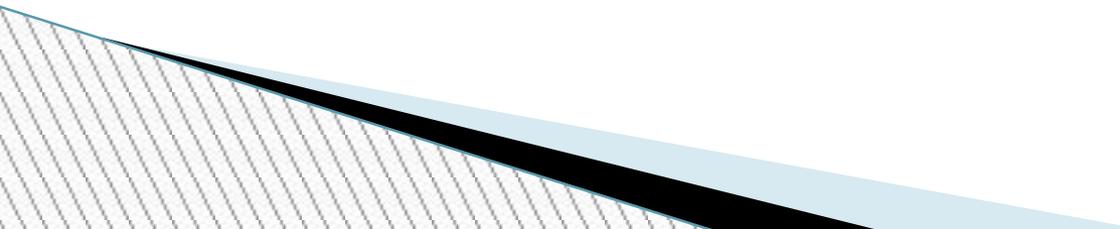


Regulating Opioid Prescribing

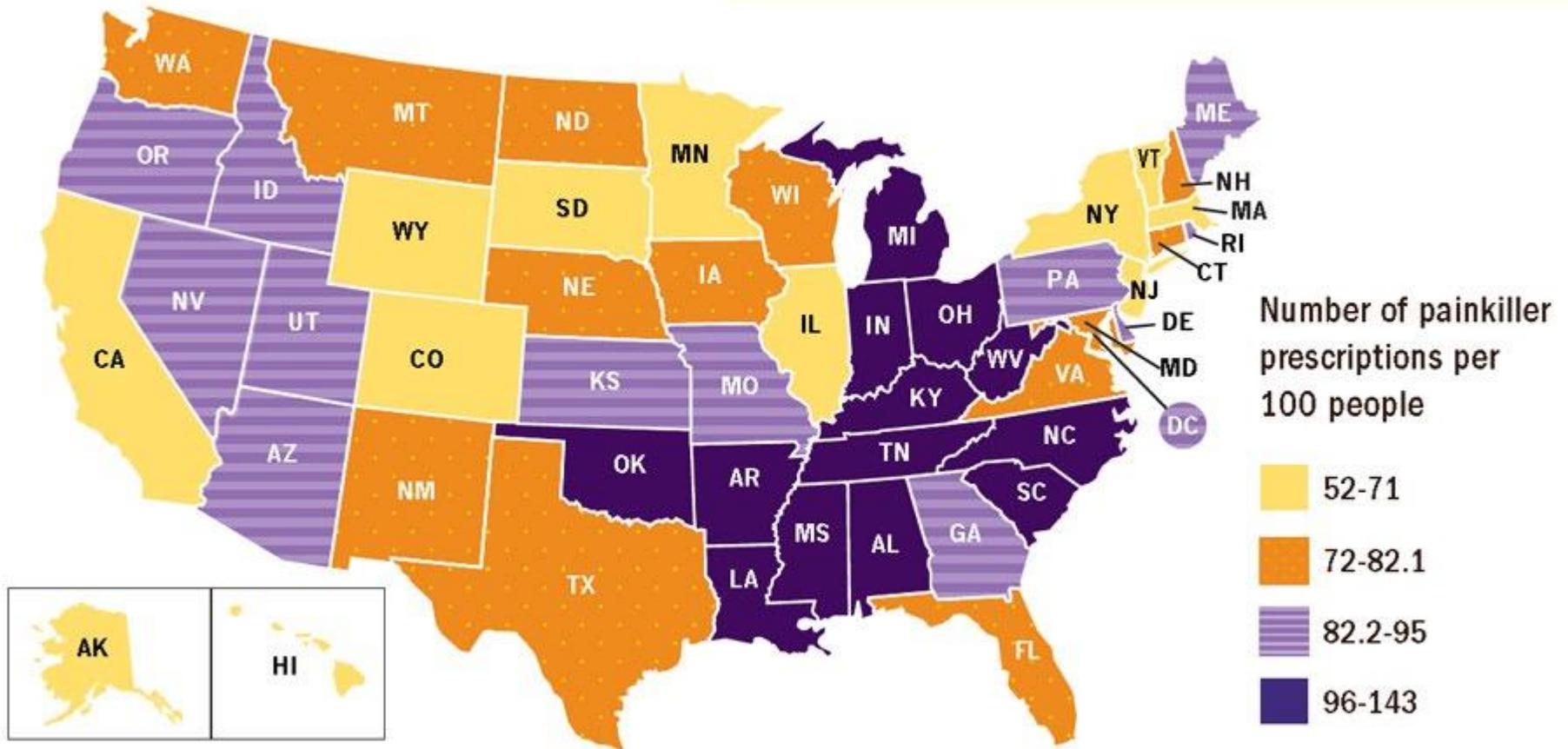
Osteopathic International Alliance
Anaheim Convention Center
Monday, 19 September at 13:30 to 14:15

