Pain Care & Prescription Drug Abuse: Current Topics, Legislation & Policy

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Disclosure

CLAAD’s funders include pharmaceutical companies, treatment centers, and laboratories, and are disclosed on its website, www.claad.org.

Preview

- American Health Care Act
- Brief background
  - CLAAD’s National Strategy
  - Drug Abuse & Overdose Trends
- Federal Activity
- State Activity
- Questions and Discussion
What Insurers Like and Dread About GOP’s Plan to Replace Obamacare

The cancellation of penalties for going without health coverage is a big blow.

CLAAD’s Comprehensive National Strategy

- Prescriber education (covering all controlled medications)
- Public awareness and patient counseling, including safe storage and responsible disposal
- Prescription monitoring programs
- Prosecution of criminals, rehabilitation of negligent prescribers
- Overdose rescues, interventions, and referrals to treatment
- Access to effective treatments for substance use disorder
- Development, use, and coverage of non-pharmacologic treatments; non-controlled, lower scheduled, and medications with abuse-deterrent and diversion-resistant properties

Obamacare repeal could be 'akin to Armageddon' for people with mental illness

By Andrew Lack / CRONKITE NEWS / OCTOBER 5, 2017 / 1:11 PM

Minister of Americans with serious mental illness could see their health coverage end as federal subsidies end.
Shift in Supply

- **DEA 2016 Drug Threat Assessment**
  - Decline in abuse of prescription opioids
  - Increase in abuse of illicit fentanyl and heroin
  - Heroin overdose deaths more than tripled between 2010 and 2014, with the most recent data reporting 10,574 people in the United States died in 2014 from heroin overdoses

- **CDC**
  - Heroin related overdose tripled from 2010 to 2015
  - One in four drug overdoses in 2015 related to heroin

Cocaine Abuse

- The number of overdose deaths in the United States involving cocaine in 2015 was the highest since 2006 and the second-highest since 1999
- Theory: cocaine laced with heroin or counterfeit fentanyl is driving a recent increase in cocaine-related overdose deaths
- Alternative theory: Increased cocaine supply is driving demand

Abuse of Non-Opioid Controlled Rx Medications

- **Prescription Stimulants**
  - 5.3 million people abused prescription stimulants in 2014
  - Between the ages of 18 to 25: One in six have abused prescription stimulants
  - College students: One in four has abused prescription stimulants
  - The most common medications of abuse are IR medications

- **Benzodiazepines**
  - Involved in > 30% of prescription drug overdose deaths in 2013
  - 4.3 fold increase in benzodiazepine-related deaths from 2002 to 2015

- **Sleep medications**
  - "Ambien-defense" to murder
  - Most common date-rape drug
Trump Administration

- Pres. Donald Trump
  - "The FDA has been far too slow to approve abuse-deterring drugs"
  - "As president, I'd work to lift the cap on the number of patients that doctors can treat, provided they follow safe prescribing practices and proper treatment supervision"
  - Vowed to "slash restraints" on drug development and emphasized need to "speed up approval of life-saving medications"
  - "We're going to expand access to abuse-deterring drugs...They're out and they're very hard to get"

- HHS Sec. Tom Price
  - "We believe that patients and doctors should be in control of their care"
  - "We need...to make certain that we are on the cutting-edge of innovation"
  - "The new FDA commissioner "understands and respects" that taking "10 to 14 years (to bring a drug to market) is simply too long"

CARA & 21st Century Cures

- HHS task force to recommend best practices for pain management
  - Must be established by July 2018; make recommendations one year from date of establishment
  - $485M in 2017 for state grants to address opioid overdose
  - No less than 80% to be spent on treatment and recovery support
  - Stationary program leads to private, for-profit methadone and buprenorphine practices

- Parity Enforcement
  - Requires HHS to produce a plan to improve federal and state parity enforcement
  - Requires a study on the enforcement of parity within three years of enactment

- HHS Assistant Secretary for Mental Health and Substance Use
  - National Mental Health and Substance Use Policy Laboratory: evidence-based practices and delivery models

U.S. Food and Drug Administration

- Class-wide REMS to be extended to short-acting and immediate release opioid analgesics
- Convening an advisory-committee to review risk-benefit of oxymorphone
- Rejected labeling claims for the newly-approved morphine sulfate extended-release tablets re: nasal and oral abuse
- Complete Response Letter to hydromorphone NME prod ng
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

