The Impacts of Law, Regulation, and Enforcement on Pain Care: An Update

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Disclosure

DCBA Law & Policy is a Washington, D.C.-based law firm with a nationwide practice in health care legislation, regulation, transactions, and compliance.
The firm’s clients include health care practitioners, clinics, investors, laboratories, and pharmaceutical developers.

Preview

- Trends
- Federal regulatory landscape
  - HHS
  - DOJ
- Federal legislation
- State laws and legislation
- Q & A
WHAT'S CHANGING?

Analysis –
2017 Follow-up

Justice Department Charges 601 Defendants for Health Care Fraud and Opioid Epidemic-Related Schemes

By SARAH GRAY June 29, 2018
FEDERAL REGULATORY LANDSCAPE

Pain Patients Urge FDA to Fix CDC Guideline
July 09, 2018

By Pat Aver, Editor

Chronic pain patients are facing access to opioid medications, can’t find doctors willing to treat them, and are often treated as addicts. Pain sufferers told FDA officials during an emotional public hearing Monday.

“FDA, we are begging you. Cancel the CDC’s usage guideline. Tell the country the truth about prescription opioids. They are unsafe and ineffective for 99% of us,” said Rees Bingham, who lives with chronic pain caused by Asthma, Bursitis, Rheumatoid and Celiac disease. “My son and my girlfriend are being admitted to the hospital, being in agony and being denied pain relief.”

“CDC Guidelines have been a disaster for pain patients,” Rick Miller, a pharmacist disabled by chronic back pain, said in prepared testimony. “There is plenty of anecdotal evidence showing (prescription opioids) (cannabis) is helpful for the elderly. While many thousands of patients who are chronically suffering, some with social disability, “The FDA needs to take action. The FDA says it wants to know about challenges or barriers to accessing treatment. The challenge and the barrier is the CDC guidelines. It should be immediately suspended. It should be reviewed and modified with pain management physicians and pain patients.”
Supplementing the CDC Guideline

- "It's quite clear that the CDC guidelines have had unintended consequences...."
  —Jianguo Cheng, President, American Academy of Pain Medicine

- Pain Management Best Practices Inter-Agency Task Force
  - HHS, VA, DoD
    - Will address gaps or inconsistencies in chronic and acute pain management
  - "Hard behind" CDC guideline

- FDA, National Academies to address acute pain treatment

- Possible outcomes
  - Narrower application of CDC guideline
  - More guidelines yield greater pressure, confusion, and reluctance to treat pain

“The Department of Justice came up with a data analytics program that examines all the prescription records of registrants around the country, and it jumps up these people who are really outliers.”

https://cs.pn/2weLavG

In the News

Study: CDC guidelines associated with declines in opioid prescribing
In the News

- One in 5 adults have chronic pain, CDC report finds

- Analyzed data from over 17,000 in-person interviews.
  - Researchers estimated 20 percent of adults in the U.S. had chronic pain.
  - For 8 percent of adults, it was so severe that it prevented them from going about their daily lives most days over the past six months.
  - Most prevalent in women, adults without private health insurance, and those living in poverty.

- Providers “are afraid to treat patients because they worry about losing their license if they need to provide certain doses, as well as the scrutiny about using opioids to treat opioid addiction.”
  —Lynn Webster, former president at the American Academy of Pain Medicine

DOJ raids could be making opioid crisis worse: report

by Mike Starkiewicz | May 11, 2018 8:21am

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ASAM, AAPA, AANP, and AOAAM Request Meeting with DOJ Regarding Recent Enforcement Actions

DEA Final Rule: Annual Opioid Quotas

- DEA can issue stricter production limits if medication is misused or diverted
  - Extent of diversion is a factor
  - DEA can require manufacturers to provide information to help detect or prevent diversion (e.g., customer identities and amounts of the controlled substance sold to each customer)
- DEA will publish proposed aggregate drug class quota in Federal Register by May 1 of each year
- DEA must share notices of proposed aggregate production quotas and final aggregate production quota orders with state attorneys general
- States may object to a proposed aggregate production quota as excessive
In the News

- Nearly 30% of all opioids Rx lack medical explanation.
  - Most common:
    - High blood pressure
    - High cholesterol
    - Opioid dependence (2.2%)

- Will this lead to stricter prescribing guidelines?

