2020 Pain Care Legislation and Public Policy

Wade Delk, ASPMN
Michael C. Barnes, Managing Partner, DCBA Law & Policy; Chairman, Center for U.S. Policy
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 >
House Casts Its 1st Remote Votes, With Parties Still Divided On The Issue

May 27, 2020 - 3:49 PM ET

House Minority Leader Rep. Kevin McCarthy, R-Calif., speaks during a news conference outside the U.S. Capitol about lawsuit he and other Republican leaders filed against House Speaker Nancy Pelosi and congressional officials in an effort to block the House of Representatives from using a proxy voting system to allow for remote voting during the coronavirus pandemic.

Drew Angerer/Getty Images
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
Management of Acute and Chronic Pain: Request for Comment

A Notice by the Centers for Disease Control and Prevention on 04/17/2020

This document has a comment period that ends in 6 days. (06/16/2020)

Submit a formal comment

Read the 2475 public comment
• 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
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
Healthcare Professionals’ Perceptions of Challenges to Chronic Pain Management

Cate Polacek, MLIS, MFA, ELS; Roni Christopher, DHSc; Michelle Mann, BS; Margarita Udall, MPH; Terri Craig, PharmD; Michael Deminski, MS, BSPharm; and Nila A. Sathe, MA, MLIS

Conclusions: Comprehensive approaches to identify and manage chronic pain are nascent and, typically, narrowly focused on reducing opioid use. Respondents, however, recognized the importance of effective systematic management across inpatient and outpatient settings. These findings underscore the need to consider chronic pain as a chronic condition that warrants coordinated approaches to care such as standardized assessments; consistent, patient-centered outcome measures; and multimodal treatments that target both physical relief and underlying psychosocial factors.

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 1. Total number and rate of opioid prescriptions dispensed, United States, 2006–2018

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Number of Prescriptions</th>
<th>Prescribing Rate Per 100 Persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>215,917,663</td>
<td>72.4</td>
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<tr>
<td>2007</td>
<td>228,543,773</td>
<td>75.9</td>
</tr>
<tr>
<td>2008</td>
<td>237,860,213</td>
<td>78.2</td>
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<tr>
<td>2009</td>
<td>243,738,090</td>
<td>79.5</td>
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<tr>
<td>2010</td>
<td>251,088,904</td>
<td>81.2</td>
</tr>
<tr>
<td>2011</td>
<td>252,167,963</td>
<td>80.9</td>
</tr>
<tr>
<td>2012</td>
<td>255,207,954</td>
<td>81.3</td>
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<tr>
<td>2013</td>
<td>247,090,443</td>
<td>78.1</td>
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<tr>
<td>2014</td>
<td>240,993,021</td>
<td>75.6</td>
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<tr>
<td>2015</td>
<td>226,819,924</td>
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<td>2016</td>
<td>214,881,622</td>
<td>66.5</td>
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<tr>
<td>2017</td>
<td>191,909,384</td>
<td>59.0</td>
</tr>
<tr>
<td>2018</td>
<td>168,158,611</td>
<td>51.4</td>
</tr>
</tbody>
</table>
Three Waves of Opioid Overdose Deaths

From 1999–2018, almost 450,000 people died from an overdose involving any opioid, including prescription and illicit opioids.\(^1\)

This rise in opioid overdose deaths can be outlined in three distinct waves.

1. The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since at least 1999.\(^3\)

2. The second wave began in 2010, with rapid increases in overdose deaths involving heroin.\(^4\)

3. The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl.\(^5,6,7\) The market for illicitly manufactured fentanyl continues to change, and it can be found in combination with heroin, counterfeit pills, and cocaine.\(^8\)

Many opioid-involved overdose deaths also include other drugs.\(^9,10\)
NIDA director: New pain meds are still years away
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.
“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.
FDA is advising consumers to beware of fraudulent products claiming to prevent, treat, mitigate, or cure coronavirus disease 2019 (COVID-19). More information is available
**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)

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<tr>
<th>Company Name</th>
<th>Test Description</th>
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<td>Zhengzhou Fortune Bioscience Co., Ltd.</td>
<td>COVID-19 IgG Antibody Rapid Test Kit</td>
<td>Removed - Should Not Be Distributed</td>
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<tr>
<td>Zhongshan Bio-Tech Co Ltd.</td>
<td>SARS-CoV-2 IgM/IgG (GICA)</td>
<td>Removed - Should Not Be Distributed*</td>
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<tr>
<td>Zhuhai Encode Medical Engineering Co., Ltd</td>
<td>Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device</td>
<td>Removed - Should Not Be Distributed*</td>
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</table>