OPIOID MISUSE STRATEGY 2016

EXECUTIVE SUMMARY

Many Medicare and Medicaid beneficiaries and their families have experienced opioid use disorders, commonly referred to as addictions. Given the growing body of evidence on the risks of misuse, highlighted in the 2016 National opioid crisis warning, the Centers for Medicare and Medicaid Services (CMS) have proposed changes in the way Medicare Advantage and Part D plans cover opioid medications. These changes are intended to reduce the risk of opioid misuse and abuse, consistent with the agency’s commitment to combating the opioid epidemic. CMS is outlining our agency’s strategy and the array of actions underway to address the national opioid misuse epidemic. Strategies outlined in this paper do not include CMS’s vision for the treatment of cancer and hospice patients. Treatment of patients in these situations requires careful medical supervision based on therapeutic goals, ethical considerations, and the balance of risks and benefits of opioid therapy.

Opioid drugs can treat both acute and chronic pain. While these types of drugs, including fentanyl, hydrocodone, hydromorphone, oxycodone, methadone, oxycodone, and oxymorphone, can have benefits for many patients with serious pain-related conditions, these drugs cause serious and substantial harm when used incorrectly. Even when used as directed, they contribute to addiction as well.

Coverage of Opioid Medications

• Centers for Medicare and Medicaid Services (CMS) proposed changes to 2018 Medicare Advantage and Part D plans
  • Utilize 90 MME cutoff to determine overutilization
  • Requires plan sponsors to adopt hard formulary-level edits based on 200 MME
• Medicare, Medicaid, and private insurance plans
  • Require PA or “fail-first” before covering opioid analgesics with ADPs (e.g. majority of states still list methadone on their preferred drug lists)
  • Deny coverage of practitioner-administered opioids for treatment of OUD
• Veterans Administration
  • Robert McDonald: “Vets are 10 times more likely to abuse opioids than the civilian population;” yet last year, VA advocated against the coverage of opioids with ADPs
  • Does not cover diversion-resistant opioids for treatment of OUD

State Legislation

• States enacting parts of the CDC Opioid Guideline as law
  • New York: 7-day supply for acute pain
  • Rhode Island: Max 30 MME/day and 20 total doses for acute pain
  • Massachusetts: 7-day supply for all initial opioid analgesic prescriptions
  • Can prescribe more if document condition in the patient record and indicate that non-opioid alternatives are not appropriate
  • Maine: Max of (1) 7-day supply for acute pain; (2) 30-day supply for chronic pain; or (3) 100 MME/day
• Product-specific legislation
  • NJ: Passed resolution urging FDA to reconsider approval of reformulated ER hydrocodone without AD labeling, despite evidence that the product “is either not desirable or unavailable for abuse”
Model Legislation for Diversion-Resistant Opioids for OUD

- Applies to FDA-approved, practitioner-administered opioids for treatment of OUD
- Insurers shall provide coverage for all diversion-resistant opioids on a basis no less favorable than coverage for self-administered opioids
- Out-of-pocket costs for diversion-resistant opioids shall not exceed the lowest tier applied to self-administered opioids
- Insurers may not require a patient to first use self-administered opioids before covering diversion-resistant opioids

State Legislation

- Bills with unintended consequences
  - Buprenorphine-mono bills meant to reduce diversion, misuse, or abuse of oral buprenorphine for the treatment of OUD
  - Could stifle treatment with practitioner-administered opioids for treatment of OUD and interfere with treatment for pain
  - Georgia bill meant to reduce prescription drug abuse
    - Initially required naloxone medications to receive a new prescription every five days
- Other relevant bills
  - IN, MO proposals would criminalize a person who has experienced an opioid overdose and is revived with naloxone
Conclusion

- Thanks to ASPMN® and PCSS-O and conference sponsors
- Thank you
- Questions and discussion
- Contacts:
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PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit:
www.pcss-o.org/colleague-support

Listserv: A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project.
To join email: pcss-o@aaap.org
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org

For questions email: pcss-o@aaap.org

Twitter: @PCSSProjects

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