Pain Care Legislation and Public Policy

Wade Delk, ASPMN®
Michael C. Barnes, DCBA Law & Policy
**PCSS** is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with:

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<thead>
<tr>
<th>American Academy of Family Physicians</th>
<th>American Psychiatric Association</th>
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<tr>
<td>American Academy of Neurology</td>
<td>American Society of Addiction Medicine</td>
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<td>Addiction Technology Transfer Center</td>
<td>American Society of Pain Management Nursing</td>
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<td>American Academy of Pain Medicine</td>
<td>Association for Medical Education and Research in Substance Abuse</td>
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<td>American Academy of Pediatrics</td>
<td>International Nurses Society on Addictions</td>
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<td>American College of Emergency Physicians</td>
<td>American Psychiatric Nurses Association</td>
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<td>American College of Physicians</td>
<td>National Association of Community Health Centers</td>
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<td>American Dental Association</td>
<td>National Association of Drug Court Professionals</td>
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<td>American Medical Association</td>
<td>Southeastern Consortium for Substance Abuse Training</td>
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<td>American Osteopathic Academy of Addiction Medicine</td>
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Target Audience

• The overarching goal of PCSS is to train a diverse range of healthcare professionals in the safe and effective prescribing of opioid medications for the treatment of pain, as well as the treatment of substance use disorders, particularly opioid use disorders, with medication-assisted treatments.
Educational Objectives

- At the conclusion of this activity, participants should be able to:
  - Recognize the current state of the U.S. opioid-heroin-fentanyl crisis.
  - Interpret federal and state legislative and regulatory actions and proposals.
  - Assess the intent and anticipated practical impacts of opioid-related policy.
Disclosure

• DCBA Law & Policy is a Washington, D.C.-based health law and policy firm with a nationwide practice.
• Our firm’s clients include health care practitioners, clinics, laboratories, and drug and device companies.
Healthcare Spending

- Americans spend around $3.5 trillion on healthcare annually (per CMS)

- $10,500 for every man, woman, and child in U.S. (nearly 18% of GDP)

- CBO projects double-digit premium increases (along with increases in deductibles and fewer benefits and services)

- Will likely reach 21% of GDP in next 6-8 years

- Cost in U.S. almost twice as much as other countries (with poorer outcomes)
NEW ENFORCEMENT TACTICS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, February 8, 2019

Justice Department Files First of its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids

The Justice Department announced an action today to stop two pharmacies, their owner, and three pharmacists from dispensing controlled substance medications, including powerful opioids that have been linked to abuse and diversion. The action is part of a coordinated effort by the Department’s Prescription Interdiction & Litigation (PIL) Task Force to deploy all available criminal, civil, and regulatory tools to reverse the tide of opioid overdoses in the United States. Assistant Attorney General Jody Hunt for the Department of Justice’s Civil Division, U.S. Attorney Don Cochran for the Middle District of Tennessee, D. Christopher Evans, Special Agent in Charge of the U.S. Drug Enforcement Administration’s (DEA) Louisville Field Division, and Derrick L. Jackson, Special Agent in Charge at the U.S. Department of Health and Human Services (HHS), Office of Inspector General made the announcement.

In a civil complaint unsealed today in the Middle District of Tennessee, the United States alleges that Celina, Tennessee, pharmacies, Oakley Pharmacy, Inc., d/b/a Dale Hollow Pharmacy (Dale Hollow) and Xpress Pharmacy of Clay County (Xpress), the pharmacies’ owner, Thomas Weir, and pharmacists John Polston, Michael Griffith, and Larry Larkin were dispensing, and billing Medicare for, prescriptions in violation of the Controlled Substances Act and the False Claims Act. According to the United States’ complaint, the defendants’ unlawful dispensing of opioids has been tied to the deaths of at least two people and numerous others have been treated at hospitals for serious overdoses within a short time of obtaining controlled substances from the pharmacies.
DEA Criminal & Administrative Actions

DEA Criminal Cases Against Physicians  
REPORT  
April 30, 2019

DEA Administrative Actions Against Registrants – 2019  
REPORT  
April 30, 2019

Full reports linked at centerforuspolicy.org.
Continuing Focus on Rx Opioids

- Opioid analgesic prescribing decreased 25% between 2012 and 2017.¹
- Illicit opioids (e.g., analog fentanyl and heroin) are now the most commonly present substances in drug overdose fatalities.
- Policy efforts remain largely focused on restricting access to opioid pain relievers.
- The federal government is seeking to cut nationwide prescription opioid dispensing by an additional one-third by 2021.²

¹[https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html](https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html)
A More Sensible Surge

Require law enforcement to obtain a referral from a state professional licensing board before instituting, aiding in, or defending a criminal investigation, indictment, or prosecution or civil action against a state-licensed health care professional or pharmacist in which medical need or patient care, including the prescribing or dispensing of controlled medications, is at issue.

Redirect federal opioid-related funding away from the DOJ to HHS. HHS should then provide grants to states to bolster the budgets of health-profession licensing boards.
Practice Considerations
Prescriber Safety Initiative

Enhancing the safety of patients and practitioners.

