2020 Pain Care Legislation and Public Policy

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Educational Objectives

At the conclusion of this activity, participants should be able to:
- Recognize current events affecting the treatment of people with pain or opioid use disorder.
- Identify recent regulatory actions and proposals that may affect people with pain or opioid use disorder.
- Assess the intent and potential practical impacts of recent policy activity.

Preview

- Congressional activity
- Centers for Disease Control and Prevention request for comments
- Pain Management Best Practices Interagency Task Force recommendations
- New treatments, cannabis, and CBD
- COVID-19 responses and impacts
  - Mental health
  - Medication supplies
  - Substance-related trends
  - Regulatory flexibility
- Q&A
Our Commitment

ASPMN recognizes the systemic racism that has affected not only our Black and Brown patients but also our healthcare professional colleagues. Our collective pain and suffering have reached new levels as our nation struggles with a crisis of conscience that has emerged on top of the COVID-19 health crisis.

We call on our peers to help us in a search for answers and invite you to join a forum to share what you are seeing, how you are feeling, and how we, as a profession, can take effective action.

Read our full statement at ASPMN.org page 3

House Casts Its 1st Remote Votes, With Parties Still Divided On The Issue

CARES Act

- Ensuring Patient and Nurses Safety
- $16 billion to the Strategic National Stockpile
- Reauthorized Title VIII Nursing Workforce Development Programs
Budget

- Title VIII - $278 million
  - 40 Senators
  - 100+ Representatives

Center for Disease Control

- Perspectives on and experiences with pain and pain management, including but not limited to the benefits and harms of opioid use
- CDC will use these comments to inform its understanding of stakeholders’ values and preferences related to pain and pain management options.
ASPMN Comments to the Centers for Disease Control and Prevention (CDC)

- Opioids may be very useful for both acute and chronic pain sufferers
- Most patients with pain do not abuse opioids or have overdose events
- Some suffer needlessly due to overly restrictive public policies
- Support for a balanced approach to opioid leading to optimized opioid safety
- Insurance companies should provide coverage not only for safe and effective opioid therapy but also for evidence supported non-opioid and non-pharmacologic therapies

ASPMN Comments to the CDC

- Recommended that the comprehensive and widely accepted Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force report be accepted and used by the CDC.

Appropriations

- Congress appropriated billions to address the opioid crisis
- How much will go to implementing pain management best practices
HHS Pain Management Task Force

- The Task Force underscored the need to address gaps to help clinicians individualize pain management:
  - Stigma
  - Risk assessment
  - Access to care, including insurance coverage and payment
  - Education for all stakeholders
- The Task Force report emphasized:
  - Multimodal and multidisciplinary approaches when clinically indicated
  - Telehealth
  - Research to improve pain treatment options
  - Mitigating unnecessary opioid exposure

HHS Pain Management Task Force

- Appropriate funds for a comprehensive public awareness and educational campaign
- Require HHS and relevant agencies to update federal policy and educational materials
- Remove barriers to non-opioid therapies
- Require CDC/NIH to collect, analyze and publish pain statistics
- Pass legislation to expand access to non-opioid medications

H.R. 5172

- Non-Opioids Prevent Addiction in the Nation (NOPAIN) Act
  - Addresses payment disincentives for non-opioid treatment alternatives in surgical settings
Task Force Recommendations
Implementation Plan

• HHS Assistant Secretary for Health, Adm. Brett Giroir will discontinue his temporary role as the head of COVID-19 testing at FEMA and return to his regular duties in June.
• Dr. Giroir testified before Congress pre-crisis and agreed to develop a Task Force implementation and dissemination plan.
• Members of Congress will reportedly follow up with him for a status update later this summer.

Congressional Hearings

• HHS Pain Management Task Force was mandated by Congress

• Hearings:
  • With CMS, FDA, NIH, to report on Implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act recommendations as authorized by Comprehensive Addiction and Recovery Act (CARA)
  • And with healthcare providers to support the application and importance of the recommendations

FDA/NIH SUPPORT Act

• FDA specific request:
  • Gather public input to inform and guide their actions

• NIH specific request:
  • Help clinicians and researchers individualize treatment plans and options
Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look

- OIG identified 71,260 Part D beneficiaries at serious risk of misuse or overdose in 2017.
- This data brief examines their Medicare claims from 2017 and 2018 and determines whether:
  - They had opioid overdoses;
  - They received naloxone; and
  - They have a diagnosis of OUD and received treatment medications.
- This information is critical to helping HHS target its Rx-opioid-related efforts.