Joseph A. Zammuto, DO, ACOFP, AAOE
President, Osteopathic Medical Board California
Delegate to Federation of State Medical Boards

The U.S. Opioid Crisis: The Facts

- ▶ In 2014, there was a record 18,893 deaths related to opioid overdose, including both medications and heroin
 - ▶ In 2012, health care providers wrote 259 million prescriptions for opioid pain relievers
 - ▶ Prescription opioid sales in the U.S. have increased by 300% since 1999
 - ▶ Almost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013
- 

Some states have more painkiller prescriptions per person than others.



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

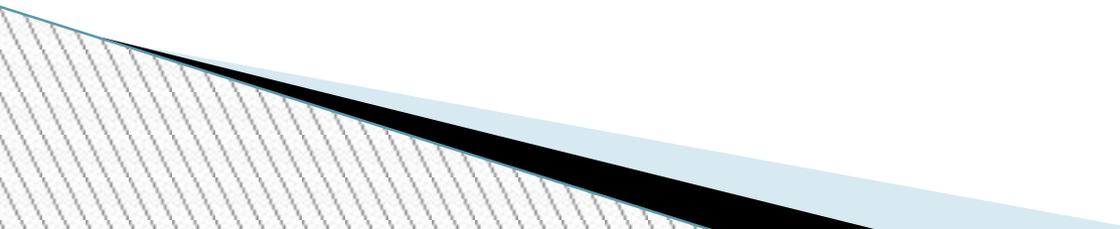
State Strategies

- ▶ States are pursuing a variety of legislative strategies to address prescription drug abuse
 - Mandating query to the state PDMP
 - Implementing Patient Review and Restriction programs (“lock-in” programs)
 - Requiring registration, certification and inspection of pain clinics (“Pill Mill” legislation)
 - Increasing access to opioid antagonists (Naloxone) and providing immunity to those that administer
 - Mandating CME
 - Mandating drug testing in certain circumstances
 - Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

Prescription Drug Monitoring Programs (PDMPs)

- 49 states, excluding Missouri and the District of Columbia, have implemented a PDMP (Missouri does not have PDMP legislation)
- 29 States – by statute, rule, or board policy – mandate that a prescriber or dispenser query the prescription
- 35 states are engaged in Interstate Data Sharing*
- 9 States are implementing Interstate Data Sharing*
 - ✗ California, Texas, Washington, Montana, Georgia, Pennsylvania, New York, Connecticut, Massachusetts and Vermont

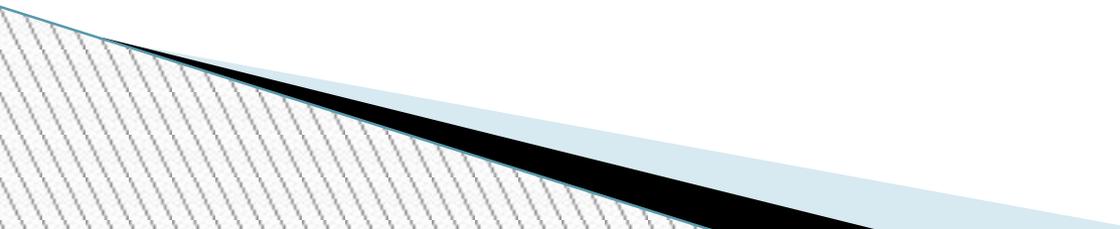
* Source: *The Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC) at Brandeis University*