The Prescriber Safety Initiative equips practitioners to understand and adhere to the laws and regulations governing the prescribing of controlled medications, including office-based opioid treatment.
Compliance Plan

• Experienced health care legal counsel
• Written policies
• Training
• Monitoring and quality improvement
• Documentation of all medical decisions

• Relationships
  • Law enforcement leaders
  • Reporters
• Engagement in policy & politics

# Know Your Rights and Create an Action Plan

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<tr>
<th>Administrative Inspection</th>
<th>Active Investigation</th>
<th>Immediate Suspension</th>
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<tr>
<td>Warrant —or— Request to inspect (may request to reschedule)</td>
<td>Subpoena specifying actions — or — Search warrant with parameters</td>
<td>Immediate Suspension Order and Order To Show Cause</td>
</tr>
<tr>
<td>DEA may inspect premises and records, make copies Employees are not required to answer questions</td>
<td>Read carefully and call counsel immediately</td>
<td>Call counsel immediately</td>
</tr>
<tr>
<td>DEA may request voluntary surrender of registration</td>
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<td>Do not prescribe controlled medications</td>
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Pain Policy
THE UNSEEN VICTIMS OF THE OPIOID CRISIS ARE STARTING TO REBEL
Recent Release - PDF

NIH • Helping to End Addiction Long-term
CDC Clarification, Oregon Stand Down

CDC Issues Key Clarification on Guideline for Prescribing Opioids for Chronic Pain

Agency Clarifies CDC Guideline Not Meant to Limit Access to Appropriate Pain Management for Individuals with Cancer, Sickle Cell Disease

No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

Oregon’s Opioid Tapering Plan Delayed

DCBA | Law & Policy
Automated Reports and Consolidated Orders System (ARCOS)

- Seeks to help identify illicit use and diversion – red flags
- Manufacturers and distributors can download six months of data (grams/dosage units each distributor sold).
- Know Your Customer
OUD Policy
HR 6
SUPPORT FOR PATIENTS AND COMMUNITIES ACT
Discussing medications that can treat OUD with patients who have this disorder is arguably the clinical standard of care.

X the X Waiver

The Mainstreaming Addiction Treatment (MAT) Act
116th Congress
Sponsors: Reps. Paul Tonko (D-NY), Antonio Delgado (D-NY), Ben Ray Lujan (D-NM), Ted Budd (R-NC), Elise Stefanik (R-NY), Mike Turner (R-OH)

"The devastation of America’s opioid crisis has touched every part of our country, and access to treatment is a matter of life and death. Our national response needs to rise to meet the unprecedented scale of this crisis."

Want to Reduce Opioid Deaths? Get People the Medications They Need

Drugs like buprenorphine could sharply curb the nation’s opioid overdose crisis. But federal laws make it difficult for people who need such medications to get them.

By The Editorial Board
The editorial board represents the opinions of the board, its editor and the publisher. It is separate from the newsroom and the Op-Ed section.

March 26, 2019
FDA Citizen Petition

FDA Blocks New Opioid-Addiction Medications amid Public Health Crisis

April 9, 2019

The US Department of Justice Drug Enforcement Administration Diversion Control Division Released Statement Clarifying the Use of Telemedicine for Medication Assisted Treatment (MAT)

by | June 4, 2018

On May 15, the Drug Enforcement Agency (DEA) Drug Diversion Division issued an email alert reiterating its position on the prescribing of controlled substances via telemedicine under the Ryan Haight Act of 2008.

The Ryan Haight Act states that to prescribe a controlled substance by means of the internet, the prescribing practitioner must have conducted an in-person medical evaluation. However, the law permits exceptions for controlled substance prescriptions via telemedicine under specific circumstances, including where the patient is being presented in a DEA-registered hospital or clinic. The Ryan Haight Act does exclude a number of circumstances where telemedicine has the potential to expand access to addiction treatment, such as excluding non-DEA-registered clinical settings where patients in underserved areas might seek access to a remote provider.
Yale Doctors to Test Telehealth to Treat Pregnant Women With OUD

Yale University researchers will use a $5.5 million PCORI grant to study whether a telehealth platform can help rural health providers improve care for pregnant women struggling with substance abuse.

Source: ThinkStock
Warm handoff interventions and mobile medical services are critical tools for healthcare providers and community organizations to use in helping drug overdose survivors start on a path to treatment and recovery. This website is a resource for stakeholders to use in implementing and enhancing warm handoff programs and mobile medical services across the U.S.

- What is a warm handoff?
- What are mobile medical services?
- Why are warm handoffs and mobile medical services important?
- What difference can warm handoffs and mobile medical services make?
Legal Precedent

Setting Precedent, A Federal Court Rules Jail Must Give Inmate Addiction Treatment

May 4, 2019 - 10:32 AM ET

Mental Health Treatment Denied to Customers by Giant Insurer’s Policies, Judge Rules

United Behavioral Health, a subsidiary of UnitedHealth Group, was found to have let “financial incentives” infect “the guideline development process,” according to a federal ruling. Mike Blake/Reuters
Additional Opioid Policy & Practice Trends

• Federal Funding
• Fentanyl-Laced Pills
• Border Seizures
• Integration of Screening and Treatment across Health Settings
• Peer Recovery Support Services
• Criminal Justice Programs
  • Pre-Arrest Diversion
  • Treatment in Jails and Prisons
  • Reentry Support

Educate. Train. Mentor

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