Toolkit for Calculating Opioid Levels and Identifying Patients at Risk of Misuse or Overdose: R and SQL

- Highly technical information to assist with analyzing opioid claims data
  - Medicare Part D plan sponsors
  - Private health plans, and
  - State Medicaid Fraud Control Units
- To analyze patients’ opioid levels to identify patients at risk of opioid misuse or overdose.
<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Opioids Dispensed</th>
<th>Opioid-Related Mortality Rate Per 100,000</th>
</tr>
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<tbody>
<tr>
<td>2011</td>
<td>22,387,218</td>
<td>6.3</td>
</tr>
<tr>
<td>2012</td>
<td>25,698,255</td>
<td>7.0</td>
</tr>
<tr>
<td>2013</td>
<td>26,192,054</td>
<td>7.5</td>
</tr>
<tr>
<td>2014</td>
<td>29,148,482</td>
<td>8.1</td>
</tr>
</tbody>
</table>

Three Waves of Opioid Overdose Deaths

From 1999-2014, nearly 450,000 people died from an overdose involving an opioid, including prescription and illicit opioids.

These numbers can be attributed to three distinct waves:
1. The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids increasing exponentially. (The herbal and over-the-counter medications, such as codeine, increasing overdose rates in the 1990s.)
2. The second wave began in 2010 with rapid increases in overdose deaths involving synthetic opioids.
3. The third wave began in 2011, with significant increases in overdose deaths involving synthetic opioids, particularly those involving fentanyl and tramadol. (The market for illicit manufactured fentanyl continued to change, and it is now found in combination with heroin, oxycodone, and cocaine.)

Many opioid-involved overdose deaths also include other drugs.

NIDA director: New pain meds are still years away

NIDA director, Dr. Samuel Offit joins Opioid Report

By HENRY OPPENHEIM and SARAH KARLIN STEIN
6/17/2020 11:06 AM EDT
NIH HEAL Initiative

- NIH Helping to End Addiction Long-term (HEAL) Initiative
  - Developed to address the opioid crisis via two goals:
    - Enhance pain management
    - Improve prevention and treatment strategies for opioid misuse and addiction
  - Looking at how COVID-19 affects the NIH research, as well as the millions with chronic pain, substance use disorders, healthcare providers, the criminal justice system, and communities.

E&C Health Subcommittee Hearing on Cannabis Policies

- "A recent report ... concluded that there is substantial evidence that cannabis or cannabinoids are effective for treating chronic pain and improving patient-reported spasticity symptoms in multiple sclerosis."
- "However, in general, adequate and well-controlled studies are lacking, which means that individuals across the country are using cannabis strains and extracts that have not undergone the rigorous clinical trials required to show they are safe and effective for medical use, and are not regulated for consistency or quality."
  
  —Nora Volkow, M.D., Director of the National Institute on Drug Abuse, January 15, 2020

U.S. House Cannabis-Related Bills

- H.R. 171, the Legitimate Use of Medicinal Marihuana Act
- H.R. 601, the Medical Cannabis Research Act of 2019
- H.R. 1151, the Veterans Medical Marijuana Safe Harbor Act
- H.R. 2843, the Marijuana Freedom and Opportunity Act
- H.R. 3797, the Medical Marijuana Research Act of 2019
- H.R. 3884, the Marijuana Opportunity Reinvestment and Expungement Act of 2019
FDA Statement on CBD Efforts
March 5, 2020

• Other than one approved prescription drug, FDA knows little about the potential effects of:
  • Sustained or cumulative use of CBD,
  • Co-administration with other medicines, or
  • Risks to vulnerable populations, unborn children, and certain animal populations.
• FDA is encouraging, facilitating, and initiating more research on CBD.
• FDA will continue to monitor the marketplace and take action against unlawful CBD products that pose a risk of harm to the public.

What Tests Should No Longer Be Distributed for COVID-19?

