to the opioid epidemic, including:

• Increased prescribing of opioids for chronic pain;
• Transition of prescription misusers to illicit opioids;
• The influx of highly potent fentanyl and fentanyl analogs.

The Opioid Epidemic

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016

Source: Centers for Disease Control and Prevention

Source: Centers for Disease Control and Prevention

www.cdc.gov
The Opioid Epidemic

Source: National Institute on Drug Abuse, Opioid Summaries by State
The Opioid Epidemic - Arizona

Source: Arizona Department of Health Services, data is preliminary and subject to change as cases are confirmed. This data does not include Part 2 programs prohibited from reporting by 42 CFR Part 2.
Fentanyl
Fentanyl

Authorities seized 30,000 fentanyl pills during a traffic stop of members of a drug crew affiliated with the Sinaloa cartel in Tempe on Aug. 13, 2017.

(Photo: DEA)
Fentanyl

Source: U.S. Department of Justice, Drug Enforcement Administration
Arizona Response to Crisis

On June 5, 2017, Governor Ducey issued a Declaration of Emergency directing the Arizona Department of Health Services to:

1) Provide consultation for an Enhanced Surveillance Advisory;

2) Issue emergency rules for opioid prescribing and treatment within health care institutions;

3) Develop guidelines to educate healthcare providers on responsible prescribing practices;

4) Develop and provide training to local law enforcement agencies on proper protocols for carrying, handling, and administering Naloxone in overdose situations;

5) Provide a report on findings and recommendations by September 5, 2017.

Source: Declaration of Emergency and Notification of Enhanced Surveillance Advisory (June 5, 2017).
Arizona Response to Crisis


Health care providers, pharmacists, emergency medical service providers, local and state law enforcement agencies, health and medical boards, and others were directed to report data on specific opioid-related health conditions to ADHS.

Arizona Department of Health Services adopted A.A.C. R9-10-120 that became effective July 28, 2017.

A.A.C. R9-10-120 requires health care institutions:

1) Establish, document, and implement policies and procedures for prescribing or ordering an opioid or administering an opioid as part of treatment;

2) Include in quality management program a process for review of incidents of opioid-related adverse reactions and surveillance and monitoring of adherence to policies and procedures;


Source: A.A.C. R9-10-120
Arizona Department of Health Services also adopted A.A.C. R9-4-601 to -602 that became effective October 9, 2017.

A.A.C. R9-4-602 requires reporting on opioid overdoses and intervention activities on a real-time basis. This continues the data reporting required under Governor Ducey’s Executive Orders.

Ambulance services, emergency medical service providers, law enforcement, health care institutions, health professionals, medical examiners, and pharmacists are required to submit opioid-related data to ADHS.

Source: A.A.C. R9-4-602
Arizona Response to Crisis

Arizona Opioid Epidemic Act

“"Our package will attack this issue from all angles, while protecting individuals who suffer from chronic pain, and maintaining compassion for those struggling with addiction.”

— Governor Doug Ducey
2018 State of the State Address
Arizona Opioid Epidemic Act

A.R.S. § 13-3423
Good Samaritans

A.R.S. § 32-3248(A)
Limits on Initial Prescriptions
• 5-day supply for initial prescription
• 14-day supply after surgical procedure

A.R.S. § 32-3248(B)
Exceptions to limits on prescriptions:
• Active oncology diagnosis,
• Traumatic injury;
• Hospice Care;
• End-of-Life Care;
• Palliative Care;
• Skilled Nursing Facility Care;
• Treatment for Burns;
• MAT for SUD;
• Infant being weaned off opioids.

Source: SB 1001 / HB 2001, Fifty –Third Legislature, First Special Session
## Arizona Opioid Epidemic Act

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Source: SB 1001 / HB 2001, Fifty –Third Legislature, First Special Session
THE PRESIDENT’S COMMISSION
ON COMBATING DRUG
ADDICTION AND THE OPIOID
CRISIS

Roster of Commissioners

Governor Chris Christie, Chairman
Governor Charlie Baker
Governor Roy Cooper
Congressman Patrick J. Kennedy
Professor Bertha Madras, Ph.D.
Florida Attorney General Pam Bondi
Federal Response to Crisis

On March 29, 2017, President Trump signed Executive Order No. 13784 establishing the President’s Commission on Combating Drug Addiction and the Opioid Crisis.

On October 26, 2017, President Trump declared the opioid crisis a national public health emergency.

On November 21, 2017, the President’s Commission issued its report with 56 recommendations.

Congress is discussing new legislation. CARA 2.0?
Federal Response to Crisis

Comprehensive Addiction & Recovery Act (CARA) (signed into law July 22, 2016)

• HHS directed to award grants to establish and implement a comprehensive state and local response to opioid abuse that includes education efforts, a prescription drug monitoring program, prescription drug and opioid addiction treatment programs, and overdose death prevention efforts.

  • Each Fiscal year, DOJ’s Office of Inspector General audits of number of grant recipients.

• Interagency task force established on pain management best practices.

Federal Response to Crisis

Comprehensive Addiction and Recovery Act (continued)

- Extended grant program for state prescription drug monitoring programs;

- Amended Omnibus Crime Control and Safe Streets Act of 1968 to authorize DOJ to award grants to states for:
  - Treatment alternative to incarceration programs;
  - Enhancing collaboration between criminal justice and substance abuse programs;
  - Expanding programs to prevent, treat and respond to opioid abuse;
  - Training first responders to administer overdose treatments;
  - Investigating unlawful opioid distribution activities.

21st Century Cures Act  
(signed into law on December 13, 2016)

- Section 1003 provided $500 million in funding to Department of Health Services to grant States to address the opioid abuse crisis;
- Funding to be used to support prevention, treatment, and recovery services;
- Arizona received $12,171,518 grant.