Showing 1 to 38 of 38 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)
• 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

By Alyssa Fowers and William Wan  May 26

For every 100 American adults, 34 show symptoms of anxiety, depression, or both

20 show symptoms of both anxiety and depression

4 show symptoms of depression alone

10 show symptoms of anxiety alone
‘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
Care for Care Providers

Thank you to all of the nurses on the front lines of the COVID-19 crisis. Click here to view the latest clinical and self-care resources.
Prognosis

Zoloft Falls Into Shortage as Virus Anxiety Strains Supplies

By Anna Edney
June 1, 2020, 2:11 PM EDT
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 Forster, a spokeswoman for Premier Inc, another large hospital purchasing organization.
Drug Overdoses, Deaths Appear To Increase During Pandemic

June 3, 2020
3/16/2020 (Updated 3/19/2020)

Opioid Treatment Program (OTP) Guidance

SAMHSA recognizes the evolving issues surrounding COVID-19 and the emerging needs OTPs continue to face.

SAMHSA affirms its commitment to supporting OTPs 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 request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient’s medication for opioid use disorder.

The state may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.
FORE Opinion Letter: Prescribing Buprenorphine During a Public Health Emergency

April 1, 2020

Legal analysis of four hypothetical scenarios for prescribing buprenorphine for opioid use disorder in the United States during the novel coronavirus outbreak.

1. Background and Questions Presented

The U.S. Department of Health and Human Services ("HHS") has declared the novel coronavirus outbreak a public health emergency. Due to the outbreak across the United States, concerns have been raised related to potential barriers to initiating or continuing treatment with buprenorphine for opioid use disorder.

Are the following three hypothetical scenarios permissible under federal controlled substance law?

Scenario 1

A patient presents to an outpatient clinic or emergency department and is seen by a Provider A, who is not X-waivered. Provider A completes a thorough in-person exam and determines that the patient meets criteria for treatment with buprenorphine for opioid use disorder. After reviewing the risks and benefits of treatment, the patient consents to treatment with buprenorphine. Using live audio-visual technology, Provider A communicates with an X-waivered colleague, Provider B, to consult on the patient’s case. Provider B remotely discusses the patient’s case with Provider A and evaluates the clinical information provided by Provider A without interviewing the patient directly. Once Provider B agrees that the patient is appropriate for treatment with buprenorphine for opioid use disorder, Provider B calls in the prescription for buprenorphine for the patient.

Scenario 2

A patient is in ongoing buprenorphine treatment at an outpatient clinic. The patient is treated by Provider C, who is X-waivered. The clinic is avoiding in-person visits to prevent transmission of the novel coronavirus. Provider C is not available, but Provider C’s colleague in the same practice, Provider D, is cross-covering for Provider C until Provider C returns. Provider D, who is also X-waivered, remotely conducts a medical evaluation and confirms that it is necessary for Provider D to issue a new prescription. Provider D calls in a new buprenorphine prescription for the patient to ensure continuity of treatment.

Scenario 3

A patient who actively uses opioids is placed into home quarantine or isolation. The patient has not had any face-to-face encounter with a provider for the purposes of opioid use disorder evaluation. Provider E, who is X-waivered, contacts the patient by telephone and conducts a thorough evaluation of the patient’s case. The patient screens positive for opioid withdrawal and Provider E determines that the patient is appropriate for treatment with buprenorphine and documents her rationale. Provider E then calls in a prescription for an oral buprenorphine product to be delivered to that patient to begin receiving treatment at home.

Pandemic Provides Avenue for Deregulation of OUD Treatment

Methadone Deregulation Should Continue Post-Pandemic

Coronavirus Compels Us To Reconsider X Waiver
QUESTIONS
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 related to medication-assisted treatment. Designed to provide a prompt response to simple practice-related questions.

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

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<th>American Academy of Family Physicians</th>
<th>American Psychiatric Association</th>
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<td>Addiction Technology Transfer Center</td>
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<td>Association for Medical Education and Research in Substance Abuse</td>
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<td>International Nurses Society on Addictions</td>
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<td>National Association of Community Health Centers</td>
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<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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<tr>
<td>American Osteopathic Academy of Addiction Medicine</td>
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Educate. Train. Mentor

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