Q: What commercial manufacturers of serological tests had previously provided notification to FDA under the policy outlined in Section IV.D of the Policy for Coronavirus Disease-2019 Tests but have now been removed from that notification list? (Updated 6/9)

<table>
<thead>
<tr>
<th>Company</th>
<th>Test Description</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shenzhen Fortune Bioscience Co., Ltd.</td>
<td>COVID-19 IgM/IgG Antibody Rapid Test Kit</td>
<td>Removed - Should Not Be Distributed</td>
</tr>
<tr>
<td>Zhengzhou Bio-Tek Co. Ltd.</td>
<td>IL-2 (Human), IL-4 (Human)</td>
<td>Removed - Should Not Be Distributed</td>
</tr>
<tr>
<td>Zhuhai Cuizhao Medical Engineering Co., Ltd.</td>
<td>Novel Coronavirus (COVID-19) IgM/IgG Rapid Test Device</td>
<td>Removed - Should Not Be Distributed</td>
</tr>
</tbody>
</table>

Showing 1 to 3 of 18 entries
HHS OCR: Telemedicine Using Mobile Apps During COVID-19 Emergency

YES: Non-public facing
- FaceTime
- Facebook Messenger
- Google Hangouts
- Skype

NO: Public facing
- Facebook Live
- Twitch
- TikTok

DEA Decision Tree for Prescribing Controlled Substances During COVID-19 Emergency (1/2)

DEA Decision Tree for Prescribing Controlled Substances During COVID-19 Emergency (2/2)
EXAMPLE: TX Medical Board Amendment to 22 TAC Chapter 174.5 (June 5, 2020)

• Treatment of chronic pain with scheduled drugs through telemedicine is prohibited, unless:
  • A patient is an established chronic pain patient of the physician and is seeking telephone refill of an existing prescription, and
  • The physician determines that such telemedicine treatment is needed due to the COVID-19 pandemic.
  • Document exception in medical record.
  • Effective for 30 days or until end of disaster declaration (whichever is shorter).

EXAMPLE: TX Board of Nursing Amendment to Rule 217.24 (June 8, 2020)

• Treatment of chronic pain with scheduled drugs through use of telemedicine is not prohibited by this rule if:
  • The patient is an established chronic pain patient of the APRN and
  • The patient is seeking telephone refill of an existing prescription, and
  • The APRN determines that telemedicine treatment is needed due to the COVID-19 pandemic.
  • Document exception in medical record.
  • Effective for 30 days or until end of disaster declaration (whichever is shorter).

A third of Americans now show signs of clinical anxiety or depression, Census Bureau finds amid coronavirus pandemic
‘I have never felt so helpless’: Front-line workers confront loss
Doctors, nurses and first responders grapple with the enormity of what they’ve witnessed during the pandemic’s first wave.
Special Report: COVID deepens the other opioid crisis - a shortage of hospital painkillers

Lisa Girone, Ben Lerner, Robin Bengard

Demand for injectable opioids more than doubled between January and early April, rapidly depleting what hospitals and drugmakers had on hand, according to Vizient, a large hospital purchasing organization. Orders for the commonly used injectable opioid fentanyl roughly tripled, but suppliers were able to ship only half of what hospitals asked for, said Amanda Forstner, a spokeswoman for Premier Inc, another large hospital purchasing organization.

Drug Overdoses, Deaths Appear To Increase During Pandemic

June 3, 2020

Opioid Treatment Program (OFT) Guidance

SAMHSA recognizes the evolving issues surrounding COVID-19 and the emerging needs of O/TAs continue to grow.

SAMHSA affirms its commitment to supporting O/TAs in any way possible during this time. As such, we are expanding our previous guidance to provide increased flexibility.

FOR ALL STATES
The state may require special exceptions for all stable patients in an O/T to increase use of O/Ts or to receive additional O/Ts or O/Ts to treat O/Ts in any way possible during this time. As such, we are expanding our previous guidance to provide increased flexibility.

3/16/2020 (Updated 3/10/2020)
PCSS Mentoring Program

- PCSS Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS Mentors are a national network of providers with expertise in addictions, pain, evidence-based treatment including medication-assisted treatment.
- 3-tiered approach allows every mentor/mentee relationship to be unique and catered to the specific needs of the mentee.
- No cost.

For more information visit: pcssnow.org/mentoring

PCSS Discussion Forum

Have a clinical question?

Ask a Colleague
A simple and direct way to receive an answer, totally free of medication-assisted treatment. (Subject to availability)

PCSS is a collaborative effort led by the American Academy of Addiction Psychiatry (AAAP) in partnership with: