

Providers' Clinical Support System (PCSS)  
Webinar  
May 16, 2018

## Pain Care Legislation and Public Policy

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## Preview

- ★ Recent trends
- ★ State and federal activity
- ★ Potential impacts of legislation
- ★ Questions and discussion

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## Supply & Demand

★ 20.8 million prescription painkillers over a decade were shipped to two pharmacies, blocks apart in West Virginia

Opioid distributor apologizes for shipping large volumes of painkillers to West Virginia



Drug firms shipped 20.8M pain pills to WV town with 2,900 people



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## House Energy and Commerce Committee

- ★ Distribution and diversion focus
  - Breakdowns in the system



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## Opioid Fight



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## Multifaceted Effort

### Addressing Needs of Patients While Stemming the Tide of the Opioid Crisis

Posted on May 14, 2018 by FDA Voice

By: Scott Gottlieb, M.D.

The biggest public health crisis facing FDA is opioid addiction. Not a day goes by in my role at FDA without hearing stories of the emotional, physical, and financial toll this epidemic is taking on Americans.



FDA is committed to making every possible effort to stem the tide of this crisis. A little over a year ago, I announced a rebalancing of that commitment through the formation of the Opioid Policy Steering Committee (OPSC). This group, comprised of the agency's most senior leaders, was tasked with developing new approaches to impacting this crisis. One overarching goal of the committee was to develop new policy solutions to reduce overall exposure to opioids, prevent new addictions, and support the development and use of better FDA-approved medications to treat those with opioid use disorder.

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## Duration Limits: Pharmacies

- ★ Pharmacies limiting supply for first time prescriptions – 7 days
  - What about exceptions?
  - What about individualized approach to care?

### How Walmart's Decision to Limit Opioid Prescriptions Could Affect U.S. Drug Abuse

HIT & RUN Blog

Walmart's 7-Day Opioid Prescription Limit to Medically Unsound and Could Backfire

Like most regulations, the chain is taking its cue from the CDC's guidelines.

Joseph Sullivan - May 10, 2016 12:30 pm

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## Dose and Duration Limits: State Laws

- ★ In response to the CDC Guideline (for PCPs), states introduced legislation setting opioid duration and dose limits
  - >30 states considered >130 bills in 2016 and 2017
  - As of April 2018, 19 states passed legislation limiting opioid prescriptions
  - Most apply to initial opioid prescriptions
    - Prevent dependence
    - Limit leftover supply in community

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## State Statutory Limits on Certain Initial Opioid Prescriptions

- ★ Most limit duration of initial opioid Rx
  - Range from 3- to 14-day supply
  - 7-day supply is most common
- ★ A few states also set MME dosage limits
- ★ Many states specify that limits apply to acute pain
- ★ Most states set exceptions to limits
  - Some states specifically exempt chronic pain
  - Other states exempt cancer, palliative, and hospice but do not specifically exempt chronic pain, leading to confusion

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## What is Optimal?

- ★ \*Researchers have suggested:
  - 4-9 days for general surgery
  - 4-13 days for women's health procedures
  - 6-15 days for musculoskeletal procedures
- ★ What initial amount will reduce the number of refills needed?
- ★ Are we driving more people to non-prescribed, illicit substances?

\*R. Scully, et al. after surgery, p=200,000

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## Example of State Requirements for Treatment of Chronic Pain: FL

- ★ Complete and document medical history and physical exam
- ★ Develop a written individualized treatment plan
- ★ Discuss w/ patient:
  - Reasons the prescription is necessary
  - Risks associated w/ use of controlled substance, e.g.:
    - Risks of addiction and overdose
    - Dangers of taking opioids w/ alcohol, benzodiazepines, and other CNS depressants
  - Opioid quantity and patient's option to fill Rx in lesser quantity
- ★ Execute a patient responsibility form
- ★ Re-evaluate every 3 months

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## Example of State Requirements for Treating Pain With Controlled Medication: NV