Source: H.R. 34, 114th Congress (2015-2016); see also HHS Press Office, Trump Administration awards grants to states to combat opioid crisis (April 19, 2017)
21st Century Cures Act

- Section 13002 directed Secretary of HHS to improve federal and state coordination related to enforcement of mental health and substance use disorder parity requirements.
- In FY 2017, Department of Labor conducted 187 investigations and cited 92 violations.
- The Departments of HHS, Labor, the Treasury, and other federal agencies have issued regulations to implement the parity law and continue to issue guidance and publications.

Source: H.R. 34 114th Congress (2015-2016); see also HHS, Action Plan for Enhanced Enforcement of Mental Health and Substance Use Disorder Coverage.
Federal Response to Crisis

21st Century Cures Act

- Section 9001 promotes access to mental health and substance use disorder care
  - SAMHSA support for integrated care;
  - Assist individuals in transitioning out of homelessness;
  - Grants to divert individuals with a mental illness from the criminal justice system to community-based services.

DEA Suspends the Registration of Morris & Dickson Company from Distributing Controlled Substances

The Drug Enforcement Administration today announced the issuance of an Immediate Suspension Order served on Morris & Dickson Company, a wholesale pharmaceutical distributor, located in Shreveport, Louisiana.

Morris & Dickson Company has been the subject of a DEA investigation that alleges that this distribution center failed to properly identify large suspicious orders for controlled substances sold to independent pharmacies with questionable need for the drugs. The investigation, which focused primarily on purchases of Oxycodeone and Hydrocodone, revealed that in some cases, pharmacies were allowed to purchase as much as six times the quantity of narcotics the pharmacy would normally order. In spite of regulations which require distributors to identify such orders, DEA alleges that Morris & Dickson Company failed to identify these large suspicious orders resulting in millions of dosage units of Oxycodeone and Hydrocodone being distributed in violation of the law.
January 19, 2017, DOJ announced an $11.75 million settlement with Costco Wholesale related to practices at certain pharmacies. Violations included:

- Filling prescriptions from practitioners who did not have valid DEA numbers;
- Incorrectly recording practitioners’ DEA numbers;
- Filling prescriptions outside the scope of practitioners’ DEA registration;
- Filling prescriptions that did not contain all required information;
- Failing to maintain accurate dispensing records;
- Failing to maintain records for the central fill pharmacy.
For Immediate Release

Former UPMC Radiologist Pleads Guilty to Health Care Fraud and Unlawfully Prescribing Vicodin

PITTSBURGH, PA – A former radiologist at the University of Pittsburgh Medical Center waived indictment and pleaded guilty in federal court to charges of unlawfully distributing controlled substances and health care fraud, United States Attorney Scott W. Brady announced today.

Marios D. Papachristou, 43, of Allison Park, PA, pleaded guilty to two counts before United States District Judge Arthur J. Schwab.

In connection with the guilty plea, the court was advised that Papachristou conspired to create and submit unlawful prescriptions for Vicodin, and then unlawfully dispensed those controlled substances to other persons not specifically named in the Indictment. Papachristou also committed health care fraud for allegedly submitting fraudulent claims to UPMC Health Plan, for payments to cover the costs of the unlawfully prescribed Vicodin.
FOR IMMEDIATE RELEASE

Department of Justice Files Motion in Multi-District Opioid Case

Attorney General Jeff Sessions today announced that the Department of Justice has filed a motion to participate in settlement discussions and as a “friend of the court” in the ongoing Multi-District Litigation against opioid manufacturers and distributors.

"Following the leadership of President Trump, for the past year the Department of Justice has vigorously fought the prescription opioid crisis, deploying new tools and resources to stop the traffickers and corrupt medical professionals who are profiting off of addiction," said Attorney General Sessions. "We are determined to continue making progress. Today, we are taking a new step to help those who have suffered the consequences of the opioid epidemic by offering our assistance as friend of the Court in ongoing litigation against opioid manufacturers and distributors. We have already filed a statement of interest in this case, arguing that the taxpayer has paid a heavy price because of dishonest opioid marketing practices, and deserves to be compensated. Now we are formally seeking to provide the federal government’s expertise and legal counsel to the court on a potential settlement. We are determined to see that justice is done in this case and that ultimately we end this nation’s unprecedented drug crisis."
Compliance Issues

For Health Care Institutions, Providers, and Pharmacies:

• Are there policies and procedures in place applicable to controlled substances, including but not limited to (i) prescribing, (ii) dispensing; (iii) re-fills; (iv) recordkeeping (v) DEA registration and verification processes; (vi) pharmacy security; (vii) reporting suspicious orders and other reporting obligations.

• Is training being conducted? CMEs?

• Are you evaluating and monitoring compliance?

• Are compliance incidences being reported, followed-up on, and corrective actions taken?
Compliance Issues

For Medicaid and Medicare Contractors and Providers:

- Do you have an internal investigations unit in place to monitor fraud, waste, and abuse? *See AHCCCS Contractor Operations Manual, Policy 103*
  - Managed Care Organizations must have internal controls, policies, and procedures to prevent, detect, and report fraud, waste and abuse activities to AHCCCS-OIG.
  - Contractors must conduct research and proactively identify changes for program integrity that are relevant to their programs. Is your internal investigations group proactively looking at its internal controls for monitoring fraud, waste, and abuse related to opioid abuse?
  - Contractors have an affirmative obligation to report fraud, waste, and abuse.
Compliance Issues

For Institutions subject to the Bank Secrecy Act and Anti-money laundering laws:

• Has your institution proactively reviewed publicly available information and performed an assessment of whether illicit monies may be moving through your institutions?

  • One good background source on the drug trafficking: United States Senate, Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, *Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail*.

• File your SARs!
Questions?

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