State Legislation

- ▶ 1,330 bills for the 2016 legislative session related to opioids, pain management, and controlled substances.
- ▶ 300+ bills directly address opioid abuse, overdose, and prevention
- ▶ 67 bills have been signed into law, such as:
 - **Hawaii SB 2392** authorizes health care professionals to prescribe an opioid antagonist directly to an at-risk individual, a person in a position to assist an at-risk individual, or an organization that provides services to at-risk individuals.
 - **Wisconsin AB 366** requires certification of a pain clinic in order for it to operate. Also requires a pain clinic to have a medical director who is a physician that practices in Wisconsin and requires a pain clinic to report annually to DHS certain information.
 - **Virginia HB 829** directs the Board of Medicine to require prescribers to complete two hours of continuing education in each biennium on topics related to pain management, the responsible prescribing of covered substances, and the diagnosis and management of addiction.

California Legislation 2016

- ▶ **CA AB 679** extended to July 1, 2016 the deadline for prescribers and pharmacists to apply to the Department of Justice to obtain approval to access information contained in the CURES database. Enacted.
 - ▶ **CA S 482** would require practitioners to consult the CURES database before prescribing Schedules II-IV for the first time. Pending
 - ▶ **CA A 2592** would authorize the State Department of Public Health to establish a pilot program to award grants to combat opioid abuse through the safe prescribing of opioids. Would require participating pharmacies to offer patients a medicine locking closure package. Pending
 - ▶ **CA A 1748** would authorize a pharmacy to furnish naloxone or another opioid antagonist to a school district, county office of education or charter school. Pending
- 

Making a Difference: State Successes



2012 Action:

New York required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a **75% drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.



2010 Action:

Florida regulated pain clinics and stopped health care providers from dispensing prescription painkillers from their offices.

2012 Result:

Saw more than **50% decrease in overdose deaths** from oxycodone.



2012 Action:

Tennessee required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a **36% drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

FSMB Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain (HoD 2013)

- ▶ 16 Boards' pain management policy is the same or similar to the FSMB's most recent model policies adopted in 2013
 - ▶ Provides an updated guidelines for assessing physicians' management of pain
 - Medically appropriate?
 - Complies with applicable state and federal laws?
 - ▶ Emphasizes physicians' professional and ethical responsibility to
 - Assess and manage patients' pain
 - Assess risk for misuse and addiction
 - Monitor for aberrant behaviors, and
 - Intervene as appropriate
- 

FSMB Model Policy Statement on Management of Chronic Pain

- ▶ The board will consider inappropriate management of chronic pain to be a departure from accepted best clinical practices, including but not limited to the following:
 - Inadequate initial assessment to determine if opioids are clinically indicated and to determine associated risks in the particular individual
 - Inadequate monitoring during clinical use
 - Inadequate attention to patient education and informed consent
 - Inadequate documentation of reason(s) for dose escalation or discussion of alternative treatment methods
 - Not making use of available tools for risk mitigations such as:
 - ✗ Advance query to the state PDMP and for ongoing monitoring
 - ✗ Treatment agreements
 - ✗ Screening tools
 - ✗ Urine drug tests

Federal Regulatory Activity

- ▶ Multiple Congressional hearings focus on the opioid epidemic
- ▶ Strong voices in Congress continue to argue that the FDA is ineffectively addressing and combatting opioid misuse, abuse and deterrence
- ▶ CDC Guideline for Prescribing Opioids for Chronic Pain remains controversial on and outside of Capitol Hill
- ▶ Addressing opioid abuse and heroin epidemic is a priority for the Obama Administration, strategies include but are not limited to --
 - Funding to Community Health Centers to increase treatment services
 - Increase patient limit for qualified physicians who prescribe buprenorphine to treat opioid addiction
 - Support for the development of generic abuse-deterrent opioids
 - Funding opportunities for states to distribute naloxone and expand medication-assisted treatment services
 - Request to medical schools to pledge to require students to enroll in courses that align with the CDC guidelines