- ★ Document in medical record reasons for prescribing a larger quantity:
  - In any period of 365 d than will be used in 365 d
  - At any one time than will be used in 90 d
- ★ May not issue >1 additional Rx for pain that increases dose unless HCP has met w/ patient to reevaluate treatment plan
- ★ Before continuing treatment of patient who has used opioid for ≥90 d
  - Complete a validated risk assessment
  - Conduct investigation to determine evidence-based Dx for cause of pain
  - Meet patient to review treatment plan to determine if medically appropriate
  - If ≥90 MME/d has been prescribed for ≥90 d, consider specialist referral
- ★ If intend to prescribe for >30 d, must enter into a medication agreement ≤30 d after initial Rx

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## Examples of State Requirements for Treating Pain With Controlled Medication

- ★ Many states have a 30-d limit (eg, ME, NJ, RI, UT, WV)
  - Exception: some allow ≤90-d supply if written instructions on each Rx (other than 1<sup>st</sup> if it is filled immediately) indicating earliest date pharmacy may fill Rx (eg, NJ, RI, UT, WV)
- ★ HI: execute written document to engage in informed consent w/ patient requiring treatment >3 months
- ★ WV:
  - Refer or prescribe treatment alternatives before starting an opioid
  - Rx >7-days requires patient to execute a patient responsibility form
  - When issuing 3<sup>rd</sup> Rx, consider referral to pain clinic or specialist

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## Opioid Opt-Outs

- ★ AK
- ★ PA
- ★ MA
- ★ CT
- ★ WV
- ★ Introduced - MO, NC

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## Change in Habits

- ★ Must occur among providers, patients, and insurers
- ★ State bills would require insurers to cover alternatives to opioids
- GA
- IN
- WV
- LA
- MA



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### Examples of Bills Requiring Coverage of Opioids with AD Properties

- ★ AZ
- ★ IL
- ★ IA
- ★ LA
- ★ MI
- ★ NJ
- ★ NY
- ★ PA
- ★ VA

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### House Ways and Means Committee

- ★ Jurisdiction over Medicare to address medication misuse and abuse
- ★ HR 5773 – Preventing Addiction for Susceptible Seniors (PASS) Act
- ★ HR 5774 – Combatting Opioid Abuse for Care in Hospitals (COACH) Act
- ★ HR 5775 – Providing Reliable Options for Patients and Educational Resources (PROPER) Act
- ★ HR 5776 – Medicare and Opioid Safe Treatment (MOST) Act

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### S.892: Opioid Addiction Prevention Act

- ★ The Attorney General shall not register, or renew the registration of, a practitioner licensed under State law to prescribe CII, III, or IV controlled substances, unless:
  - Practitioner certifies that he/she will not prescribe any CII, III, or IV opioid for initial treatment of acute<sup>†</sup> pain in excess of the lesser of:
    - A 7-day supply (no refill is available)
    - An opioid prescription limit established under State law

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**H.R.5197/S.2516: Alternatives to Opioids (ALTO) in the Emergency Department Act**

- ★ Directs HHS to carry out a 3-year demonstration program
  - Grants to hospitals and emergency departments
  - Alternative pain management protocols and treatments
  - Appropriately limit the use of opioids in emergency departments
- ★ Appropriates \$10 million annually from FYs 2019 to 2021 for demonstration program

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**S.2680: Opioid Crisis Response Act**

- ★ Introduced by US Senate HELP Committee on 4/17/2018
- ★ Includes provisions to:
  - Clarify FDA authority to require packaging options for opioids to support a set treatment duration, eg, blister packs for patients who only need 3- or 7-d supply
  - Study prescribing limits
    - Impact of federal and state laws that limit the length, quantity, or dosage of opioid prescriptions

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**H.R.4733/S.2260: Opioids and STOP Pain Initiative Act**

- ★ Appropriates \$5 billion to support NIH research authorized under CARA 1.0 to understand pain, discover new chronic pain therapies, and develop alternatives to opioid pain treatments
- ★ NIH will develop a new Pain Therapy Screening Program, which will support the development of new pre-clinical models for pain disorders, and the application of these models in drug, device, or other therapy screening