FEDERAL OPIOID LEGISLATION
H.R. 6 - SUPPORT for Patients and Communities Act
- Requires all Medicaid providers to check PDMPs before prescribing CII medication
- Requires CMS to establish opioid prescriber thresholds
- Directs HHS to review whether Medicare outpatient reimbursement encourages opioids over other pain treatments
- Includes Jessie’s Law, intended to disclose a patient’s addiction history, with consent
- Directs DOJ to establish a special registration to prescribe controlled substances via telemedicine
- Directs FDA to issue guidance on developing “non-addictive” treatments

S.2680 - Opioid Crisis Response Act of 2018
- Not as far reaching as H.R. 6 regarding Medicare and Medicaid
- Directs HHS to study the impact of federal and state opioid prescribing limits on overdoses, OUD, and use of and access to opioids
- Allows NIH more flexibility to approve research into nonaddictive pain treatment
- Allows a pharmacist to deliver a controlled substance injection or implant to an administering prescriber
- Establishes grant program to assist hospitals in developing alternatives to opioid-based pain management
- Includes Jessie’s Law
- Directs DOJ to establish a special registration to prescribe controlled substances via telemedicine

STATE LAWS AND LEGISLATION
**In the News**

- Maryland sued the Trump Administration in federal court on September 13, seeking a decision declaring that Obamacare is constitutional.
- A week after attorneys for 20 red states argued before a judge in Texas that the entire Affordable Care Act should be struck down.

**State Opioid Dosing and Duration Limit Laws**

- State response to CDC Guideline for PCPs
  - >30 states considered >130 bills in 2016 and 2017
  - As of August 2018, 31 states passed laws limiting opioid prescribing
- Most apply to initial opioid prescriptions
  - Prevent dependence
  - Limit leftover supply in community
- Most limit duration of initial opioid Rx
  - Range from 3- to 14-day supply
  - 7-day supply is most common
- Some states set MME dosage limits
- Many states limit scope to acute pain; may set additional exceptions
  - Some exempt chronic pain
  - Others exempt cancer, palliative, and hospice but do not specifically exempt chronic pain, causing confusion

**State Laws Requiring Coverage of Alternative Treatments**

- **MA:** Requires insurance coverage for a broad spectrum of pain management services, including alternatives to opioids, which will be determined by the state’s Division of Insurance
- **WV:**
  - PT, OT, acupuncture, massage therapy, osteopathic manipulation, chiropractic care, chronic pain management program (not required to exhaust alternatives)
  - Min. 20 visits/event for chronic pain
- **LA:** Cannot deny non-opioid for chronic pain in favor of opioid
Governor Baker Signs Second Major Piece of Legislation to Address Opioid Epidemic in Massachusetts

New law strengthens state’s education and prevention efforts, expands role of recovery coaches, and improves access to treatment


- Federal and state law enforcement, including the Medicaid Fraud Unit, must obtain a warrant for probable cause before searching PDMP
- Establishes state-funded program that will allow practitioners to contact pain specialists for remote consultation
- Requires public and private payer “coverage and access to a broad spectrum of pain management services,” as alternatives to opioids
- Requires providers to check the PDMP before prescribing any CII, a CIII opioid, or a benzodiazepine


- Requires warm hand-offs
  - Hospital EDs must establish protocols to provide evidence-based interventions, prior to discharge, to people who overdose
- Creates a pilot program for delivery of all FDA-approved forms of MAT in certain county correctional facilities
Other Relevant State Laws and Legislation

- Several states have introduced (MO, MC) or enacted (AK, MA, CT, PA, WV) legislation allowing patients to opt out of receiving opioids.
- Three states (IN, FL, CA) have introduced bills requiring pharmacists to dispense certain opioids in a lockable vial.

In the News

How the opioid crackdown is backfiring

Hundreds of chronic pain patients responding to a POLITICO survey described being refused pain medication they had relied on for years with sometimes devastating consequences.

Last August, Ann Pawlowski told her wife she planned to kill herself.

The former law enforcement officer was in constant pain after her doctor had abruptly cut off her pain medication of hydrocodone that had helped her endure excruciating back pain from a spine injury she suffered almost two decades ago that had left her nearly paralyzed despite multiple surgeries.

"I came into the office one day and he said, 'You have to find another doctor,'" she said. "I had to find another doctor that would even prescribe me anything else, as well as a new pain management center."

"My doctors, the whole family missed me, and they all thought I was dead," she said.

The doctor gave her five days to receive her prescription and send him..."
Conclusion

• Thanks to ASPMN®
• Thank you
• Questions and discussion
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