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)
DOJ CRACKDOWN

DOJ Establishes Opioid Fraud & Abuse Detection Unit - August 2017
DOJ Creates Prescription Opioid Strike Force - October 2018
DOJ Charges 601 Defendants - June 2018
DOJ 45-day Surge - April 2018
DOJ Forms Prescription Interdiction & Litigation Task Force - February 2018
DOJ Establishes Opioid Fraud & Abuse Detection Unit - August 2017

DOE CRACKDOWN

DEA Criminal & Administrative Actions

DEA CRACKDOWN

DEA Criminal Cases Against Physicians

DEA Administrative Actions Against Registrants - 2019

New Enforcement Tactics

Justice Department Files First of Kind Antitrust Case to Stop Tennessee Pharmacist

DEA Criminal & Administrative Actions

Full reports linked at centerforuspolicy.org.
Opioid analgesic prescribing decreased 25% between 2012 and 2017. 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.

Continuing Focus on Rx Opioids

- Opioid analgesics prescribing decreased 25% between 2012 and 2017.
- 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.

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.

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

<table>
<thead>
<tr>
<th>Administrative Inspection</th>
<th>Active Investigation</th>
<th>Immediate Suspension</th>
</tr>
</thead>
<tbody>
<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>
<td>DEA may request voluntary surrender of registration</td>
<td>Do not prescribe controlled medications</td>
</tr>
</tbody>
</table>
Pain Management Best Practices Inter-Agency Task Force

Recent Update PDF
The final report on new practices guidelines, updates, and recommendations.

HEAL
NIH - Helping to End Addiction Long term

CDC Clarification, Oregon Stand Down

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

No Shortcuts to Safer Opioid Prescribing

Oregon’s Opioid Tapering Plan Delayed
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.

1. [https://store.samhsa.gov/system/files/sma18-5063fulldoc_0.pdf](https://store.samhsa.gov/system/files/sma18-5063fulldoc_0.pdf)

X the X Waiver

FDA Citizen Petition
Legal Precedent

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

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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