Federal Regulatory Activity

- ▶ FDA Advisory Committees held hearings on Risk Evaluation and Mitigation Strategies (REMS) for long acting/extended release opioids in May, 2016
 - Recommendations include --
 - ✗ Mandating CME for prescribers
 - ✗ Tie CME mandate to DEA registration
 - ✗ Expand REMS to shorter-acting opioids
 - ✗ Require manufacturers to follow strategies to ensure drug benefits outweigh the risks
- ▶ CDC published Guidelines in March, 2016
- ▶ Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing), outside of end-of-life care
 - When to initiate or continue opioids for chronic pain;
 - Opioid selection, dosage, duration, follow-up, and discontinuation; and
 - Assessing risk and addressing harms of opioid use

Federal Regulatory Activity

- ▶ US Surgeon General launched “Turn the Tide” campaign in August 2016
 - Letters sent to 2.3 million health care professionals seeking their commitment to combating opioid misuse by
 - × Enhancing education for treating pain
 - × Screening patients for opioid use disorder
 - × Leading a shift in the public perception of addiction so that it is treated as a chronic illness rather than a moral failing.
- ▶ TurnTheTideRx.org

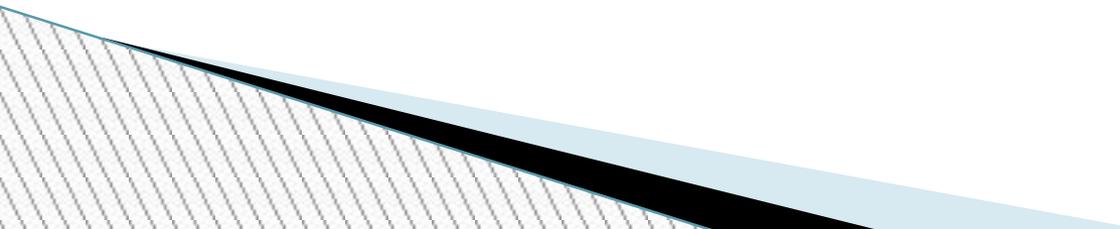
Federal Regulatory Activity

▶ National Pain Strategy

- HHS' Interagency Pain Research Coordinating Committee (IPRCC) published recommendations in March, 2016 – government's first coordinated plan for reducing the burden of chronic pain
- Recommendations for improving overall pain care in 6 key areas: population research; prevention and care; disparities; service delivery and payment; professional education and training; and public education and communication.

Federal Regulatory Activity

▶ The National Pain Strategy calls for:

- Developing methods and metrics to monitor and improve the prevention and management of pain
 - Supporting the development of a system of patient-centered integrated pain management practices based on a biopsychosocial model of care that enables providers and patients to access the full spectrum of pain treatment options
 - Taking steps to reduce barriers to pain care and improve the quality of pain care for vulnerable, stigmatized and underserved populations
 - Increasing public awareness of pain, increasing patient knowledge of treatment options and risks, and helping to develop a better informed health care workforce with regard to pain management
- 

Key Pain Federal Legislative Activity

- ▶ S. 524, The Comprehensive Addiction and Recovery Act (CARA)
 - Authorizes the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use
 - Directs HHS to convene a Pain Management Best Practices Inter-Agency Task Force to develop: best practices for pain management and prescribing pain medication, and a strategy for disseminating such best practices
 - ✗ Includes developing a strategy for disseminating information about the best practices developed to prescribers, health professionals, pharmacists, State medical boards, and other parties
 - Signed into law by President Obama on July 22nd

Key Pain Federal Legislative Activity

- ▶ HR 4641, Establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes
 - Representatives include HHS, VA, FDA, DoD, DEA, CDC, HRSA, HIS, NIH, ONDCP, and SAMHSA
 - FSMB successfully advocated to amend to include state medical boards to serve on the taskforce
 - Passed in the House of Representatives by a vote of 412-4 on June 11th

Other Pain Legislative Activity

- ▶ Bipartisan group of more than 70 Representatives have introduced a slate of 15 bills aimed at targeting the opioid abuse and heroin epidemic, including –
 - Decoupling Medicare reimbursement from patient satisfaction surveys on pain management
 - Sentencing reform for some drug offenses
 - Mandating DEA to establish and implement a national system for drug take back and disposal

Questions?