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## Senate Health, Education, Labor, and Pensions (HELP) Committee

- ★ Legislation requiring FDA to clarify the development and regulatory pathways for non-addictive non-opioid pain medications
- ★ Public meeting
  - Challenges and barriers
  - Real-world evidence

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## S.2456: CARA 2.0

- ★ Introduced in Senate on 2/27/2018
- ★ Limits initial opioid prescriptions for acute pain to 3 days
  - Chronic pain, cancer pain, end-of-life, and other palliative care treatments are exempted from limit
- ★ Requires prescribers to check and pharmacists to report to state PDMPs upon initial prescription and fill of a schedule II, III, or IV controlled substance
- ★ Increased civil and criminal penalties for opioid manufacturers who fail to report suspicious orders or fail to maintain effective controls against diversion

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## Potential Unintended Consequences

- ★ Scaling back/transitioning too fast
- ★ Corresponding shifts in supply, risks of overdose
- ★ Focus is on opioids
  - What about other drugs, eg. ADHD medications?
- ★ Is pain being adequately treated?
  - Or has access just being reduced?
  - Surgery, cancer, hospice and palliative care patients?
  - Will the suicide crisis worsen?

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## Data Collection

- ★ Quality of information-gathering efforts by CDC, or other government agencies?
- ★ Quality of data on chronic pain?

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## Lawsuits

### Defendants

- ★ Manufacturers, advocacy groups, key opinion leaders
- ★ Distributors

### Plaintiffs

- ★ State & local governments (and possibly U.S. Government)
- ★ Individuals & class actions (with varying claims)

Delaware lawsuit claims doctor, drug maker colluded to create patient opioid addiction

“the country’s opioid crisis is costing the counties’ taxpayers millions of dollars and urged the supervisors to join their effort to try to recover some of that money”



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## Prescription Opioid Supply

- ★ DEA quotas

**DEA Proposed Rule Would Limit Drug Manufacturer’s Annual Opioid Production**

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## DEA Medication Disposal

- ★ April 2018
  - 5900 takeback sites - 475 tons
- ★ Since Fall 2010
  - 4,982 tons
- ★ National Rx Drug Takeback Day – October 27, 2018



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## Oxycodone & Heroin – AD Properties

- ★ University of Notre Dame and Boston University research
  - Oxycodone consumption stopped rising in August 2010
  - Heroin deaths began climbing the following month
  - Readily available substitutes

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## Inter-Agency Task Force: First Meeting

- ★ Authorized by the Comprehensive Addiction and Recovery Act (CARA)
- ★ Inaugural public meeting – May 30, 9:30-5:00 pm, and May 31, 9:00-3:30

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## Interagency Task Force: Purpose

- ★ Determine whether there are gaps or inconsistencies in pain management best practices among federal agencies;
- ★ Propose updates to best practices and recommendations on addressing gaps or inconsistencies;
- ★ Provide the public with an opportunity to comment on any proposed updates and recommendations; and
- ★ Develop a strategy for disseminating information about best practices.

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## Conclusion

- ★ Thanks to ASPMN® and PCSS
- ★ Thank you
- ★ Questions and discussion
- ★ Contacts:
  - mbarnes@dcbalaw.com
  - wadebdelk@gmail.com

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## 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](http://pcssnow.org/mentoring)**

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## PCSS Discussion Forum

Have a clinical question?

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P C S S

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

American Academy of Family Physicians	American Psychiatric Association
American Academy of Neurology	American Society of Addiction Medicine
Addiction Technology Transfer Center	American Society of Pain Management Nursing
American Academy of Pain Medicine	Association for Medical Education and Research in Substance Abuse
American Academy of Pediatrics	International Nurses Society on Addictions
American College of Emergency Physicians	American Psychiatric Nurses Association
American College of Physicians	National Association of Community Health Centers
American Dental Association	National Association of Drug Court Professionals
American Medical Association	Southeastern Consortium for Substance Abuse Training
American Osteopathic Academy of Addiction Medicine	

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